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Contents

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The Minutes of this session have been published in OJ C 132, 23.4.2015.

The text adopted of 16 April 2014 concerning the discharge for the financial year 2012 has been published in OJ L 266, 5.9.2014.

TEXTS ADOPTED 1

I Resolutions, recommendations and opinions

RESOLUTIONS

European Parliament

Tuesday 15 April 2014

2017/C 443/01	European Parliament resolution of 15 April 2014 on consumer protection — protection of consumers in utilities services (2013/2153(INI))	2
2017/C 443/02	European Parliament resolution of 15 April 2014 on the proposal for a Council decision on a Tripartite Social Summit for Growth and Employment (COM(2013)0740 — 2013/0361(APP)) ...	7
2017/C 443/03	European Parliament resolution of 15 April 2014 on negotiations on the MFF 2014-2020: lessons to be learned and the way forward (2014/2005(INI))	11
2017/C 443/04	European Parliament resolution of 15 April 2014 on 'How can the European Union contribute to creating a hospitable environment for enterprises, businesses and start-ups to create jobs?' (2013/2176(INI))	18
2017/C 443/05	European Parliament resolution of 15 April 2014 on new technologies and open educational resources (2013/2182(INI))	31

EN

Wednesday 16 April 2014

2017/C 443/06	European Parliament legislative resolution of 16 April 2014 on a proposal for a regulation of the European Parliament on the detailed provisions governing the exercise of the European Parliament's right of inquiry and repealing Decision 95/167/EC, Euratom, ECSC of the European Parliament, the Council and the Commission (2009/2212(INL))	39
2017/C 443/07	European Parliament resolution of 16 April 2014 on relations between the European Parliament and the national parliaments (2013/2185(INI))	40
2017/C 443/08	European Parliament legislative resolution of 16 April 2014 on the draft Council regulation (EU, Euratom) laying down implementing measures for the system of own resources of the European Union (05600/2014 — C7-0047/2014 — 2011/0184(APP))	46
2017/C 443/09	European Parliament resolution of 16 April 2014 on implementing measures for the system of own resources of the European Union (2014/2020(INI))	47

Thursday 17 April 2014

2017/C 443/10	European Parliament resolution of 17 April 2014 containing the European Parliament's recommendation to the Council, the Commission and the European External Action Service on the negotiations of the EU-Japan Strategic Partnership agreement (2014/2021(INI))	49
2017/C 443/11	European Parliament resolution of 17 April 2014 on EU foreign policy in a world of cultural and religious differences (2014/2690(RSP))	53
2017/C 443/12	European Parliament resolution of 17 April 2014 on Russian pressure on Eastern Partnership countries and in particular destabilisation of eastern Ukraine (2014/2699(RSP))	58
2017/C 443/13	European Parliament resolution of 17 April 2014 on the state of play of the EU-Vietnam Free Trade Agreement (2013/2989(RSP))	64
2017/C 443/14	European Parliament resolution of 17 April 2014 on the 'top ten' consultation process and lightening the burden of EU regulation on SMEs (2013/2711(RSP))	70
2017/C 443/15	European Parliament resolution of 17 April 2014 on Pakistan: recent cases of persecution (2014/2694(RSP))	75
2017/C 443/16	European Parliament resolution of 17 April 2014 on Syria: situation in certain vulnerable communities (2014/2695(RSP))	79
2017/C 443/17	European Parliament resolution of 17 April 2014 on the situation in North Korea (Democratic People's Republic of Korea) (2014/2696(RSP))	83

II *Information*

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

European Parliament

Tuesday 15 April 2014

2017/C 443/18	European Parliament decision of 15 April 2014 on the request for defence of the immunity and privileges of Alexander Mirsky (2014/2026(IMM))	86
---------------	--	----

2017/C 443/19	European Parliament decision of 15 April 2014 concerning voting in the context of procedures concerning the immunity of Members (interpretation of Rules 166, 167(1) and 195(3)) (2014/2028(REG))	88
Wednesday 16 April 2014		
2017/C 443/20	European Parliament decision of 16 April 2014 on amendment of Parliament's Rules of Procedure with regard to parliamentary questions (2013/2083(REG))	89
2017/C 443/21	European Parliament decision of 16 April 2014 on amendment of Rule 90 of Parliament's Rules of Procedure on international agreements (2013/2259(REG))	98
2017/C 443/22	European Parliament decision of 16 April 2014 on amendment of Parliament's Rules of Procedure so as to allow for the possibility of electronic signatures (2014/2011(REG))	100

III Preparatory acts

EUROPEAN PARLIAMENT

Tuesday 15 April 2014

2017/C 443/23	European Parliament decision to raise no objections to Commission delegated regulation of 13 March 2014 supplementing Regulation (EU) No 223/2014 of 11 March 2014 of the European Parliament and of the Council on the Fund for European Aid to the Most Deprived (C(2014)1627 — 2014/2676(DEA))	101
2017/C 443/24	P7_TA(2014)0341 Resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Bank Resolution Fund ***I European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Bank Resolution Fund and amending Regulation (EU) No 1093/2010 of the European Parliament and of the Council (COM(2013)0520 — C7-0223/2013 — 2013/0253(COD)) P7_TC1-COD(2013)0253 Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Bank Resolution Fund and amending Regulation (EU) No 1093/2010	102
2017/C 443/25	P7_TA(2014)0343 Technical requirements for inland waterway vessels ***I European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council laying down technical requirements for inland waterway vessels and repealing Directive 2006/87/EC of the European Parliament and of the Council (COM(2013)0622 — C7-0266/2013 — 2013/0302(COD)) P7_TC1-COD(2013)0302 Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council laying down technical requirements for inland waterway vessels and repealing Directive 2006/87/EC	105

2017/C 443/26	<p>P7_TA(2014)0344</p> <p>Correct application of the law on customs and agricultural matters ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters (COM(2013)0796 — C7-0421/2013 — 2013/0410(COD))</p> <p>P7_TC1-COD(2013)0410</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EC) No 515/97 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters</p>	121
2017/C 443/27	<p>P7_TA(2014)0345</p> <p>Information in the field of technical regulations and rules on Information Society services ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the amended proposal for a directive of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codified text) (COM(2013)0932 — C7-0006/2014 — 2010/0095(COD))</p> <p>P7_TC1-COD(2010)0095</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) ⁽¹⁾</p>	136
2017/C 443/28	<p>European Parliament legislative resolution of 15 April 2014 on the recommendation for a Council decision concerning the accession of Croatia to the Convention of 23 July 1990 on the elimination of double taxation in connection with the adjustment of profits of associated enterprises (COM(2013)0586 — C7-0381/2013 — 2013/0308(CNS))</p>	151
2017/C 443/29	<p>European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation establishing the Shift2Rail Joint Undertaking (COM(2013)0922 — C7-0034/2014 — 2013/0445(NLE))</p>	152
2017/C 443/30	<p>European Parliament resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the mobilisation of the European Globalisation Adjustment Fund, in accordance with point 13 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management (application EGF/2012/007 IT/VDC Technologies from Italy) (COM(2014)0119 — C7-0089/2014 — 2014/2025(BUD))</p>	178
2017/C 443/31	<p>European Parliament resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the mobilisation of the European Globalisation Adjustment Fund, in accordance with point 13 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management (application EGF/2012/004 ES/Grupo Santana from Spain) (COM(2014)0116 — C7-0101/2014 — 2014/2027(BUD))</p>	182

⁽¹⁾ Text with EEA relevance.

2017/C 443/32 European Parliament legislative resolution of 15 April 2014 on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council Deposit Guarantee Schemes (recast) (05199/1/2014 — C7-0094/2014 — 2010/0207(COD)) 186

2017/C 443/33 P7_TA(2014)0352
Alternative fuels infrastructure ***I
European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on the deployment of alternative fuels infrastructure (COM(2013)0018 — C7-0022/2013 — 2013/0012(COD))
P7_TC1-COD(2013)0012
Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the deployment of alternative fuels infrastructure 187

2017/C 443/34 P7_TA(2014)0353
Dimensions and weights of road vehicles circulating within the Community ***I
European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (COM(2013)0195 — C7-0102/2013 — 2013/0105(COD))
P7_TC1-COD(2013)0105
Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Council Directive 96/53/EC laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic ⁽¹⁾ 188

2017/C 443/35 P7_TA(2014)0354
Framework for the recovery and resolution of credit institutions and investment firms ***I
European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directives 77/91/EEC and 82/891/EEC, Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC and 2011/35/EU and Regulation (EU) No 1093/2010 (COM(2012)0280 — C7-0136/2012 — 2012/0150(COD))
P7_TC1-COD(2012)0150
Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council 202

⁽¹⁾ Text with EEA relevance.

2017/C 443/36	<p>P7_TA(2014)0355</p> <p>Undertakings for collective investment in transferable securities (UCITS V) ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Directive 2009/65/EC on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) as regards depositary functions, remuneration policies and sanctions (COM(2012)0350 — C7-0178/2012 — 2012/0168(COD))</p> <p>P7_TC1-COD(2012)0168</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Directive 2009/65/EC on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) as regards depositary functions, remuneration policies and sanctions</p>	203
2017/C 443/37	<p>P7_TA(2014)0356</p> <p>Payment accounts ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features (COM(2013)0266 — C7-0125/2013 — 2013/0139(COD))</p> <p>P7_TC1-COD(2013)0139</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features</p>	204
2017/C 443/38	<p>P7_TA(2014)0357</p> <p>Key information documents for investment products ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on key information documents for investment products (COM(2012)0352 — C7-0179/2012 — 2012/0169(COD))</p> <p>P7_TC1-COD(2012)0169</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on key information documents for packaged retail and insurance based investment products (PRIIPs)</p>	205
2017/C 443/39	<p>P7_TA(2014)0358</p> <p>Court of Justice of the European Union: number of judges at the General Court ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the draft regulation of the European Parliament and of the Council amending the Protocol on the Statute of the Court of Justice of the European Union by increasing the number of Judges at the General Court (02074/2011 — C7-0126/2012 — 2011/0901B(COD))</p> <p>P7_TC1-COD(2011)0901B</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending the Protocol on the Statute of the Court of Justice of the European Union by increasing the number of Judges at the General Court [Amendment No 1]</p>	206

2017/C 443/40	<p>P7_TA(2014)0359</p> <p>Deployment of the interoperable EU-wide eCall ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the deployment of the interoperable EU-wide eCall (COM(2013)0315 — C7-0173/2013 — 2013/0166(COD))</p> <p>P7_TC1-COD(2013)0166</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the deployment of the interoperable EU-wide eCall service</p>	209
2017/C 443/41	<p>P7_TA(2014)0360</p> <p>Measures to reduce the cost of deploying high-speed electronic communications networks ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on measures to reduce the cost of deploying high-speed electronic communications networks (COM(2013)0147 — C7-0082/2013 — 2013/0080(COD))</p> <p>P7_TC1-COD(2013)0080</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on measures to reduce the cost of deploying high-speed electronic communications networks</p>	210
2017/C 443/42	<p>P7_TA(2014)0361</p> <p>Inland waterway transport ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 718/1999 on a Community-fleet capacity policy to promote inland waterway transport (COM(2013)0621 — C7-0265/2013 — 2013/0303(COD))</p> <p>P7_TC1-COD(2013)0303</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 718/1999 on a Community-fleet capacity policy to promote inland waterway transport</p>	211
2017/C 443/43	<p>P7_TA(2014)0362</p> <p>Agricultural products on the internal market and in third countries ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on information provision and promotion measures for agricultural products on the internal market and in third countries (COM(2013)0812 — C7-0416/2013 — 2013/0398(COD))</p> <p>P7_TC1-COD(2013)0398</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on information provision and promotion measures concerning agricultural products implemented in the internal market and in third countries and repealing Council Regulation (EC) No 3/2008</p>	212

2017/C 443/44

P7_TA(2014)0363

Active and Assisted Living Research and Development Programme ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in the Active and Assisted Living Research and Development Programme jointly undertaken by several Member States (COM(2013)0500 — C7-0219/2013 — 2013/0233(COD))

P7_TC1-COD(2013)0233

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the Union in the Active and Assisted Living Research and Development Programme jointly undertaken by several Member States

213

2017/C 443/45

P7_TA(2014)0364

Research and Development Programme for research performing SMEs ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in a Research and Development Programme jointly undertaken by several Member States aimed at supporting research performing small and medium-sized enterprises (COM(2013)0493 — C7-0220/2013 — 2013/0232(COD))

P7_TC1-COD(2013)0232

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the Union in a Research and Development Programme jointly undertaken by several Member States aimed at supporting research and development performing small and medium-sized enterprises

214

2017/C 443/46

P7_TA(2014)0365

European Metrology Programme for Innovation and Research ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in a European Metrology Programme for Innovation and Research jointly undertaken by several Member States (COM(2013)0497 — C7-0221/2013 — 2013/0242(COD))

P7_TC1-COD(2013)0242

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the Union in a European Metrology Programme for Innovation and Research (EMPIR) jointly undertaken by several Member States

215

2017/C 443/47

P7_TA(2014)0366

European and Developing Countries Clinical Trials Partnership Programme ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States (COM(2013)0498 — C7-0222/2013 — 2013/0243(COD))

P7_TC1-COD(2013)0243

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States

216

2017/C 443/48	<p>P7_TA(2014)0367</p> <p>European Account Preservation Order ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council creating a European Account Preservation Order to facilitate cross-border debt recovery in civil and commercial matters (COM(2011)0445 — C7-0211/2011 — 2011/0204(COD))</p> <p>P7_TC1-COD(2011)0204</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council establishing a European Account Preservation Order procedure to facilitate cross-border debt recovery in civil and commercial matters</p>	217
2017/C 443/49	<p>P7_TA(2014)0368</p> <p>Disclosure of non-financial and diversity information by certain large companies and groups ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Council Directives 78/660/EEC and 83/349/EEC as regards disclosure of non-financial and diversity information by certain large companies and groups (COM(2013)0207 — C7-0103/2013 — 2013/0110(COD))</p> <p>P7_TC1-COD(2013)0110</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups</p>	218
2017/C 443/50	<p>P7_TA(2014)0369</p> <p>Conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer (COM(2010)0378 — C7-0179/2010 — 2010/0209(COD))</p> <p>P7_TC1-COD(2010)0209</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer</p>	219
2017/C 443/51	<p>P7_TA(2014)0370</p> <p>Clean Sky 2 Joint Undertaking *</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the Clean Sky 2 Joint Undertaking (COM(2013)0505 — C7-0255/2013 — 2013/0244(NLE))</p> <p>P7_TC1-NLE(2013)0244</p> <p>Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council regulation (EU) No .../2014 establishing the Clean Sky 2 Joint Undertaking</p>	222

2017/C 443/52	<p>P7_TA(2014)0371</p> <p>Bio-Based Industries Joint Undertaking *</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the Bio-Based Industries Joint Undertaking (COM(2013)0496 — C7-0257/2013 — 2013/0241(NLE))</p> <p>P7_TC1-NLE(2013)0241</p> <p>Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council regulation (EU) No .../2014 establishing the Bio-based Industries Joint Undertaking 223</p>
2017/C 443/53	<p>P7_TA(2014)0372</p> <p>SESAR Joint Undertaking *</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation amending Regulation (EC) No 219/2007 on establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR) as regards the extension of the Joint Undertaking until 2024 (COM(2013)0503 — C7-0254/2013 — 2013/0237(NLE))</p> <p>P7_TC1-NLE(2013)0237</p> <p>Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council regulation (EU) No .../2014 amending Regulation (EC) No 219/2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR) as regards the extension of the Joint Undertaking until 2024 224</p>
2017/C 443/54	<p>P7_TA(2014)0373</p> <p>Innovative Medicines Initiative 2 Joint Undertaking *</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the Innovative Medicines Initiative 2 Joint Undertaking (COM(2013)0495 — C7-0259/2013 — 2013/0240(NLE))</p> <p>P7_TC1-NLE(2013)0240</p> <p>Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council regulation (EU) No .../2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking . . . 225</p>
2017/C 443/55	<p>P7_TA(2014)0374</p> <p>ECSEL Joint Undertaking *</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the ECSEL Joint Undertaking (COM(2013)0501 — C7-0258/2013 — 2013/0234(NLE))</p> <p>P7_TC1-NLE(2013)0234</p> <p>Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council Regulation (EU) No .../2014 establishing the ECSEL Joint Undertaking 226</p>

2017/C 443/56	<p>P7_TA(2014)0375</p> <p>Fuel Cells and Hydrogen 2 Joint Undertaking *</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the Fuel Cells and Hydrogen 2 Joint Undertaking (COM(2013)0506 — C7-0256/2013 — 2013/0245(NLE))</p> <p>P7_TC1-NLE(2013)0245</p> <p>Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council Regulation (EU) No .../2014 establishing the Fuel Cells and Hydrogen 2 Joint Undertaking 227</p>
2017/C 443/57	<p>European Parliament decision of 15 April 2014 on the modification of the interinstitutional agreement on the Transparency Register (2014/2010(ACI)) 228</p>
2017/C 443/58	<p>European Parliament legislative resolution of 15 April 2014 on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on minimum requirements for enhancing worker mobility between Member States by improving the acquisition and preservation of supplementary pension rights (17612/1/2013 — C7-0059/2014 — 2005/0214(COD)) 249</p>
2017/C 443/59	<p>P7_TA(2014)0380</p> <p>Food and feed law, rules on animal health and welfare, plant health, plant reproductive material and plant protection products ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official Controls Regulation) (COM(2013)0265 — C7-0123/2013 — 2013/0140(COD))</p> <p>P7_TC1-COD(2013)0140</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 1/2005, (EC) No 396/2005, (EC) No 834/2007, (EC) No 1099/2009, (EC) No 1069/2009, (EC) No 1107/2009, Regulations (EU) No 1151/2012, (EU) No .../2013, and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation) [Am. 1] ⁽¹⁾ 250</p>

⁽¹⁾ Text with EEA relevance.

2017/C 443/60	<p>P7_TA(2014)0381</p> <p>Animal health ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on Animal Health (COM(2013)0260 — C7-0124/2013 — 2013/0136(COD))</p> <p>P7_TC1-COD(2013)0136</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on Animal Health <i>the prevention and control of animal diseases which are transmissible among animals or to humans</i> [Am. 1]</p>	393
2017/C 443/61	<p>P7_TA(2014)0382</p> <p>Protective measures against pests of plants ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on protective measures against pests of plants (COM(2013)0267 — C7-0122/2013 — 2013/0141(COD))</p> <p>P7_TC1-COD(2013)0141</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on protective measures against pests of plants</p>	611
2017/C 443/62	<p>P7_TA(2014)0383</p> <p>Consumer product safety ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC (COM(2013)0078 — C7-0042/2013 — 2013/0049(COD))</p> <p>P7_TC1-COD(2013)0049</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council ⁽¹⁾</p>	722
2017/C 443/63	<p>P7_TA(2014)0384</p> <p>Market surveillance of products ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council (COM(2013)0075 — C7-0043/2013 — 2013/0048(COD))</p> <p>P7_TC1-COD(2013)0048</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EC) No 764/2008, Regulation (EC) No 765/2008 and Regulation (EU) No 305/2011 of the European Parliament and of the Council ⁽¹⁾</p>	746

⁽¹⁾ Text with EEA relevance.

2017/C 443/64	<p>P7_TA(2014)0385</p> <p>Markets in financial instruments and amendment of the EMIR Regulation on OTC derivatives, central counterparties and trade repositories ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on markets in financial instruments and amending Regulation [EMIR] on OTC derivatives, central counterparties and trade repositories (COM(2011)0652 — C7-0359/2011 — 2011/0296(COD))</p> <p>P7_TC1-COD(2011)0296</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on markets in financial instruments and amending Regulation (EU) No 648/2012 781</p>
2017/C 443/65	<p>P7_TA(2014)0386</p> <p>Markets in financial instruments and repeal of Directive 2004/39/EC ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on markets in financial instruments repealing Directive 2004/39/EC of the European Parliament and of the Council (recast) (COM(2011)0656 — C7-0382/2011 — 2011/0298(COD))</p> <p>P7_TC1-COD(2011)0298</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (recast) 782</p>
2017/C 443/66	<p>P7_TA(2014)0387</p> <p>Statistics in trade ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 638/2004 on Community statistics relating to trading of goods between Member States as regards conferring of delegated and implementing powers upon the Commission for the adoption of certain measures, the communication of information by the customs administration, the exchange of confidential data between Member States and the definition of statistical value (COM(2013)0578 — C7-0242/2013 — 2013/0278(COD))</p> <p>P7_TC1-COD(2013)0278</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EC) No 638/2004 on Community statistics relating to trading of goods between Member States as regards conferring delegated and implementing powers on the Commission for the adoption of certain measures, the communication of information by the customs administration, the exchange of confidential data between Member States and the definition of statistical value 784</p>
2017/C 443/67	<p>P7_TA(2014)0388</p> <p>Securities settlement and central securities depositories ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on improving securities settlement in the European Union and on central securities depositories (CSDs) and amending Directive 98/26/EC (COM(2012)0073 — C7-0071/2012 — 2012/0029(COD))</p> <p>P7_TC1-COD(2012)0029</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012 785</p>

2017/C 443/68	<p>P7_TA(2014)0389</p> <p>Marine equipment ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on marine equipment and repealing Directive 96/98/EC (COM(2012)0772 — C7-0414/2012 — 2012/0358(COD))</p> <p>P7_TC1-COD(2012)0358</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on marine equipment and repealing Council Directive 96/98/EC</p>	786
2017/C 443/69	<p>P7_TA(2014)0390</p> <p>Pressure equipment ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of pressure equipment (recast) (COM(2013)0471 — C7-0203/2013 — 2013/0221(COD))</p> <p>P7_TC1-COD(2013)0221</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast)</p>	787
2017/C 443/70	<p>P7_TA(2014)0391</p> <p>Judgments in civil and commercial matters ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (COM(2013)0554 — C7-0239/2013 — 2013/0268(COD))</p> <p>P7_TC1-COD(2013)0268</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EU) No 1215/2012 as regards the rules to be applied with respect to the Unified Patent Court and the Benelux Court of Justice</p>	790
2017/C 443/71	<p>P7_TA(2014)0392</p> <p>Labour force sample survey ***I</p> <p>European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 577/98 on the organisation of a labour force sample survey in the Community (COM(2013)0155 — C7-0086/2013 — 2013/0084(COD))</p> <p>P7_TC1-COD(2013)0084</p> <p>Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 577/98 on the organisation of a labour force sample survey in the Community</p>	791

2017/C 443/72	P7_TA(2014)0393	
	European Maritime Safety Agency and response to pollution ***I	
	European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on multiannual funding for the action of the European Maritime Safety Agency in the field of response to pollution caused by ships and to marine pollution caused by oil and gas installations (COM(2013)0174 — C7-0089/2013 — 2013/0092(COD))	
	P7_TC1-COD(2013)0092	
	Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on multiannual funding for the action of the European Maritime Safety Agency in the field of response to marine pollution caused by ships and oil and gas installations	792

Wednesday 16 April 2014

2017/C 443/73	P7_TA(2014)0397	
	Protection of species of wild fauna and flora ***I	
	European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on the protection of species of wild fauna and flora by regulating trade therein (recast) (COM(2012)0403 — C7-0197/2012 — 2012/0196(COD))	
	P7_TC1-COD(2012)0196	
	Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the protection of species of wild fauna and flora by regulating trade therein (recast)	794

2017/C 443/74	European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion, on behalf of the European Union, of the Protocol setting out the fishing opportunities and the financial contribution provided for by the Fisheries Partnership Agreement between the European Union and the Republic of Seychelles (16651/2013 — C7-0020/2014 — 2013/0375(NLE))	903
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2017/C 443/75	European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion, on behalf of the European Union, of the Protocol between the European Union and the Union of the Comoros setting out the fishing opportunities and financial contribution provided for in the Fisheries Partnership Agreement currently in force between the two parties (16130/2013 — C7-0011/2014 — 2013/0388(NLE))	904
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2017/C 443/76	European Parliament legislative resolution of 16 April 2014 on the draft Council Decision on the conclusion of the Protocol agreed between the European Union and the Republic of Madagascar setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement between the two parties currently in force (14164/1/2012 — C7-0408/2012 — 2012/0238(NLE))	905
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2017/C 443/77	European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion of the Framework Agreement between the European Union and its Member States, on the one part, and the Republic of Korea, on the other part, as regards matters related to readmission (05290/2014 — C7-0046/2014 — 2013/0267A(NLE))	906
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2017/C 443/78	European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion of the Framework Agreement between the European Union and its Member States, on the one part, and the Republic of Korea, on the other part, with the exception of matters related to readmission (05287/2014 — C7-0044/2014 — 2013/0267B(NLE))	907
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2017/C 443/79	European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion on behalf of the European Union and its Member States of the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Montenegro, of the other part, to take account of the accession of the Republic of Croatia to the European Union (14187/2013 — C7-0007/2014 — 2013/0262(NLE))	908
2017/C 443/80	European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion of a Protocol to the Partnership and Cooperation Agreement between the European Communities and their Member States, of the one part, and Georgia of the other part, on a Framework Agreement between the European Union and Georgia on the general principles for the participation of Georgia in Union programmes (16612/2013 — C7-0486/2013 — 2013/0257(NLE))	909
2017/C 443/81	European Parliament legislative resolution of 16 April 2014 on the proposal for a Council decision authorising Portugal to apply a reduced rate of excise duty in the autonomous region of Madeira on locally produced and consumed rum and liqueurs and in the autonomous region of the Azores on locally produced and consumed liqueurs and eaux-de-vie (COM(2014)0117 — C7-0104/2014 — 2014/0064(CNS))	910
2017/C 443/82	European Parliament legislative resolution of 16 April 2014 on the proposal for a Council decision on the AIEM tax applicable in the Canary Islands (COM(2014)0171 — C7-0106/2014 — 2014/0093(CNS))	911
2017/C 443/83	European Parliament legislative resolution of 16 April 2014 on the proposal for a Council decision amending the period of application of Council Decision 2004/162/EC concerning the dock dues in the French overseas departments (COM(2014)0181 — C7-0129/2014 — 2014/0101(CNS))	912
2017/C 443/84	European Parliament resolution of 16 April 2014 on the Council position on Draft amending budget No 1/2014 of the European Union for the financial year 2014, Section III — Commission (08219/2014 — C7-0146/2014 — 2014/2018(BUD))	913
2017/C 443/85	European Parliament legislative resolution of 16 April 2014 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on the establishment of rules and procedures with regard to the introduction of noise-related operating restrictions at Union airports within a Balanced Approach and repealing Directive 2002/30/EC (05560/2/2014 — C7-0133/2014 — 2011/0398(COD))	915
2017/C 443/86	European Parliament legislative resolution of 16 April 2014 on the Council position at first reading in view of the adoption of a Decision of the European Parliament and of the Council establishing a Union action for the European Capitals of Culture for the years 2020 to 2033 and repealing Decision No 1622/2006/EC (05793/1/2014 — C7-0132/2014 — 2012/0199(COD))	917
2017/C 443/87	European Parliament legislative resolution of 16 April 2014 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 812/2004 laying down measures concerning incidental catches of cetaceans in fisheries (06103/1/2014 — C7-0100/2014 — 2012/0216(COD))	918
2017/C 443/88	<p>P7_TA(2014)0415</p> <p>Posting of workers in the framework of the provision of services ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council on the enforcement of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services (COM(2012)0131 — C7-0086/2012 — 2012/0061(COD))</p> <p>P7_TC1-COD(2012)0061</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the enforcement of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services and amending Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation')</p>	919

2017/C 443/89

P7_TA(2014)0416

Return of cultural objects unlawfully removed from the territory of a Member State ***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council on the return of cultural objects unlawfully removed from the territory of a Member State (recast) (COM(2013)0311 — C7-0147/2013 — 2013/0162(COD))

P7_TC1-COD(2013)0162

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the return of cultural objects unlawfully removed from the territory of a Member State and amending Regulation (EU) No 1024/2012 (Recast) 921

2017/C 443/90

P7_TA(2014)0417

Reducing the consumption of lightweight plastic carrier bags ***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Directive 94/62/EC on packaging and packaging waste to reduce the consumption of lightweight plastic carrier bags (COM(2013)0761 — C7-0392/2013 — 2013/0371(COD))

P7_TC1-COD(2013)0371

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Directive 94/62/EC on packaging and packaging waste to reduce the consumption of lightweight plastic carrier bags ⁽¹⁾ 923

2017/C 443/91

P7_TA(2014)0418

Surveillance of external sea borders ***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council establishing rules for the surveillance of the external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (COM(2013)0197 — C7-0098/2013 — 2013/0106(COD))

P7_TC1-COD(2013)0106

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council establishing rules for the surveillance of the external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union 931

⁽¹⁾ Text with EEA relevance.

2017/C 443/92	<p>P7_TA(2014)0419</p> <p>Financial responsibility linked to investor-state dispute settlement tribunals established by international agreements to which the EU is party ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council establishing a framework for managing financial responsibility linked to investor-state dispute settlement tribunals established by international agreements to which the European Union is party (COM(2012)0335 — C7-0155/2012 — 2012/0163(COD))</p> <p>P7_TC1-COD(2012)0163</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council establishing a framework for managing financial responsibility linked to investor-to-state dispute settlement tribunals established by international agreements to which the European Union is party</p>	932
2017/C 443/93	<p>P7_TA(2014)0420</p> <p>Protection against dumped and subsidised imports from countries not members of the EU ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1225/2009 on protection against dumped imports from countries not members of the European Community and Council Regulation (EC) No 597/2009 on protection against subsidised imports from countries not members of the European Community (COM(2013)0192 — C7-0097/2013 — 2013/0103(COD))</p> <p>P7_TC1-COD(2013)0103</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 1225/2009 on protection against dumped imports from countries not members of the European Community and Council Regulation (EC) No 597/2009 on protection against subsidised imports from countries not members of the European Community</p>	934
2017/C 443/94	<p>P7_TA(2014)0421</p> <p>Statute and funding of European political parties and European political foundations ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on the statute and funding of European political parties and European political foundations (COM(2012)0499 — C7-0288/2012 — 2012/0237(COD))</p> <p>P7_TC1-COD(2012)0237</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the statute and funding of European political parties and European political foundations</p>	952
2017/C 443/95	<p>P7_TA(2014)0422</p> <p>Financing of European political parties ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU, Euratom) No 966/2012 as regards the financing of European political parties (COM(2012)0712 — C7-0393/2012 — 2012/0336(COD))</p> <p>P7_TC1-COD(2012)0336</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EU, Euratom) No 966/2012 as regards the financing of European political parties</p>	953

2017/C 443/96	<p>P7_TA(2014)0423</p> <p>Financial rules applicable to the general budget of the Union ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (COM(2013)0639 — C7-0303/2013 — 2013/0313(COD))</p> <p>P7_TC1-COD(2013)0313</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union</p>	954
2017/C 443/97	<p>P7_TA(2014)0424</p> <p>Carbon dioxide emissions from maritime transport ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport and amending Regulation (EU) No 525/2013 (COM(2013)0480 — C7-0201/2013 — 2013/0224(COD))</p> <p>P7_TC1-COD(2013)0224</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the monitoring, reporting and verification of carbon dioxide greenhouse gas emissions from maritime transport and amending Regulation (EU) No 525/2013 [Am. 1] ⁽¹⁾</p>	956
2017/C 443/98	<p>P7_TA(2014)0425</p> <p>Invasive alien species ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species (COM(2013)0620 — C7-0264/2013 — 2013/0307(COD))</p> <p>P7_TC1-COD(2013)0307</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species</p>	980
2017/C 443/99	<p>P7_TA(2014)0426</p> <p>Technical implementation of the Kyoto Protocol to the UN Framework Convention on Climate Change ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 525/2013 as regards the technical implementation of the Kyoto Protocol to the United Nations Framework Convention on Climate Change (COM(2013)0769 — C7-0393/2013 — 2013/0377(COD))</p> <p>P7_TC1-COD(2013)0377</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EU) No 525/2013 as regards the technical implementation of the Kyoto Protocol to the United Nations Framework Convention on Climate Change</p>	981

⁽¹⁾ Text with EEA relevance.

2017/C 443/100	<p>P7_TA(2014)0427</p> <p>Fight against fraud to the Union's financial interests by means of criminal law ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council on the fight against fraud to the Union's financial interests by means of criminal law (COM(2012)0363 — C7-0192/2012 — 2012/0193(COD))</p> <p>P7_TC1-COD(2012)0193</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the fight against fraud to the Union's financial interests by means of criminal law 982</p>
2017/C 443/101	<p>European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the system of own resources of the European Union (05602/2014 — C7-0036/2014 — 2011/0183(CNS)) 994</p>
2017/C 443/102	<p>European Parliament legislative resolution of 16 April 2014 on the draft Council regulation on the methods and procedure for making available the traditional, VAT and GNI-based own-resources and on the measures to meet cash requirements (recast) (05603/2014 — C7-0037/2014 — 2011/0185(CNS)) 999</p>
2017/C 443/103	<p>P7_TA(2014)0435</p> <p>Public employment services ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a decision of the European Parliament and of the Council on enhanced co-operation between Public Employment Services (PES) (COM(2013)0430 — C7-0177/2013 — 2013/0202(COD))</p> <p>P7_TC1-COD(2013)0202</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on enhanced co-operation between Public Employment Services (PES) 1001</p>
2017/C 443/104	<p>P7_TA(2014)0436</p> <p>European Union Solidarity Fund ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 2012/2002 establishing the European Union Solidarity Fund (COM(2013)0522 — C7-0231/2013 — 2013/0248(COD))</p> <p>P7_TC1-COD(2013)0248</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 2012/2002 establishing the European Union Solidarity Fund 1003</p>

2017/C 443/105

P7_TA(2014)0437

Capital increase of the European Investment Fund ***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the European Union in the capital increase of the European Investment Fund (COM(2014)0066 — C7-0030/2014 — 2014/0034(COD))

P7_TC1-COD(2014)0034

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the European Union in the capital increase of the European Investment Fund 1004

2017/C 443/106

P7_TA(2014)0438

European Medicines Agency (conduct of pharmacovigilance activities in respect of medicinal products for human use)***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (COM(2013)0472 — C7-0196/2013 — 2013/0222(COD))

P7_TC1-COD(2013)0222

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use 1006

2017/C 443/107

P7_TA(2014)0439

Macro-financial assistance to the Republic of Tunisia ***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a decision of the European Parliament and of the Council providing macro-financial assistance to the Republic of Tunisia (COM(2013)0860 — C7-0437/2013 — 2013/0416(COD))

P7_TC1-COD(2013)0416

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council providing macro-financial assistance to the Republic of Tunisia 1007

2017/C 443/108

P7_TA(2014)0440

Recovery plan for Bluefin tuna in the eastern Atlantic and Mediterranean ***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 302/2009 concerning a multiannual recovery plan for Bluefin tuna in the eastern Atlantic and Mediterranean (COM(2013)0250 — C7-0117/2013 — 2013/0133(COD))

P7_TC1-COD(2013)0133

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 302/2009 concerning a multiannual recovery plan for Bluefin tuna in the eastern Atlantic and Mediterranean 1008

2017/C 443/109	<p>P7_TA(2014)0441</p> <p>Protection of the euro and other currencies against counterfeiting by criminal law ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council on the protection of the euro and other currencies against counterfeiting by criminal law, and replacing Council Framework Decision 2000/383/JHA (COM(2013)0042 — C7-0033/2013 — 2013/0023(COD))</p> <p>P7_TC1-COD(2013)0023</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the protection of the euro and other currencies against counterfeiting by criminal law, and replacing Council Framework Decision 2000/383/JHA 1009</p>
2017/C 443/110	<p>P7_TA(2014)0442</p> <p>Honey ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Council Directive 2001/110/EC relating to honey (COM(2012)0530 — C7-0304/2012 — 2012/0260(COD))</p> <p>P7_TC1-COD(2012)0260</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Council Directive 2001/110/EC relating to honey 1010</p>
2017/C 443/111	<p>P7_TA(2014)0443</p> <p>European Maritime and Fisheries Fund ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the amended proposal for a regulation of the European Parliament and of the Council on the European Maritime and Fisheries Fund repealing Council Regulation (EC) No 1198/2006 and Council Regulation (EC) No 861/2006 and Council Regulation No XXX/2011 on integrated maritime policy (COM(2013)0245 — C7-0108/2013 — 2011/0380(COD))</p> <p>P7_TC1-COD(2011)0380</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the European Maritime and Fisheries Fund and repealing Council Regulations (EC) No 2328/2003, (EC) No 861/2006, (EC) No 1198/2006 and (EC) No 791/2007 and Regulation (EU) No 1255/2011 of the European Parliament and of the Council 1011</p>
2017/C 443/112	<p>P7_TA(2014)0444</p> <p>European Police College ***I</p> <p>European Parliament legislative resolution of 16 April 2014 on the draft regulation of the European Parliament and of the Council amending Decision 2005/681/JHA establishing the European Police College (CEPOL) (17043/2013 — C7-0435/2013 — 2013/0812(COD))</p> <p>P7_TC1-COD(2013)0812</p> <p>Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Decision 2005/681/JHA establishing the European Police College (CEPOL) 1013</p>

Thursday 17 April 2014

2017/C 443/113	European Parliament legislative resolution of 17 April 2014 on the draft Council decision on the conclusion, on behalf of the European Union and its Member States, of the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Albania, of the other part, to take account of the accession of the Republic of Croatia to the European Union (14783/2013 — C7-0075/2014 — 2013/0311(NLE))	1014
2017/C 443/114	European Parliament legislative resolution of 17 April 2014 on the draft Council decision on the conclusion of the Arrangement between the European Union and the Kingdom of Norway on the modalities of its participation in the European Asylum Support Office (18141/2013 — C7-0107/2014 — 2013/0427(NLE))	1015
2017/C 443/115	European Parliament legislative resolution of 17 April 2014 on the draft Council decision on the conclusion of the Arrangement between the European Union and the Principality of Liechtenstein on the modalities of its participation in the European Asylum Support Office (18116/2013 — C7-0091/2014 — 2013/0423(NLE))	1016
2017/C 443/116	Amendments adopted by the European Parliament on 17 April 2014 on the proposal for a regulation of the European Parliament and of the Council on European Long-term Investment Funds (COM(2013)0462 — C7-0209/2013 — 2013/0214(COD)) ⁽¹⁾	1017
2017/C 443/117	P7_TA(2014)0449 Maritime spatial planning and integrated coastal management ***I European Parliament legislative resolution of 17 April 2014 on the proposal for a directive of the European Parliament and of the Council establishing a framework for maritime spatial planning and integrated coastal maritime spatial planning and integrated coastal management (COM(2013)0133 — C7-0065/2013 — 2013/0074(COD)) P7_TC1-COD(2013)0074 Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council establishing a framework for maritime spatial planning	1041
2017/C 443/118	European Parliament resolution of 17 April 2014 on Parliament's estimates of revenue and expenditure for the financial year 2015 (2014/2003(BUD))	1042
2017/C 443/119	P7_TA(2014)0451 Infringements of competition law ***I European Parliament legislative resolution of 17 April 2014 on the proposal for a directive of the European Parliament and of the Council on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union (COM(2013)0404 — C7-0170/2013 — 2013/0185(COD)) P7_TC1-COD(2013)0185 Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union	1047

⁽¹⁾ Text with EEA relevance.

2017/C 443/120	<p>P7_TA(2014)0452</p> <p>Shipments of waste ***I</p> <p>European Parliament legislative resolution of 17 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1013/2006 on shipment of waste (COM(2013)0516 — C7-0217/2013 — 2013/0239(COD))</p> <p>P7_TC1-COD(2013)0239</p> <p>Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EC) No 1013/2006 on shipments of waste 1048</p>
2017/C 443/121	<p>P7_TA(2014)0453</p> <p>New psychoactive substances ***I</p> <p>European Parliament legislative resolution of 17 April 2014 on the proposal for a regulation of the European Parliament and of the Council on new psychoactive substances (COM(2013)0619 — C7-0272/2013 — 2013/0305(COD))</p> <p>P7_TC1-COD(2013)0305</p> <p>Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on new psychoactive substances ⁽¹⁾ 1050</p>
2017/C 443/122	<p>P7_TA(2014)0454</p> <p>Criminal acts and penalties in the field of illicit drug trafficking ***I</p> <p>European Parliament legislative resolution of 17 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug (COM(2013)0618 — C7-0271/2013 — 2013/0304(COD))</p> <p>P7_TC1-COD(2013)0304</p> <p>Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug . . . 1067</p>

⁽¹⁾ Text with EEA relevance.

Key to symbols used

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure: first reading
- ***II Ordinary legislative procedure: second reading
- ***III Ordinary legislative procedure: third reading

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments by Parliament:

New text is highlighted in ***bold italics***. Deletions are indicated using either the **■** symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

EUROPEAN PARLIAMENT

2014-2015 SESSION

Sittings of 14 to 17 April 2014

The Minutes of this session have been published in OJ C 132, 23.4.2015.

The text adopted of 16 April 2014 concerning the discharge for the financial year 2012 has been published in OJ L 266, 5.9.2014.

TEXTS ADOPTED

Tuesday 15 April 2014

I

(Resolutions, recommendations and opinions)

RESOLUTIONS

EUROPEAN PARLIAMENT

P7_TA(2014)0342

Protection of consumers in utilities services

European Parliament resolution of 15 April 2014 on consumer protection — protection of consumers in utilities services (2013/2153(INI))

(2017/C 443/01)

The European Parliament,

- having regard to its resolution of 22 May 2012 on a strategy for strengthening the rights of vulnerable consumers ⁽¹⁾,
- having regard to its resolution of 25 October 2011 on mobility and inclusion of people with disabilities and the European Disability Strategy 2010-2020 ⁽²⁾,
- having regard to its resolution of 11 June 2013 on a new agenda for European Consumer Policy ⁽³⁾,
- having regard to its resolution of 15 November 2011 on reform of the EU State aid rules on Services of General Economic Interest ⁽⁴⁾,
- having regard to Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (the Unfair Commercial Practices Directive),
- having regard to Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council,
- having regard to Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services ⁽⁵⁾,
- having regard to the Commission proposal of 13 September 2013 for a regulation of the European Parliament and of the Council laying down measures concerning the European single market for electronic communications and to achieve a Connected Continent, and amending Directives 2002/20/EC, 2002/21/EC and 2002/22/EC and Regulations (EC) No 1211/2009 and (EU) No 531/2012 (COM(2013)0627),

⁽¹⁾ OJ C 264 E, 13.9.2013, p. 11.

⁽²⁾ OJ C 131 E, 8.5.2013, p. 9.

⁽³⁾ Texts adopted, P7_TA(2013)0239.

⁽⁴⁾ OJ C 153 E, 31.5.2013, p. 51.

⁽⁵⁾ OJ L 373, 21.12.2004, p. 37.

Tuesday 15 April 2014

- having regard to the Commission communication of 15 November 2012 to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions entitled ‘Making the internal energy market work’ (COM(2012)0663),
 - having regard to Directive 2008/6/EC of the European Parliament and of the Council of 20 February 2008 amending Directive 97/67/EC with regard to the full accomplishment of the internal market of Community postal services,
 - having regard to Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on Electronic Commerce),
 - having regard to Directive 2009/72/EC of the European Parliament and of the Council of 13 July 2009 concerning common rules for the internal market in electricity and repealing Directive 2003/54/EC,
 - having regard to the Commission communication entitled ‘Towards a European Charter on the Rights of Energy Consumers’ (COM(2007)0386),
 - having regard to the Charter of Fundamental Rights of the European Union, as incorporated into the Treaties by Article 6 of the Treaty on European Union (TEU), and in particular Article 8 (protection of personal data), Article 11 (freedom of expression and information), Article 21 (non-discrimination), Article 23 (equality between men and women), Article 25 (the rights of the elderly), Article 26 (integration of persons with disabilities), Article 34 (social security and social assistance), Article 36 (access to services of general economic interest), Article 37 (environmental protection) and Article 38 (consumer protection),
 - having regard to Article 12 TEU,
 - having regard to Article 14 TEU and Protocol No 26 to the TEU,
 - having regard to Rule 48 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection (A7-0163/2014),
- A. whereas enhanced consumer information regarding utility services is particularly important, and whereas there is a need to ensure that consumers have access to such services while Member States have the necessary flexibility to take vulnerable consumers into account;
- B. whereas sectorial legislation is in place and has already enhanced consumer protection, but whereas the Member States are reminded that, to that end, correct implementation and enforcement is still needed;
- C. whereas, in the case of utility services, national powers and the right of self-administration at local government level must be respected, and whereas the sectoral provisions form an adequate legal framework for utility services;

General considerations

1. Notes that some aspects of basic consumer rights are covered by Directive 2011/83/EU and that common characteristics of utility services are outlined in the relevant sectorial legislation;
2. Reminds the Member States that it was necessary to transpose the Directive on consumer rights by mid-December 2013 and that it will be applicable to all contracts concluded after 13 June 2014;
3. Points out that consumer protection is effective only if consumers’ rights can be enforced; calls, therefore, on the Member States to implement fully the provisions of the Unfair Commercial Practices Directive (2005/29/EC), the Directive on Misleading and Comparative Advertising (2006/114/EC) and the Consumer Rights Directive (2011/83/EU); highlights, in this context, the importance of alternative dispute resolution (ADR) systems as efficient, cost-saving mechanisms for solving conflicts between both consumers and providers of utilities services; calls, therefore, on the Member States to implement the recently agreed Directive on ADR (2013/11/EU) and Regulation (EU) No 524/2013 on online dispute resolution (ODR);

Tuesday 15 April 2014

4. Highlights that raising consumers' awareness concerning their rights plays a key role in obtaining a high level of consumer protection, but underlines also the fundamental role of customer service on behalf of utility service providers; stresses that individuals responsible for contacts with clientele should be trained and aware of the rights of consumers; encourages, therefore, utility service providers to train their employees accordingly and ensure that all customers have easy access to personalised assistance at all times;
5. Stresses the need for consumers to have access to affordable and high-quality utility services throughout the EU, given that such services are essential for ensuring social and territorial cohesion while contributing to European economic competitiveness;
6. Supports the existence of strong and independent consumer organisations in facilitating comprehensive consumer protection, yet stresses the importance of striking a proper balance between the needs of consumers and the needs of providers;
7. Emphasises that access to utility services should be facilitated for all consumers, irrespective of their financial circumstances; suggests that, in specific circumstances, Member States may deem that 'vulnerable consumers' may require appropriate arrangements;
8. Calls on the Commission and the Member States to pay more attention to, and invest more in, consumer information and education campaigns in the context of utility services that target the right messages at the right consumer segment;

Energy

9. Believes that an open, transparent and integrated internal energy market is needed to help achieve competitive energy prices, security of supply, sustainability and efficient large-scale deployment of renewable energy, and calls on the Member States properly to transpose, apply and better monitor the third internal energy market package; points out the need for enhanced consumer information, in particular with a view to improving the services offered, and to allowing for the comparability and transparency of tariffs, hence achieving non-discriminatory pricing;
10. Stresses the crucial importance of timely, correct and full implementation of existing legislation, including the regulatory work called for by the third internal energy market package, in order to achieve an integrated and competitive European internal energy market by 2014;
11. Welcomes the work of the Vulnerable Consumers working group in the framework of the Citizens Energy Forum, and welcomes the Commission communication of 22 January 2014 on energy prices and costs in Europe (COM(2014)0021) and the annexed report, which analyse the impact and relationship of energy prices and costs in the Member States; recalls that it is also the task of the Member States to address the various factors and situations linked to energy and vulnerable consumers;
12. Notes that terminating energy contracts often involves restrictive conditions and complex procedures, which makes switching provider difficult; calls for procedures for switching providers to be sped up and simplified; points out that the existing evaluation criteria of the internal energy market package are completed in the respective Electricity and Gas Directives of the third internal energy market package; stresses the importance of regular Commission reports on the enforcement of the Internal Energy Market;
13. Emphasises the need for the Commission to present its conclusion on e-billing as it pertains to consumer online energy account management;
14. Regrets that current energy prices do not necessarily factor in external costs, namely the environmental damage associated with a given energy source or production method, which may nevertheless be passed on to society as a whole in the long run; calls for measures to encourage greater price transparency for consumers in this regard;

Tuesday 15 April 2014

15. Takes the view that undertakings should publish information about prices, price changes and changes to contracts in a readily understandable form; reminds the Member States of the fact that the third internal energy market package already obliges them to ensure this; calls on the Member States and the businesses concerned to take appropriate measures to ensure that consumers have access to clear, understandable and comparable information about tariffs, conditions and means of redress;

16. Recalls that the third internal energy market package suggests that the Member States undertake cost-benefit-analyses before starting the roll-out of smart metering; highlights that smart grids allow consumers to observe and adapt their energy consumption, but points out that some of the cost-benefit analyses that have been conducted by Member States give no indication of substantial cost savings for consumers; highlights that both customers and data protection provisions must be respected, and stresses that the use of smart meters must remain the choice of the consumer;

Telecommunications

17. Stresses that the consumer aspect of the digital single market and the electronic communications sector is of utmost importance, and notes the significant enhancements to consumer protection that have been introduced following the implementation of the 2009 Telecoms Package (Directives 2009/136/EC and 2009/140/EC); highlights the important updates and improvements for consumer protection and empowerment currently being proposed by the Parliament; underlines the significance of access for all consumers to high-quality electronic communications services, and the importance of deploying new infrastructures in order to narrow the digital divide;

18. Reiterates its proposals to make it easier for customers to switch electronic communication service providers without additional fees other than the actual switching cost, without loss of data and with a minimum of formalities, and to encourage them to do so; supports as well proposals to promote independent information on pricing, billing and service quality, including data speeds;

Postal services

19. Notes that consumers benefit from a more quality-focused service in the postal sector and from savings passed on to them through cost reductions; highlights that more delivery options and better transparency, information and prices are preconditions for increasing consumers' confidence in the delivery market; notes that Directive 97/67/EC, as amended by Directives 2002/39/EC and 2008/6/EC, ensures that postal services provide a universal service; reminds the Commission to examine, in its implementation report, whether this guarantee is fulfilled by the Member States; asks the Commission to encourage postal services operators to improve interoperability and to accelerate the roll-out of streamlined processes aimed at reducing costs, increasing the availability and quality of delivery services;

20. Emphasises the importance of a comprehensive parcel delivery service throughout the Union; stresses that it is crucial that parcel services provided by postal services and private operators are fast and reliable, not least in order to meet the needs of consumers ordering online; reiterates the suggestions made in its resolution of 4 February 2014 on parcel delivery ⁽¹⁾ on the need to assist service improvements and reduce costs;

21. Welcomes all the efforts already made by delivery market operators to meet the needs of online consumers and retailers in a better way, such as the introduction of flexible delivery and return options; stresses, at the same time, that further incentives to improve interoperability and the quality of services are welcome;

Public transport

22. Notes that in recent years the rights of consumers using transport services have been strengthened through sectoral measures;

⁽¹⁾ Texts adopted, P7_TA(2014)0067.

Tuesday 15 April 2014

23. Emphasises that consumers with access to efficient local public transport should be targeted, regardless of whether they reside in areas where such service would be less profitable; acknowledges the responsibility of the Member States in this respect, and calls on them to take appropriate action;

24. Points out that, as a result of an ageing population, efficient public transport services will gain in importance in the future, and that they are also essential if the Europa 2020 climate objectives are to be achieved; calls for the development of common tools to ensure optimised multimodality in efficient, high-quality public transport services with a view to ensuring both the free movement of people and the competitiveness of such services;

25. Calls for a holistic approach with regard to elderly people and people with limited mobility; believes that the whole public transport chain must be taken into consideration, including access to public transport nodes; wishes to address the need for a coherent focal point system in order to help people with limited mobility;

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26. Instructs its President to forward this resolution to the Council and the Commission.

Tuesday 15 April 2014

P7_TA(2014)0377

Tripartite social summit for growth and employment**European Parliament resolution of 15 April 2014 on the proposal for a Council decision on a Tripartite Social Summit for Growth and Employment (COM(2013)0740 — 2013/0361(APP))**

(2017/C 443/02)

The European Parliament,

- having regard to the proposal for a Council decision (COM(2013)0740),
- having regard to Rule 81(3) of its Rules of Procedure,
- having regard to the interim report of the Committee on Employment and Social Affairs (A7-0136/2014),

1. Requests the Council to take into account the following modifications:

The proposal for a Council decision should be modified as follows:

Modification 1**Proposal for a Council decision****Recital 8***Text proposed by the Commission*

- (8) In its conclusions of 28 June 2013, the European Council noted that the social dimension of the EMU should be strengthened and highlighted in this context the key role of the social partners and social dialogue. Accordingly, the Commission in its Communication (COM(2013)0690) of 2 October 2013 on the social dimension of the EMU, addressed the issue of promoting social dialogue at national and EU levels and announced a proposal to revise the 2003 Council Decision.

Modification

- (8) In its conclusions of 28 June 2013, the European Council noted that the social dimension of the EMU should be strengthened and highlighted in this context the key role of the social partners and social dialogue. Accordingly, the Commission in its Communication (COM(2013)0690) of 2 October 2013 on the social dimension of the EMU, addressed the issue of promoting social dialogue at national and EU levels and announced a proposal to revise the 2003 Council Decision, **and referred to the Tripartite Social Summit as a key opportunity to involve the social partners in the European Semester process.**

Modification 2**Proposal for a Council decision****Recital 9 a (new)***Text proposed by the Commission**Modification*

- (9a) ***In the Declaration by the European Social Partners on Social Partner Involvement in European Economic Governance adopted on 24 October 2013, the EU social partners confirmed their support for the Tripartite Social Summit for growth and employment and called for a coherent process of consultation of the social partners in the context of the European Semester.***

Tuesday 15 April 2014

Modification 3

Proposal for a Council decision

Article 1

Text proposed by the Commission

The task of the Tripartite Summit for Growth and Employment shall be to ensure, in compliance with the Treaty and with due regard for the powers of the institutions and bodies of the Union, that there is a continuous concertation between the Council, the Commission and the social partners. It will enable the social partners at European level to contribute, in the context of their social dialogue, to the various components of the Union's strategy for growth and jobs. For that purpose, it shall draw on the upstream work of and discussions between the Council, the Commission and the social partners in the different concertation forums on economic, social and employment matters.

Modification

The task of the Tripartite Summit for Growth and Employment shall be to ensure, in compliance with the Treaty and with due regard for the powers of the institutions and bodies of the Union, that there is a continuous concertation between the Council, the Commission and the social partners, **as well as a coordination of their strategies towards a high level of quality and sustainable employment**. It will enable the social partners at European level to contribute, in the context of their social dialogue **and their expertise**, to the various components of the Union's strategy for growth and jobs. For that purpose, it shall draw on the upstream work of and discussions between the Council, the Commission and the social partners in the different concertation forums on economic, social and employment matters.

Modification 4

Proposal for a Council decision

Article 2 — paragraph 1

Text proposed by the Commission

1. The Summit shall consist of the President of the European Council, the Council Presidency and the two subsequent presidencies, the Commission and the social partners, represented at the highest level. The ministers from those three presidencies and the Commissioner responsible for employment and social affairs shall also be present. Depending on the agenda, other ministers from these three presidencies **and** other Commissioners may also be invited to take part.

Modification

1. The Summit shall consist of the President of the European Council, the Council Presidency and the two subsequent presidencies, the Commission and the social partners, represented at the highest level. The ministers from those three presidencies and the Commissioner responsible for employment and social affairs shall also be present. Depending on the agenda, other ministers from these three presidencies, other Commissioners **and the Chair of the Committee on Employment and Social Affairs of the European Parliament** may also be invited to take part. .

Modification 5

Proposal for a Council decision

Article 2 — paragraph 3 — subparagraph 1

Text proposed by the Commission

Each delegation shall consist of representatives of European cross-industry organisations, either representing general interests or more specific interests of supervisory and managerial staff and small and medium-sized businesses at European level.

Modification

Each delegation shall consist of representatives of European cross-industry organisations, either representing general interests or more specific interests of supervisory and managerial staff and **micro**, small and medium-sized businesses at European level.

Tuesday 15 April 2014

Modification 6**Proposal for a Council decision****Article 2 — paragraph 3 — subparagraph 2***Text proposed by the Commission*

Technical coordination shall be provided for the workers' delegation by the European Trade Union Confederation (ETUC) and for the employers' delegation by the Confederation of European Business (BUSINESSEUROPE). The ETUC and BUSINESSEUROPE shall ensure that the views expressed by the specific and sectoral organisations are fully taken into account in their contributions and shall, where appropriate, include representatives from some of those organisations in their delegations.

Modification

Technical coordination shall be provided for the workers' delegation by the European Trade Union Confederation (ETUC) and for the employers' delegation by the Confederation of European Business (BUSINESSEUROPE). The ETUC and BUSINESSEUROPE shall ensure that the views expressed by the specific and sectoral organisations are fully taken into account in their contributions and shall, where appropriate, include representatives from some of those organisations **with the authority to speak** in their delegations.

Modification 7**Proposal for a Council decision****Article 3 — paragraph 1***Text proposed by the Commission*

1. The agenda for the Summit shall be determined jointly by the Council, the Commission and the workers' and employers' cross-industry organisations taking part in the work of the Summit. To this end, preparatory meetings take place between the services of the Council, the Commission and with ETUC and BUSINESSEUROPE.

Modification

1. The agenda for the Summit shall be determined jointly **by, and based on the equal partnership between,** the Council, the Commission and the workers' and employers' cross-industry organisations taking part in the work of the Summit. To this end, preparatory meetings take place between the services of the Council, the Commission and with ETUC and BUSINESSEUROPE.

Modification 8**Proposal for a Council decision****Article 3 — paragraph 2***Text proposed by the Commission*

2. The matters on the agenda shall be discussed by the Council meeting in its Employment, Social Policy, Health and Consumer Affairs configuration.

Modification

2. The matters on the agenda shall be discussed by the Council meeting in its Employment, Social Policy, Health and Consumer Affairs configuration, **based as appropriate on a contribution of all its preparatory bodies.**

Tuesday 15 April 2014

Modification 9

Proposal for a Council decision

Article 4 — paragraph 1

Text proposed by the Commission

1. The Summit shall meet at least twice a year. The meetings shall be held before the respective spring and autumn sessions of the European Council.

Modification

1. The Summit shall meet at least twice a year. The meetings shall be held before the respective spring and autumn sessions of the European Council, **and the outcome of the Summit shall be presented to the following European Council for decision-making.**

Modification 10

Proposal for a Council decision

Article 5

Text proposed by the Commission

The joint chairmen shall draw up a summary of the Summit's discussions in order to inform the relevant Council configurations and the general public.

Modification

The joint chairmen shall draw up a summary of the Summit's discussions in order to inform the relevant Council configurations, **the European Parliament** and the general public.

2. Instructs its President to forward this resolution to the Council and the Commission.
-

Tuesday 15 April 2014

P7_TA(2014)0378

MFF negotiations 2014-2020: lessons to be learned and the way forward**European Parliament resolution of 15 April 2014 on negotiations on the MFF 2014-2020: lessons to be learned and the way forward (2014/2005(INI))**

(2017/C 443/03)

The European Parliament,

- having regard to the proposal for a Council regulation laying down the multiannual financial framework (MFF) for the years 2014-2020 (COM(2011)0398), amended on 6 July 2012 (COM(2012)0388), and to the Draft Interinstitutional Agreement (IIA) between the European Parliament, the Council and the Commission on cooperation in budgetary matters and on sound financial management (COM(2011)0403),
 - having regard to its consent of 19 November 2013 to the MFF Regulation ⁽¹⁾, in accordance with Article 312 of the Treaty on the Functioning of the European Union, and to its approval, on the same day, of the conclusion of the IIA ⁽²⁾,
 - having regard to the MFF and IIA, as finally adopted on 2 December 2013 and published in the Official journal on 20 December 2013,
 - having regard to its resolution of 8 June 2011 on 'Investing in the future: a new Multiannual Financial Framework (MFF) for a competitive, sustainable and inclusive Europe' ⁽³⁾,
 - having regard to its resolution of 23 October 2012 in the interests of achieving a positive outcome of the Multiannual Financial Framework 2014-2020 approval procedure ⁽⁴⁾,
 - having regard to its resolution of 13 March 2013 on the European Council conclusions of 7-8 February 2013 concerning the Multiannual Financial Framework ⁽⁵⁾,
 - having regard to its resolution of 3 July 2013 on the political agreement on the Multiannual Financial Framework 2014-2020 ⁽⁶⁾,
 - having regard to its resolution of 12 December 2013 on relations between the European Parliament and the institutions representing the national governments ⁽⁷⁾,
 - having regard to Rule 48 of its Rules of Procedure,
 - having regard to the report of the Committee on Budgets and the opinions of the Committee on Constitutional Affairs, the Committee on Employment and Social Affairs, the Committee on Regional Development and the Committee on Civil Liberties, Justice and Home Affairs (A7-0254/2014),
- A. whereas the agreement on the MFF 2014-2020 was the outcome of long and strenuous negotiations that lasted two and a half years; whereas the final political agreement could only be reached at the highest political level between the three Presidents (Parliament, the Council Presidency and the Commission) according to Article 324 of the TFEU;

⁽¹⁾ Texts adopted, P7_TA(2013)0455.

⁽²⁾ Texts adopted, P7_TA(2013)0456.

⁽³⁾ OJ C 380 E, 11.12.2012, p. 89.

⁽⁴⁾ OJ C 68 E, 7.3.2014, p. 1.

⁽⁵⁾ Texts adopted, P7_TA(2013)0078.

⁽⁶⁾ Texts adopted, P7_TA(2013)0304.

⁽⁷⁾ Texts adopted, P7_TA(2013)0599.

Tuesday 15 April 2014

- B. whereas the overall level of the next MFF (EUR 960 billion in commitments, EUR 908 billion in payments at 2011 prices), as decided by the European Council and eventually endorsed by Parliament, represents a cut of 3,5 % in commitments and 3,7 % in payments compared to the 2007-2013 financial framework, despite the growing EU competences following the Lisbon Treaty and the enlargement of the Union to 28 Member States; whereas this level falls short of EU political goals and commitments, in particular in relation to the Europe 2020 strategy;
- C. whereas the EU annual budget will continue to represent approximately 1 % of EU GNI in the coming years, a level reached already in the early 1990s, and well below the own resources ceiling of 1,29 % of EU GNI for commitments and 1,23 % of EU GNI for payments, as decided initially in 1992 and reconfirmed in 2010;
- D. whereas, faced politically with the impossibility of changing the overall MFF figures decided by the European Council, Parliament focused on improving the implementation of the MFF by successfully negotiating the inclusion of new provisions that will help to make the new financial framework and the new EU annual budget more operational, consistent, transparent and responsive to the needs of EU citizens and to allow the MFF ceilings to be used to the fullest possible extent; whereas these provisions concern, in particular, the new arrangements relating to the MFF revision, flexibility, the unity and transparency of the EU budget, along with a further engagement on reforming the financing of the EU budget (Joint Declaration on own resources);
- E. whereas, in adherence to the guiding principle that 'nothing is agreed until everything is agreed', Parliament gave its consent to the new MFF Regulation and approved the new Interinstitutional Agreement on 19 November 2013, following the Council's fulfilment of the conditions set out in Parliament's resolution of 3 July 2013, including the adoption of an additional EUR 11,2 billion in payments for 2013;
- F. whereas the Council failed to make any progress on a much needed reform of the current system for financing the EU budget, despite the ambitious proposals put forward by the Commission aimed not only at overcoming the stalemate caused by the lack of a genuine own resources system but also at making the system of financing the EU budget simpler, fairer and transparent to EU citizens;
- G. whereas, following the agreement on the MFF 2014-2020, the MFF remains non-coterminous with the mandates of the Parliament and Commission whose terms begin in 2014;
- H. whereas the possibilities made available in the Treaty of Lisbon to modify the decision-making procedures for the MFF and own resources decisions were not exploited;
1. Strongly regrets the fact that both the procedure leading up to the agreement on the MFF 2014-2020 and the political debate surrounding these negotiations demonstrated a clear lack of shared vision as regards the EU budget and political priorities, showed that there are very divergent approaches among the EU institutions, and fell short of Parliament's increased role and prerogatives under the Treaty of Lisbon; considers it of the utmost importance, therefore, that this report draw the necessary political and institutional lessons, which can serve as a basis for the preparation of future negotiations, notably in relation to the post-electoral revision of the MFF, due to be launched by the Commission before the end of 2016 at the latest;

Political considerations

2. Acknowledges that the fiscal consolidation that Member States are currently facing made a more ambitious agreement on the MFF 2014-2020 infeasible; deeply regrets, however, the fact that the role of the EU budget as an important and common policy instrument for overcoming the current economic and social crisis was not properly recognised; points out that the EU budget is primarily an investment budget that offers a unique framework for coordinating and enhancing national efforts made to regain growth, stimulate competitiveness and generate employment in the whole EU;
3. Is deeply concerned at the fact that budgetary debates in the Council have been for many years poisoned by the logic of 'fair returns' instead of being driven by the logic of the European added-value; considers that, while this debate already existed before the introduction of a GNI-based resource, the situation has seriously intensified due to the current system of EU financing, whereby some 74 % of revenues stem from national contributions based on GNI instead of genuine own resources, as foreseen in the Treaty of Rome and all successive EU Treaties; considers that such a system places disproportionate emphasis on net balances between the Member States and has led to the progressive introduction of complex and opaque rebates and other correction mechanisms for the financing of the EU budget;

Tuesday 15 April 2014

4. Believes that this logic also prevailed in the way the MFF agreement was struck by the European Council on 8 February 2013; considers it regrettable that this was reflected in the fact that the national allocations, especially from the two biggest areas of expenditure in the EU budget, agriculture and cohesion policy, were determined at that moment; criticises, in particular, the increased number of special allocations and 'gifts' granted in the course of negotiations between Heads of State and Government, which are not based on objective and verifiable criteria, but rather reflect the bargaining power of Member States, trying to secure their national interests and maximise their net returns; denounces the lack of transparency in striking this agreement and the reluctance of the Council and the Commission to provide Parliament with all relevant documents; highlights that the European added value should prevail over national interests;

5. Strongly rejects this purely accounting vision of the EU budget, which disregards the European added value, contradicts the principle of EU solidarity and underestimates the current and potential role of the EU budget in strengthening economic governance; stresses that the EU budget is predominantly an investment budget with a strong leverage effect that makes possible a number of projects that would otherwise be difficult or impossible to implement, a catalyst for growth, competitiveness and jobs across the Union and a powerful agent for reform; strongly regrets, therefore, that some Member States seem to regard national contributions to the EU budget purely as a cost to be minimised;

6. Regrets that the European Council took a top-down approach to deciding the overall size of the MFF 2014-2020, which in turn demonstrates a worrying discrepancy between EU political commitments which the European Council has been making and its reluctance to adequately finance them; believes, on the contrary, that this decision should be based on a bottom-up process, resulting from a thorough assessment of EU financial needs and political objectives as set out in EU multiannual programmes and policies defined by the legislative authority;

7. Is, therefore, convinced that any decision on the financial framework should be preceded by — and based on — a genuine political debate on the role, function and added value of the EU budget and on its compatibility with the political strategy adopted by the Union and operational priorities and objectives assigned to the Union; considers that, in order to bridge the gap between divergent visions on what the EU budget stands for and what it can achieve, this debate should be organised in due time and involve the three EU institutions and all national parliaments, but also engage the highest political level in the Member States;

8. Is convinced, moreover, that tangible progress can only be achieved following an in-depth reform of the financing of the EU budget that should respect the letter and the spirit of the Treaty and return to a system of genuine, clear, simple and fair own resources; stresses that the introduction of one or several new own resources will reduce the share of GNI-based contributions to the EU budget to a minimum and, accordingly, reduce the burden on national treasuries; reiterates its strong commitment to any process leading to the reform of the system of own resources, which is currently characterised by its complexity, opacity and inefficiency; regrets that the final Council agreement on own resources is even more complex than the previous one since it has introduced new rebates and exceptions;

Institutional considerations

9. Recalls that Parliament was the first EU institution to present its vision on the MFF 2014-2020 and the need to reform the financing of the EU budget, with the report of its specialised SURE Committee, in June 2011; believes that this early preparation helped Parliament to establish a large consensus on political priorities and remain united throughout the subsequent negotiating process; considers further that this report provided guidance for the Commission in drafting its own proposals on the MFF and own resources and appreciates the regular political dialogue that was established between the two institutions at all stages of the preparation of this report; considers that this practice should be further developed into a more structured dialogue between the two institutions ahead of the presentation of any MFF proposals;

10. Recalls that, pursuant to Article 312 TFEU, the Council unanimously adopts the MFF Regulation after obtaining the consent of Parliament, while the three EU institutions 'shall take any measure necessary to facilitate its adoption'; notes, therefore, that the Treaty does not set out any concrete procedure for the involvement of Parliament in the MFF negotiations and that these modalities were subsequently determined in practice through a number of ad hoc arrangements agreed at political level at Parliament's initiative;

Tuesday 15 April 2014

11. Considers it regrettable that, prior to the European Council agreement on the MFF of 8 February 2013, no meaningful negotiations were held between Parliament and the Council; considers that the numerous meetings held between its negotiating team and the successive Council presidencies on the margins of the relevant General Affairs Council meetings, and its participation in informal Council meetings dealing with the MFF, facilitated only some information-sharing between the Council and Parliament; sees, therefore, the need for Parliament to build further on the experience acquired and to use all means available to strengthen its influence on the spirit, calendar and content of the negotiations with the Council, by making the Council better acknowledge Parliament's arguments and positions;

12. Deplores the fact that, despite Parliament's strong objections, all successive 'negotiating boxes' presented by different Council presidencies and, ultimately, the European Council MFF agreement of 8 February 2013 contained a significant number of legislative elements that should have been decided under the ordinary legislative procedure; stresses that the legally required unanimity in the Council on the MFF Regulation could only be achieved by pre-empting certain major policy changes in EU sectoral policies, thereby hindering, in clear contradiction with the Treaties, Parliament's prerogatives under co-decision, and in particular its right to amend on an equal footing with the Council;

13. Notes that genuine negotiations on the MFF Regulation and the IIA were launched only in May 2013, with Council negotiators not having a formal negotiating mandate but instead considering the MFF agreement by the European Council as the only point of reference, with no margin for any discussion; stresses that this attitude not only led to an unnecessary loss of time but also to the unacceptable attempt by Council to exclude certain topics from the negotiations, forcing Parliament to struggle, including at the highest political level, in order to engage in negotiations on every article of the MFF Regulation / IIA;

14. Recalls that, according to the Treaty, the European Council does not exercise legislative functions; insists, therefore, that the conclusions of the European Council are to be seen as negotiating instructions for the Council and that they in no case constitute red lines which cannot be negotiated with Parliament; calls for a standard formula recalling the provisions of Article 15(1) TFEU to be included in the conclusions of the European Council;

15. Deeply regrets the fact that the same problem marked the negotiations on EU multiannual programmes, notably in agriculture and cohesion policy; notes that the Council refused in several instances even to refer to the 'MFF-related aspects' of those legal bases; stresses the considerable effort and time that was needed by Parliament to ensure that all points of the legal bases decided by co-decision between the Council and Parliament remained on the negotiating table; notes with satisfaction that Parliament's negotiators were eventually successful in challenging some parts of the European Council agreement;

16. Notes that the MFF figures (overall level and distribution per heading), as decided by the European Council, were not challenged in the end by Parliament, which acknowledged the particularly difficult economic and financial context at the time of this decision; stresses, however, that this should by no means be perceived as a precedent and reiterates its position that the MFF figures, and every other part of the European Council's relevant political agreement, are subject to negotiations with Parliament;

17. Stresses the need to significantly improve the modalities of any future MFF negotiations, in order to avoid deadlocks and save valuable time and resources in the course of negotiations; considers that these modalities should be formalised in an agreement at the highest political level, which should take account of the shortcomings of the recent negotiations and fully safeguard Parliament's role and prerogatives, as set out in the EU Treaty; considers that this procedure should eventually be enshrined in the IIA itself, as is the case for the budgetary procedure;

18. Points to the tremendous amount of information exchange and coordination required inside Parliament to ensure consistency in the parallel negotiations of the MFF and the legislative bases of over 60 multiannual programmes; underlines that it is of high importance to distinguish the issues that are to be adopted by codecision and keep them in the remit of the respective committees to the maximum extent possible; suggests that in the next MFF negotiations the European Parliament should approach the legislative proposals in parallel and finally adopt them as a package, applying the principle that nothing is agreed until everything is agreed to the maximum extent possible;

19. Is convinced that the unanimity rule in the Council means that the agreement represents the lowest common denominator, based on the need to avoid the veto of a single Member State; stresses that a shift towards qualified majority voting for the MFF Regulation would be in line not only with the ordinary legislative procedure, used for the adoption of virtually all EU multiannual programmes, but also with the annual procedure for adopting the EU budget;

Tuesday 15 April 2014

20. Notes that the general passerelle clause (Article 48(7) TEU) could be deployed by the European Council to make the shift towards qualified majority voting and the ordinary legislative procedure for the own resources and MFF decisions; recalls, moreover, that Article 312(2) TFEU in any case allows for the adoption of qualified majority voting for the MFF; urges the European Council to use both these passerelles for their intended purpose in order to streamline decision-making in the Council and to limit the extent to which the politics of national 'juste retour' prevail over the articulation of the common interest of the Union as a whole;

MFF 2014-2020: the way forward

21. Declares its intention to ensure that all new provisions that were successfully incorporated into the MFF Regulation and IIA are utilised in full in the annual budgetary procedure; expects that the Council will not attempt to impose restricted interpretations of these provisions, especially on the nature and scope of all special instruments, but that it will instead act responsibly and approve the necessary appropriations to meet both its previous commitments and unforeseen expenditure even if, as a result, the annual MFF ceilings need to be exceeded; recalls, in that context, that the MFF 2014-2020 ceilings have been set far below the own resources ceilings;

22. Places particular emphasis on the new rules on flexibility that should allow maximum use of the respective MFF ceilings for commitments and payments; stresses that the practice of previous financial frameworks whereby the annual EU budget remained far below the MFF ceilings, particularly in payment appropriations, can no longer be sustained;

23. Stresses, in this context, that the accumulated RALs have reached a critical level that might eventually lead the EU budget into structural deficit against the provisions of the Treaty (Articles 310 and 323 TFEU); is deeply concerned that the amount of unpaid bills at the end of the year has been constantly growing since 2011 (EUR 23,4 billion at the end of 2013 from cohesion policy alone), which will put significant pressure on the payment ceilings of the MFF 2014-2020; stresses the need to set the annual payments' ceilings of the MFF accurately by taking due account of, *inter alia*, the dynamics of cohesion policy, including the timing of programming, implementation, final closure of the programmes and decommitments;

24. Emphasises that the purpose of the global margin for commitments is to support investments for growth and employment in Europe, and in particular youth employment; recalls that this instrument was an initiative by the European Parliament;

25. Recalls that the next Commission, which will come into office after the 2014 European elections, is due to launch a compulsory review and revision of the MFF 2014-2020 by the end of 2016; underlines the fact that this post-electoral MFF review/revision clause was one of Parliament's key demands in the MFF negotiations, based on the need to allow the next Commission and Parliament to reassess the EU's political priorities, hence endowing the MFF with renewed democratic legitimacy; emphasises that, following the economic crisis, investment levels in Europe dropped significantly between 2008 and 2012 and recalls that according to some estimates⁽¹⁾, this will cost the continent EUR 540 billion in lost returns by 2020;

26. Stresses the need, in view of the post-electoral MFF review/revision, for the next Parliament to reflect in good time on political priorities, i.e. to identify areas for which more investments will be deemed necessary in the second half of the MFF 2014-2020; invites, for this purpose, the next Commission and the next Parliament to carefully evaluate the achievements of the targets of the Europe 2020 strategy, particularly in terms of employment and combatting the economic crisis, as well as the performance of key EU programmes, like Horizon 2020, in order to focus on areas of proven added value of EU spending and for which additional financial resources will be required;

27. Calls for the MFF mid-term review to prepare for an eventual reduction in the period for which the next MFF is agreed, so as to ensure its subsequent renegotiation during the mandate of each Parliament and Commission, thus ensuring full democratic legitimacy for regular decisions on the financial perspectives of the Union, while taking steps to meet the need for stability of programming cycles and for investment predictability; strongly believes that a five-year MFF cycle would enhance democratic legitimacy, improve the prioritisation of budgetary means and could be considered a precondition for more political debate;

⁽¹⁾ Address by the Chairman of the Board of Governors of the EIB during 2014 European Interparliamentary Week, 21 January 2014.

Tuesday 15 April 2014

28. Stresses that the Commission proposals for the MFF revision should take full account of the latest macroeconomic projections and include a thorough assessment of the operation of all special instruments, in particular the global margins in commitments and payments; recalls that this process will not have a downward impact on any pre-allocated national envelopes, including the ESF share of these national envelopes; expects, in this context, the Commission to provide Parliament and Council with identical and consistent data on figures and estimates in order to avoid misunderstandings in the negotiations with regard to the basis of discussion;

29. Stresses the need to stimulate a broad and open discussion on the results achieved with the EU's funding programmes, and in particular an assessment of the extent to which these programmes contribute to the achievement of the Europe 2020 objectives;

30. Emphasises that innovative financial instruments such as the European project bonds can have a very important role to play in stimulating much needed investments if designed correctly; urges the Commission in this regard to make optimal use of the upcoming evaluation also in the context of the review/revision of the MFF 2014-2020;

31. Welcomes the Joint Declaration by the three institutions agreed in the context of the MFF negotiations according to which the annual budgetary procedures will integrate, as appropriate, gender-responsive elements, taking into account the ways in which the overall financial framework of the Union contributes to increased gender equality (and ensures gender mainstreaming); stresses that these principles should be integrated into the Commission's proposals on the MFF revision;

32. Reiterates its intention to make the compulsory MFF revision a key demand in the investiture of the next Commission; calls, therefore, on the next European Parliament to make the election of the proposed candidate for President of the Commission conditional upon a strong and non-ambiguous commitment to implementing the post-electoral review/revision clause and engaging in a genuine and deep political dialogue on its content;

33. Notes that the new Rules 70 and 70a (interinstitutional negotiations in legislative procedures) of Parliament's Rules of Procedure will apply for the next round of negotiations; recommends that, early in Parliament's next mandate, the committee responsible for the Rules of Procedure be asked to look at rationalising those rules with Rule 75 (MFF), Rule 75c (financial trialogue) and Rule 81(3) (consent procedure) with a view to drafting a single coherent Rule specific to the special legislative procedures laid down in Articles 311 and 312 TFEU concerning the determination of the mandate, the conduct of the trialogues (including the role of the President), and scrutiny by the plenary;

34. Considers that, at the time of the next revision of the Treaties, the Convention should make proposals for a system of genuine codecision between the Council and Parliament on the adoption of the MFF and own resources decisions;

35. Strongly believes that the High Level Group on Own Resources represents a unique opportunity to overcome the deadlock that has arisen over the reform of the current own-resources system; expects that it will contribute significantly to understanding the shortcomings of the current system and the benefits that can derive from an in-depth, comprehensive reform and the introduction of new and genuine own resources which can significantly reduce the share of GNI contributions to the EU budget;

36. Recalls that the High Level Group has a mandate to examine all aspects of the reform of the own resources system; is firmly committed to working intensively, through its three representatives, at all stages of this process and to bringing it to a successful conclusion; counts on the Council's equal 'ownership' and commitment to this process; emphasises the need to raise awareness also among national parliaments of the issues at stake; stresses that the findings and conclusions of this High Level Group should be ready in good time to be considered during the 2016 MFF review/revision, in order to pave the way for possible reforms to become operational by the next multiannual financial framework;

37. Expresses its firm conviction that any new fiscal capacity or budget developed specifically for eurozone Member States whose fiscal functions are not covered by the MFF must be developed within the Union framework and must be subject to proper democratic scrutiny and accountability through the existing institutions;

Tuesday 15 April 2014

38. Instructs its President to forward this resolution to the European Council, the Council, the Commission and the national parliaments.

Tuesday 15 April 2014

P7_TA(2014)0394

Hospitable environment for enterprises, businesses and start-ups to create jobs

European Parliament resolution of 15 April 2014 on ‘How can the European Union contribute to creating a hospitable environment for enterprises, businesses and start-ups to create jobs?’ (2013/2176(INI))

(2017/C 443/04)

The European Parliament,

- having regard to the Treaty on the Functioning of the European Union,
 - having regard to the Commission communication of 3 March 2010 entitled ‘Europe 2020: a strategy for smart, sustainable and inclusive growth’ (COM(2010)2020),
 - having regard to the Small Business Act (COM(2008)0394),
 - having regard to the work of the Commission’s High Level Group of Independent Stakeholders on Administrative Burdens,
 - having regard to the Commission report ‘Minimising regulatory burden for SMEs — Adapting EU regulation to the needs of micro-enterprises’ (COM(2011)0803),
 - having regard to the Commission communication on EU regulatory fitness (COM(2013)0685),
 - having regard to the Commission’s Entrepreneurship 2020 action plan,
 - having regard to the Commission communication ‘An action plan to improve access to finance for SMEs’ (COM(2011)0870),
 - having regard to its resolution of 5 February 2013 on improving access to finance for SMEs ⁽¹⁾,
 - having regard to the Late Payments Directive (Directive 2000/35/EC of the European Parliament and of the Council),
 - having regard to the survey conducted by the Council of European Employers of the Metal, Engineering and Technology-Based Industries (CEEMET) entitled ‘Flexible employment contracts responding to changing market circumstances and meeting employee needs’ ⁽²⁾,
 - having regard to the new programme for Employment and Social Innovation (EaSI) which will, among other things, extend the support given to microcredit providers under the current European Progress Microfinance Facility,
 - having regard to the Eurofound report of January 2013 entitled ‘Born global: The potential of job creation in new international businesses’,
 - having regard to the Eurofound report of 2013 entitled ‘Public policy and support for restructuring in SMEs’,
 - having regard to the Eurofound report of 2010 entitled ‘Job creation measures’,
 - having regard to Rule 48 of its Rules of Procedure,
 - having regard to the report of the Committee on Employment and Social Affairs and the opinions of the Committee on Industry, Research and Energy and the Committee on Regional Development (A7-0101/2014),
- A. whereas the time it takes to start a business in Europe differs between Member States and varies from 4 to 40 days, which can impact on job creation;

⁽¹⁾ Texts adopted, P7_TA(2013)0036.

⁽²⁾ <http://www.ceemet.org/en/News/News/CEEMET-Survey-Flexible-employment-contracts-responding-to-changing-market-circumstances-and-meeting-employee-needs.htm>

Tuesday 15 April 2014

- B. whereas various factors including labour market rigidities have been identified in some Member States as having a negative impact on job creation, and the combination of job flexibility and security can provide a more favourable framework;
- C. whereas the single market and European human resources potential can play a key role in achieving the Europe 2020 employment targets;
- D. whereas SMEs are the backbone of the EU economy and have a huge potential for job creation, being responsible for 85 % of newly created jobs;
- E. whereas 20,7 million SMEs account for over 67 % of private-sector employment in the EU, with 30 % deriving from micro-enterprises;
- F. whereas the cost per employee of complying with regulatory obligations can be up to ten times higher for SMEs than for large businesses (COM(2011)0803);
- G. whereas due to the financial crisis and the credit crunch that arose in consequence SMEs are facing an extremely high cost of credit and the contraction of its availability; whereas, according to the Institute of International Finance, smaller businesses in the peripheral Member States are paying between 4 and 6 percentage points more for bank loans than their counterparts in central Europe, which is putting them at a significant disadvantage and thus hampering the region's prospects for economic revival and net job creation;
- H. whereas corporate bond, equity and securitisation markets in Europe remain relatively underdeveloped compared to other economies, and non-bank financing remains largely inaccessible to SMEs, undermining their potential to grow and create jobs;
- I. whereas the effective provision of services is crucial for future growth, innovation and job creation;
- J. whereas while we have the best-educated generation of youth in Europe's history, and Member States have invested huge amounts of money in education and training, our young people are largely cut off from the labour market and their skills remain unused as they compete for temporary and underpaid positions;
- K. whereas the European Social Fund has played an important role in assisting Member States to provide opportunities and training for unemployed people to re-enter the labour market;
- L. whereas the unemployment rate for young Europeans aged between 15 and 24 has reached the unsustainable level of 23 % and is above 50 % in those Member States most severely hit by the crisis; whereas this massive youth unemployment leads to a huge brain drain and significantly undermines our capacity for sustainable growth in the future;
- M. whereas the EU is threatened by the prospect of 'jobless growth', which will further undermine the social and economic fabric of our societies as well as the long-term prospects of the EU competing on an equal footing within a globalised knowledge-based economy;

Job creation

1. Is concerned at the cost, complexity and time involved in establishing a business in some parts of the European Union, all of which can impact negatively on future job creation; believes that if the EU is to improve its competitiveness and create more jobs, Member States must work to simplify and speed up this process, offer adequate assistance and support arrangements and make it less costly;
2. Notes that young enterprises that quickly and intensively internationalise after start-up show promising contributions to the economy by creating innovation themselves, fostering innovation in other companies, engaging in international supply chains and creating sustainable and good quality jobs; stresses, however, that these companies are confronted with considerable challenges at the start-up phase which have to be met quickly, while at the same time they have low levels of capital, so that low-cost, simple and quick start-up procedures would be beneficial for them;

Tuesday 15 April 2014

3. Notes that global trends have created competitive pressures as well as opportunities for businesses; stresses the need for Member States to create the right regulatory and fiscal framework to foster the creation of jobs whilst ensuring a safe working environment;
4. Believes that in order to create a more hospitable environment for job creation, Member States must, with support from the Union where appropriate, put in place the reforms needed to address the following factors: skills, levels of qualification, entrepreneurship, the impact of demographic change, market access, finance, the labour market, rights at work, administrative costs and better regulation;
5. Emphasises the importance of research and innovation for enhancing the competitiveness, productivity, sustainability and job-creation potential of European SMEs, and notes the significant focus that Horizon 2020 and the EIT place on creating and supporting high-growth, innovative SMEs;
6. Highlights the job potential of the green economy, which, according to Commission estimates, could create 5 million jobs by 2020 in the energy efficiency and renewable energy sectors alone, provided that ambitious climate and energy policies are put in place; calls on the Member States to ensure sufficient levels of investment in these sectors, anticipate workers' future skills, and guarantee the quality of 'green jobs';
7. Notes the important role of EU free trade agreements in creating and maintaining investment and jobs in EU Member States;
8. Takes the view that the steady development and deepening of the EU internal market is creating many substantial new opportunities for businesses of all sizes, clearly necessitating flexible framework provisions to promote entrepreneurship and self-employment, while the smooth functioning thereof requires a set of minimum regulatory standards, particularly in respect of public health and safety, health and safety in the workplace, food safety and environmental protection;

Skills

9. Believes the EU is faced with serious skills shortages and mismatches in certain regions and sectors, which are hindering economic growth and the achievement of the Europe 2020 strategy; notes that there are over 1,85 million unfilled vacancies in the EU; is concerned that the latest results of the Survey of Adult Skills (PIAAC), conducted by the OECD and supported by the Commission's DG Education and Culture, show that 20 % of the EU working-age population has low literacy and low numeracy skills and 25 % of adults lack the skills to make effective use of ICTs;
10. Notes the trend towards more skill-intensive jobs, with almost 90 % of jobs expected to be created or become vacant by 2020 requiring medium or high qualifications;
11. Considers that active policies to promote training courses and further training of workers, continuing education, school-business partnerships and apprenticeships could permit better matching of skills to those sought by businesses;
12. Recognises, in view of the skills shortage, the benefits that lifelong learning and free movement of workers in the EU can offer in addressing labour market demand;
13. Stresses that, while excellence, innovation and human resources are what constitute the comparative advantages of the Union, dwindling investment in research, education and training, coupled with the particularly high unemployment rates in individual Member States and in the euro area, are driving many Europeans to seek employment on other labour markets; stresses that the brain drain is a major obstacle to growth, greater Union competitiveness and measures to promote entrepreneurship;

Tuesday 15 April 2014

14. Believes that some Member States' education and training systems should be better adapted to and should converge with future businesses' skills needs; notes with concern that in 2015 the estimated shortage of qualified ICT personnel in the EU will rise to between 384 000 and 700 000 and that the supply of STEM skills (science, technology, engineering and mathematics) will not match the increasing demands of businesses in the coming years, while the declining rate of women participating in those subjects has not been properly addressed; advocates that Member States be encouraged to establish dual education and training systems focusing on STEM subjects and to promote the retraining and further training of workers, particularly those with low or obsolete skills;

15. Underscores the importance of dual education and training systems, focusing particularly on STEM subjects and combining practice-based education in vocational schools with learning in the workplace, since this has proved the most effective means of smoothing the transition from school to labour market;

16. Welcomes the Commission's communication 'Opening up Education', which aims to ensure that young people are equipped with digital skills;

17. Believes it is indispensable to introduce the teaching of entrepreneurship skills and programmes for learning how the market, the economy and the financial system operate, function and interact into basic education systems; believes that a well-prepared business plan is the first step towards better access to finance and viability; calls on the Commission and the Member States to include financial education and business start-up advice in their education programmes and to regard investment in entrepreneurial learning as a resource; supports, in this connection, the 'Erasmus for Young Entrepreneurs' programme, which is designed to promote an entrepreneurial culture and develop the single market and competitiveness;

18. Underlines the need to improve the pace of the school-to-work transition, thus enabling the young to enter the labour market as soon as possible and avoiding the risk of the NEET ('not in employment, education or training') phenomenon;

19. Notes that the European Structural and Investment (ESI) Funds provide support for authorities and stakeholders at the local, regional and national levels to foster, inter alia, work-based learning, research, development and innovation and to improve the competitiveness of micro-enterprises (especially one-person businesses) and SMEs, through cooperation with science and research facilities, thereby helping tackle the current economic and social challenges, in particular the high unemployment rate;

20. Stresses that efforts to support growth, innovation and job creation in a sustainable economy should guarantee health and safety standards and ensure a balance between economic, social and environmental requirements, while, inter alia, supporting smart specialisation, respecting the ecosystem and leading to adequately paid, quality jobs in all regions of the EU; underlines, in this connection, the important role to be played by businesses and the education sector through cross-border projects, cooperation between universities and other high-quality educational institutions and the creation of innovative 'clusters'; calls for local and regional funding programmes for apprenticeship training to be facilitated;

21. Considers that completion of the digital single market will help support and develop SMEs; considers it necessary to ensure that the necessary qualified ICT staff are available and that the European public possesses the digital skills necessary to make use of ICTs;

22. Stresses that, in order to address the skills shortage Europe is currently facing, urgent action is needed to speed up women's access to scientific and technological training and occupations, particularly in the new information and communications technology sector;

23. Calls for initiatives that will foster partnerships between businesses, research centres and universities and provide the necessary skills to enable Europeans to access ICT-related, energy-related and high-tech manufacturing jobs;

Tuesday 15 April 2014

Entrepreneurship

24. Is concerned that the number of EU citizens who want to be self-employed has dropped from 45 % to 37 % in the last three years, almost one half being afraid of going bankrupt and more than 50 % saying it is difficult to obtain sufficient information on how to start a business; considers that SME growth is linked to entrepreneurship; stresses that start-ups and self-employment create employment opportunities and help build strong industrial and services sectors, and advocates, therefore, that Member States be encouraged to promote entrepreneurial mindsets and skills at different education levels and to put in place business start-up advice in universities and vocational training colleges; notes with concern that women represent only 30 % of all entrepreneurs in Europe; stresses the need to promote female entrepreneurship by facilitating access to technical, scientific and business support networks and the development of coaching/mentoring programmes for women entrepreneurs;

25. Notes that the 'risk' factor regarding self-employment and the adverse effect of the recent economic crisis on borrowing conditions is a deterrent to engaging in such entrepreneurial activities; recommends, accordingly, that consideration be given to adoption of measures by Member States to balance the welfare safety net for the self-employed without detracting from the flexibility of this particular type of activity;

26. Notes with concern that the financial crisis and the subsequent recession have hit many European SMEs hard and that a significant number have ended up in liquidation, rather than with the company getting a fresh start; highlights the importance of a favourable regulatory framework to favour healthy restructuring and therefore job retention; welcomes the Commission's Entrepreneurship Action Plan supporting Member States' efforts to make it easier for sound businesses to survive and for honest entrepreneurs to get a second chance, since this will have a positive impact on job creation; urges the Commission to come forward with an overview of actions taken in the different Member States to enhance the climate for entrepreneurship; underlines the responsibility of the Member States to fully use the support offered by the Commission for improving the climate for entrepreneurs; welcomes the Commission's efforts to inform citizens and businesses about funding opportunities through publications such as 'Overview of the financial rules' and 'Funding opportunities 2007-2013';

27. Welcomes the Programme for the Competitiveness of Enterprises and SMEs (COSME) and the SME instrument provided for under Horizon 2020; laments the fact, however, that the budget for COSME and for SMEs in Horizon 2020 under the multiannual financial framework is limited;

28. Welcomes, in particular, the specific actions provided for under COSME which are designed to improve framework conditions for enterprises, particularly SMEs, to facilitate access to finance and markets, and to promote entrepreneurship and entrepreneurial culture; stresses that in order to promote the development of entrepreneurship in Europe a predictable and clear regulatory environment is essential; expects measures and actions promoting entrepreneurship at European or national level to cover enterprise models of all types, including cooperatives, craft businesses, liberal professions and social enterprises; welcomes especially the continued support for equity and debt finance provided under Horizon 2020 and COSME;

29. Believes that young entrepreneurs are enablers of innovation and job creation; underlines the need to connect experienced mentors to aspiring young entrepreneurs and facilitate the creation of support structures in innovative start-ups; welcomes schemes such as Erasmus for Young Entrepreneurs that are aimed at helping new entrepreneurs acquire relevant skills for managing a business, and believes that such programmes should be further promoted in order to help more entrepreneurs develop and create jobs; calls on the Member States to promote the practical aspects of entrepreneurial education and training in schemes such as school-company projects and training placements; calls on the Commission and the Member States to take this into account in the implementation of the COSME programme; welcomes the strengthening of the European Institute of Innovation and Technology (EIT), with its clear focus on providing entrepreneurial and innovative skills to 10 000 Masters' students and 10 000 Ph.D. students by 2020;

30. Calls for support for EU mobility programmes for entrepreneurs, such as Erasmus for Young Entrepreneurs, and for entrepreneurship education to be included in national school curricula through the exchange of best practice;

Tuesday 15 April 2014

31. Notes the importance of establishing and supporting business incubators, to provide young entrepreneurs with the opportunity to test their ideas and familiarise themselves with business networks and help them contact potential partners, clients and investors; believes that EU funding can play an essential role, and stresses the success of EU-funded projects and university programmes such as the ERDF-financed Birmingham Skills for Enterprise and Employability Network (BSEEN) in the UK which nurture enterprises and entrepreneurial skills by providing mentoring, intensive start-up support and incubator space for new ventures, and are thus key to future job creation;

32. Draws attention to the fact that, faced with the threat of closure, workers in many European companies can take over the ownership of those companies through cooperative societies; calls for consideration to be given to possible new lines of support through the European Globalisation Adjustment Fund and the European Investment Bank for companies involved in key sectors under the Europe 2020 strategy;

33. Is concerned at the growing phenomenon of bogus self-employment in the European Union; calls on the Member States to adopt specific policies to prevent this, such as sufficient employment opportunities or better labour inspection;

34. Calls on the Member States to promote a culture of internationalisation through information, the presentation of good practices and the provision of a platform for information exchange; urges them to provide skills development in the field of entrepreneurship with an international focus, to promote transparency as regards available support tools for start-ups, to support networking and exchanges that link young entrepreneurs with potential investors and business partners, and to provide operational advice and support even after the start-up phase in order to help them get through the critical early years and provide incentives for employment;

35. Emphasises the importance of providing young Europeans with entrepreneurial education and encouraging entrepreneurial attitudes; notes, in this context, the landmark role that the EIT plays in promoting an entrepreneurial culture through education, training and practice; notes that all the EIT's Knowledge and Innovation Communities actively promote entrepreneurship in their respective fields, through the development of curricula that combine excellent science and innovation with entrepreneurial skills and experiences, thus preparing the entrepreneurs of tomorrow and infusing existing businesses with an innovative and entrepreneurial mindset;

36. States that it is of the utmost importance for the EU's social cohesion to tackle the high unemployment rates, in particular among young people and other vulnerable groups, in the EU by boosting regional competitiveness and employment and fostering an entrepreneurial spirit; calls, therefore, on the Member States to use the ESI Funds to focus on creating sustainable jobs and business opportunities by providing a hospitable environment and the right regulatory framework for micro-, small and medium-sized enterprises, businesses and start-ups;

37. Points out that the ESI Funds have an important role to play in supporting employment and concrete projects aimed at enhancing entrepreneurial, enterprise and creative skills, including those of young people; underlines the need for all Member States and regions to make full use of this opportunity in order to tackle youth unemployment; stresses that, through the ESI Funds, local and regional authorities should pay particular attention to promoting entrepreneurship at local and regional level, including a focus on start-ups by young people;

38. Welcomes the growth in recent years of the social economy as a new form of entrepreneurship in the European Union, particularly for young people; calls on the Member States to develop strategies and programmes promoting the social economy;

Demographics

39. Believes that, given the widespread phenomenon of ageing populations, Member States should be encouraged, inter alia in the context of solidarity between the generations, to promote the retention of older workers, both women and men, on the labour market, by valuing experience; stresses that an older labour force and longer working lives can make a positive contribution to the recovery and to future growth; emphasises, therefore, the importance of lifelong learning, in particular for older workers; stresses, finally, that older people are indispensable with a view to passing on knowledge and experience to younger generations;

Tuesday 15 April 2014

40. Believes in the importance of promoting senior entrepreneurship as a means of engaging the senior population with significant business experience in the innovation process, thereby extending working lives and retaining indispensable skills in the labour market;
41. Calls on the Member States to effectively implement the EU legislation outlawing discrimination in the workplace on the grounds of age, disability, sexual orientation or religion or belief;
42. Recognises the importance of taking into account the situation of people who have to reconcile work and family life;

Market access

43. Stresses that the opportunities afforded directly by the EU single market must be used to inject new life into Europe's economies by opening up borders, removing existing obstacles that hamper workers' mobility, and creating new business opportunities and jobs;
44. Calls for the remaining barriers to the cross-border provision of services to be dismantled, thus enabling them to create more jobs;
45. Stresses that for SMEs, size does matter, and that a larger scale allows SMEs to more easily withstand economic cycles, build deeper expertise, find new customers and markets, link into global supply chains, and obtain easier access to bank financing and broaden funding sources, thus creating more jobs; believes that the Commission and the Member States should encourage the provision of education in management and business strategy for SME owners looking to expand their businesses; highlights the importance of aid to SMEs to develop connections to untapped foreign markets by redirecting existing public agencies to work with banks and SMEs' associations towards that end;
46. Stresses that the introduction of suitable and flexible single market framework provisions to promote entrepreneurship and support the small and medium-sized undertakings that form the economic backbone of the Union must not, under any circumstances, be achieved to the detriment of minimum European labour standards and fundamental labour rights;
47. Notes that it is crucial to ensure support for SMEs aiming to internationalise through medium- and long-term loans or equity investments, and to educate SMEs in how to access trade financing;
48. Notes the importance that the digital economy has for creating jobs, especially when linked to sectors in which Europe is traditionally strong, such as the creative industries, cultural heritage and tourism;
49. Stresses that free and fair competition in the single market, underpinned by common social standards, is of crucial importance for boosting growth and innovation and thereby increasing employment in the Union;

Finance

50. Notes that bank lending is still the most common source of finance in Europe; believes however, that there are real benefits in new forms of financing through innovative schemes and non-bank routes, such as crowdfunding, SME angels, peer-to-peer lending, micro-lending, easily accessible microcredit agencies and other tools, which can provide vital investment for start-ups and SMEs to grow and create jobs; believes that new forms of financing would be beneficial for young, dynamic businesses which have difficulties in accessing more traditional sources of finance due to their 'newness'; stresses that such new forms of financing should not be limited to start-up and growth phases and that fostering alternative capital markets would also be beneficial for realising positive outcomes for both companies and their employees, for example in cases of restructuring;

Tuesday 15 April 2014

51. Considers it extremely important for Member States to implement Directive 2011/7/EU on combating late payment in commercial transactions, under which, with regard to transactions between undertakings and public authorities, the contractual payment period must not exceed the time limits laid down in Article 4(3) unless otherwise expressly agreed in the contract and provided it is objectively justified in the light of the particular nature or features of the contract and in any event does not exceed 60 calendar days;
52. Emphasises that non-innovative and established SMEs looking to expand into new markets or to transfer their ownership often also need public support in order to secure the necessary financing;
53. Stresses that the cohesion policy for the 2014-2020 period is an important and effective instrument for generating smart, sustainable and inclusive growth and achieving the Europe 2020 targets while supporting, through a wide range of measures and innovative financial instruments, the start-up and development of small and medium-sized enterprises (SMEs), including micro-enterprises, as a key motor of job creation in the EU;
54. Welcomes initiatives to make it easier for citizens, organisations and businesses, in particular SMEs, to access EU support via a single multilingual portal offering information on the Structural Funds, including the ESF Horizon 2020 and COSME; also welcomes the Enterprise Europe Networks endeavours in this field; believes, nonetheless, that more must be done to disseminate clear and comprehensive information about funding opportunities to existing and potential entrepreneurs through 'one-stop shops' throughout the regions, and to encourage financial intermediaries to make greater use of the funding sources available;
55. Asks for a better coordination of EU funding mechanisms, including Structural Funds, ERDF, Horizon 2020 and EIB investments, especially when it comes to funding innovative SMEs, and asks for an assessment of current obstacles arising from the fact that in several Member States banks fail to transfer funds and loan guarantees to SMEs and the real economy;
56. Underlines the importance of research and innovation for enhancing the competitiveness, productivity, sustainability and job-creation potential of European SMEs, and notes the significant focus that Horizon 2020 and the EIT place on creating and supporting high-growth innovative SMEs;
57. Welcomes the creation of an SME instrument under the Horizon 2020 programme enabling SMEs to access financial and non-financial support in order to implement innovative ideas; calls on the Commission to introduce this instrument as of 2014 in the most SME-friendly way, i.e. through a single dedicated agency, allowing for the genuine 'bottom-up' submission of projects and supporting all types of innovation, including non-technological and social innovation;
58. Points out that firms, however, often face problems in finding money to finance their research, develop new products or access new markets;
59. Supports EU initiatives which help SMEs access more financial resources with greater ease, on the grounds that they make for easier, faster access to funding for young and innovative companies, encourage Member States to adopt mechanisms to foster innovation (e.g. tax credit mechanisms to fund research and innovation) and redress inequalities between Member States; supports initiatives seeking to encourage entrepreneurs whose businesses have failed, so as to offer them a second chance and not discourage risk-taking;
60. Welcomes the simplification of reimbursement methods as part of the Commission's proposal for a Common Provisions Regulation on the Structural Funds, given the important role that these instruments play in many regions in the promotion of entrepreneurship and skills; asks the Commission to monitor SMEs' access to Community funding and to report to Parliament on the matter;
61. Takes the view that public investment and state support for the setting-up and continued operation of undertakings is crucial; believes that Member States should demand safeguards and guarantees from companies setting up in each Member State and receiving public support; with the objective of preserving jobs;

Tuesday 15 April 2014

Labour market

62. Strongly believes that businesses could create more jobs if the right conditions exist, including access to a qualified and highly-skilled workforce, work-life balance, reasonable costs and taxes, and keeping administrative and regulatory burdens to a minimum;

63. Notes the importance of workplace flexisecurity, on the one hand in giving workers a fair degree of security and on the other in allowing economic operators to react in a flexible way to changes in the market;

64. Sees the introduction of 'youth coaches' in employment agencies as an important step towards further reducing the numbers of young people who fail to make the transition from education to the labour market;

65. Believes Member States must invest more in human capital and be more responsive to labour market needs, notably by ensuring strong links between the world of education and the world of work, ensuring that young people are equipped with the right information, advice and guidance to make sound career choices, and fostering work-based learning apprenticeships, as well as retraining of employees and provision of lifelong learning opportunities;

66. Considers that there is major scope for increasing the involvement of the social partners and the bodies concerned in the formulation of a long-term strategy for small and medium-sized enterprises, this being the only way to identify malfunctions, formulate intelligent and flexible legislation, avoid market fragmentation and promote the creation and development of sustainable and quality employment;

67. Calls on the Commission and the Member States to create viable transition schemes from higher education and vocational training to the labour market, especially for first-time young professionals;

68. Calls on the Member States to continue taking policy measures, accompanied by economic and regulatory incentive mechanisms, which shape culture and educational systems through the creation of partnerships and exchange networks between all the various levels of education and companies, in order to bridge the current gap between academia and the market and make it easier for researchers to move from universities to companies, thereby fostering innovation;

SMEs and micro-enterprises

69. Considers that SMEs are the main drivers of innovation and economic growth in the EU and play a crucial role in providing pathways into work for people of all ages and for both women and men; regrets that in many Member States they are excluded from public research, innovation and development policy;

70. Highlights the importance of SMEs not only in creating but also in preserving jobs;

71. Points out that more than 20 million SMEs in the EU represent 99 % of businesses, and that SMEs are a key driver of economic growth, innovation, employment and social integration;

72. Believes that public policy measures play an important role in supporting and stimulating the creation and development of SMEs (e.g. affordable loans, advisory services on public initiatives and legislation, incubators and accelerators, clusters, technology transfer offices, coaching and mentoring schemes, etc); considers that networking and the exchange of best practice play an important role in this respect; believes that intangible and non-financial forms of support, such as access to knowledge and information, financial education and business networks, are essential for new entrepreneurs and SMEs to develop their businesses; considers that, in order to stimulate the internal market and trade among small businesses, it is particularly important to ensure the mutual recognition of occupational qualifications and the interoperability of different commercial regulatory systems;

Tuesday 15 April 2014

73. Believes that innovation in SMEs is an important route to job creation; points out that if SMEs are to participate successfully in the innovation system, it is essential that they are in the driving seat with regard to their innovative activities and that support is better tailored to their real needs;
74. Underlines the 'think small first' principle; recognises the benefits of crossborder e-commerce in providing new opportunities for SMEs to access the single market, create employment opportunities, reduce costs and compete globally;
75. Stresses the opportunities offered by ICTs in terms of enhancing productivity and competitiveness; emphasises the need for the potential of the digital single market to be unleashed, and points out that the cost of creating an innovative ICT start-up has fallen by a factor of 100 in the last ten years, mainly as a result of technologies such as ultra-fast and ubiquitous broadband, cloud computing, open-source software, open data and access to public-sector information;
76. Highlights the fact that eGovernment is particularly beneficial for entrepreneurs (particularly SMEs, who often face insurmountable barriers when operating across borders within the EU), as it brings reduced administrative costs and burdens, increased productivity, efficiency, competitiveness, transparency, openness, policy effectiveness, accessibility and streamlining of procedures;
77. Believes that the lack of adequate protection for SMEs can in many cases cripple businesses and stall economic growth, and may also discourage entrepreneurs from taking chances, which will impact on their ability to grow and create jobs;
78. Notes that the main barriers facing start-ups and affecting the development of high-growth SMEs are difficult access to and cost of finance, burdensome regulation, lack of knowledge of regulations, indirect costs, restricted access to export markets, average payment times and skills shortages;
79. Welcomes the introduction of the 'SME test' and the Commission's commitment to propose lighter regulatory regimes for SMEs and exemptions for micro-businesses on a case-by-case basis, without compromising on health, safety and employment standards; believes that mitigating measures must be introduced across a range of legislative proposals, e.g. longer implementation time, efficient and effective inspections, or guidelines to simplify firms' paperwork, but without creating a two-tier labour market;
80. Welcomes initiatives such as the CREATE project which address the barriers to growth and job creation and competitiveness experienced by SMEs in rural areas;
81. Believes that Member States must be encouraged to share best practice — for example, through the European Network of SME Envoys on innovative ways to create jobs, by reducing bureaucracy and red tape and improving communication, particularly for SMEs and microenterprises;
82. Urges the Commission and the Member States to help local authorities and SMEs' associations promote local production and product quality, for example through the formation of business clusters for joint research and development projects;
83. Believes that also organisations representing SMEs should be encouraged to share cross-border best practices on innovative ways to reduce bureaucracy and red tape;
84. Regrets that the labour reforms taking place in various Member States are resulting in many workers no longer being protected by collective agreements, especially in SMEs; considers that any improvements in labour flexibility should be accompanied by adequate labour protection;
85. Believes that the framework for SME participation in public procurement should be improved;

Tuesday 15 April 2014

86. Notes that in many Member States there is insufficient support and/or an insufficient regulatory framework to ensure appropriate conditions for young and innovative companies and start-ups, and stresses the need for better coordination of the different European, national, regional and local policies and instruments concerning SMEs;

87. Stresses the need to strengthen EU rules on product traceability, so as to combat counterfeiting and create an effective means of encouraging the development of SMEs;

Better regulation

88. Stresses the need for more efficient and more clearly-worded regulations that can be implemented in a simple manner and can help all actors, including entrepreneurs, operate within the rule of law and enable both entrepreneurs and employees to benefit from the opportunities and protection afforded by employment and health and safety legislation;

89. Underlines the need for greater integration of Union policies in favour of SMEs as regards innovation, growth, competitiveness, internationalisation, entrepreneurship, resource productivity, reducing bureaucracy, the quality of human resources, and environmental and social responsibility;

90. Acknowledges the Commission's actions to address the results of the review of the 'Top 10' most burdensome laws for SMEs, which will help businesses create more employment opportunities; believes that the Commission should urgently prioritise the improvement of these regulations in ways that address SMEs' concerns; believes there is a need to ensure that the EU and Member States take account of the specific needs of, and considers support measures for businesses, in particular SMEs and micro-enterprises, in the policy process;

91. Points out that young companies which internationalise rapidly and intensively after their start-up phase make useful contributions to the economy by creating innovation, encouraging other companies to innovate, taking part in international supply chains and creating sustainable high-quality employment; notes, however, that since these companies face considerable challenges during the start-up phase due to low levels of capital, low-cost, simple and quick start-up procedures would be of benefit to them;

92. Stresses that rules on health and safety at work and workers' protection cannot be considered as burdensome regulations; calls on the Commission to simplify excessive administrative burdens while always ensuring health and safety at work and guaranteeing that SMEs have adequate knowledge and resources enabling them to manage their employees' working environment properly;

93. Notes the new health and safety strategy; hopes it will focus on prevention, usability, clarification, simplification, prevention, and better implementation of existing legislation in order to ensure workers' health and safety;

94. Welcomes the reduction of REACH registration fees for SMEs, even though fees represent a fraction of overall compliance costs; is extremely concerned, however, that initial cost estimates from REACH were underestimated, with this difference already amounting to over EUR1 billion — a figure that will continue to rise;

95. Stresses the need to improve overall business efficiency through projects and instruments which make it possible to confront the challenge of energy recovery with a view to encouraging reduced energy costs;

96. Points out that the provisions of the regulations for the 2014-2020 cohesion policy period aim to reduce the administrative burden on micro-enterprises and SMEs, particularly as regards the activation of unemployed people, thereby contributing to better conditions for job creation; calls on the Member States to do away with the obstacles standing in the way of better implementation of the ESI Funds for the benefit of micro-enterprises and SMEs;

Tuesday 15 April 2014

Recommendations

97. Calls on the Commission and the Member States to act with speed and ambition to reduce the regulatory burden on SMEs, while ensuring that any proposed solutions are evidence-based and respecting health and safety and Article 9 TFEU;

98. Calls on the Commission and the Member States to fully exploit the job potential of the green economy by developing a Renaissance of Industry for a Sustainable Europe (RISE) strategy that pursues technological, business and social innovation towards a third industrial revolution including a low-carbon modernisation offensive; argues that RISE will create new markets, business models and creative entrepreneurs, new jobs and decent work, bringing an industrial renewal with economic dynamism, confidence and competitiveness; believes that energy and resource efficiency are key pillars of such a strategy;

99. Considers that an appropriate approach could be offered by the Commission's proposal that micro-entities should be excluded from the scope of future proposed legislation unless there is a need for them to be covered;

100. Calls on the Commission to ensure that national SME organisations are part of the newly-established network of SME Envoys and the SME Assembly and are properly informed of EU initiatives and policy proposals; stresses, in this context, the equally important role of the European Information Centres (EICs), which have so far not managed to provide a service that lives up to the expectations and needs of European businesses;

101. Calls on the Member States to promote language learning through lifelong learning (vocational training), for employees of SMEs and micro-entities, as a means of reinforcing access to and participation in the single market for such firms;

102. Asks the Commission to ensure easier access for SMEs to structural funds, notably by relaxing the requirements for pre-financed projects, reducing the requirements for cofinancing, better targeting different types of SMES, closing the financing gap between call cycles, and supporting capacity-building for SME funding;

103. Recommends MEPs to make full use of the Impact Assessment and European Added Value Directorate in order to scrutinise the cost, benefits and other implications of proposed draft legislation on SMEs and job creation in particular;

104. Calls on the Commission and the Member States to be more rigorous in assessing the impact of future and existing regulation on SMEs and competitiveness in general;

105. Reminds Member States of their commitment under the Small Business Act to make it possible to start a business within 48 hours maximum; calls on the Member States, in this context, to make every effort to reach this target in order to achieve the employment targets contained in the Europe 2020 strategy;

106. Calls on the Commission to address any identified negative effects that EU legislation has on businesses and their ability to create jobs, particularly with regard to the aspects of lack of knowledge, overall perception and lack of support for the practical application of EU legislation; calls on the Commission to improve the flow of information to SMEs;

107. Calls on the Commission, in the context of the REFIT programme, to check that all legislation is doing what it was intended to do, and to identify areas where there are inconsistencies or ineffective measures affecting employment opportunities;

108. Highlights the recent trend of companies returning production and services to Europe and the opportunities this brings for job creation; believes that the economies of the EU have a unique opportunity to accelerate this trend of re-shoring jobs and calls on the Member States, together with the Commission, to consider dedicating support, including the possibility of setting up 'one-stop shops', to help businesses take advantage of the opportunities offered by re-shoring;

109. Calls on the Member States and the Commission to support self-employment, possibly across borders and especially among women and young people, by creating an environment and developing an education and social protection system that will encourage entrepreneurs to set up and develop their businesses and create new jobs by, for example, promoting entrepreneurship among students and professionals;

Tuesday 15 April 2014

110. Expresses its hope that entrepreneurship will be a more prominent topic in the next years; notes that this will require reflection, particularly with regard to the implementation of the Entrepreneurship 2020 Action Plan; considers that developing entrepreneurial spirit and skills is a sustainable way forward in terms of job creation, more start-ups and business innovation; would like to see the Commission name 2017 the 'European Year for Entrepreneurship';

111. Calls on the social partners to embrace smart regulation tools, increase the use of impact assessments in their negotiations, and refer agreements proposing legislative action to the Commission's Impact Assessment Board;

112. Insists that the Data Protection Regulation should follow a balanced approach, protecting data privacy while stimulating the digital economy, job creation and growth;

113. Calls on the EU to work with Member States, universities, research establishments and businesses in order to coordinate and make full use of EU funding sources (e.g. ESF, ERDF, COSME, Horizon 2020 and Erasmus+), in order to promote an entrepreneurial culture, particularly among women and young people, develop and upgrade the qualifications and skills needed by the labour market, and support the creation of new businesses;

114. Calls on the EU and the Member States to cooperate on introducing entrepreneurship skills into curricula at all stages of education;

115. Calls on the EU to work with Member States, schools and universities on the implementation of open technology-based education;

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116. Instructs its President to forward this resolution to the Council and Commission.

Tuesday 15 April 2014

P7_TA(2014)0395

New technologies and open educational resources**European Parliament resolution of 15 April 2014 on new technologies and open educational resources (2013/2182(INI))**

(2017/C 443/05)

The European Parliament,

- having regard to Articles 165 and 166 of the Treaty on the Functioning of the European Union,
- having regard to Article 14 of the Charter of Fundamental Rights of the European Union,
- having regard to the Commission Communication of 25 September 2013 entitled ‘Opening up Education: Innovative teaching and learning for all through new Technologies and Open Educational Resources’ (COM(2013)0654) and the accompanying staff working document on analysis and mapping of innovative teaching and learning for all through new Technologies and Open Educational Resources in Europe (SWD(2013)0341),
- having regard to the Commission Communication of 11 July 2013 entitled ‘European higher education in the world’ (COM(2013)0499),
- having regard to Regulation (EU) No 1288/2013 of the European Parliament and of the Council of 11 December 2013 establishing ‘Erasmus+’: the Union programme for education, training, youth and sport and repealing Decisions No 1719/2006/EC, No 1720/2006/EC and No 1298/2008/EC⁽¹⁾,
- having regard to the Council conclusions of 24 February 2014 on efficient and innovative education and training to invest in skills — supporting the 2014 European Semester⁽²⁾,
- having regard to the Council recommendation of 20 December 2012 on the validation of non-formal and informal learning⁽³⁾,
- having regard to the Council conclusions of 14 February 2011 on the role of education and training in the implementation of the Europe 2020 strategy⁽⁴⁾,
- having regard to the Council conclusions of 11 May 2010 on the social dimension of education and training⁽⁵⁾,
- having regard to the Council conclusions of 11 May 2010 on the internationalisation of higher education⁽⁶⁾,
- having regard to its resolution of 22 October 2013 on rethinking education⁽⁷⁾,
- having regard to its resolution of 12 September 2013 on the digital agenda for growth, mobility and employment: time to move up a gear⁽⁸⁾,

⁽¹⁾ OJ L 347, 20.12.2013, p. 50.

⁽²⁾ OJ C 62, 4.3.2014, p. 4.

⁽³⁾ OJ C 398, 22.12.2012, p. 1.

⁽⁴⁾ OJ C 70, 4.3.2011, p. 1.

⁽⁵⁾ OJ C 135, 26.5.2010, p. 2.

⁽⁶⁾ OJ C 135, 26.5.2010, p. 12.

⁽⁷⁾ Texts adopted, P7_TA(2013)0433.

⁽⁸⁾ Texts adopted, P7_TA(2013)0377.

Tuesday 15 April 2014

- having regard to its resolution of 11 September 2012 on education, training and Europe 2020 ⁽¹⁾,
 - having regard to its resolution of 20 April 2012 on modernising Europe's higher education systems ⁽²⁾,
 - having regard to its resolution of 26 October 2011 on the agenda for new skills and jobs ⁽³⁾,
 - having regard to its resolution of 12 May 2011 on Youth on the Move — a framework for improving Europe's education and training systems ⁽⁴⁾,
 - having regard to the opinion of the European Economic and Social Committee of 26 February 2014 ⁽⁵⁾,
 - having regard to the opinion of the Committee of the Regions of 31 January 2014 ⁽⁶⁾,
 - having regard to Rule 48 of its Rules of Procedure,
 - having regard to the report of the Committee on Culture and Education (A7-0249/2014),
- A. whereas education and training systems need to be geared towards achieving equal opportunities in learning and towards meeting an increasing need for the continuous updating of knowledge and skills and an increasingly international labour market while aiming at greater efficiency and equity;
- B. whereas the Europe 2020 strategy aims to boost innovation, create new employment opportunities, improve social cohesion and build solid foundations for sustainable and inclusive growth in the EU through a highly skilled workforce that enjoys equal access to education;
- C. whereas high unemployment levels, particularly among young people, including university graduates, coincide with a significant number of vacancies in Europe that cannot be filled, pointing to a marked skills gap that could best be overcome, inter alia, through dual vocational training models; whereas in 2012 15,8 % of young people in the EU were neither in employment nor in education or training (NEET), and thus at risk of being excluded from the labour market due to increased skills mismatches;
- D. whereas it is expected that by 2020, 90 % of jobs will require digital skills, and whereas by 2015 there will be up to 900 000 unfilled information and communication technologies (ICT)-related vacancies in the EU;
- E. whereas the number of university graduates is expected to quadruple by 2030;
- F. whereas 18-28 % of students in the EU have few possibilities to access and use the internet either at school or at home; whereas only 30 % of students in the EU can be considered as digitally competent; whereas only 20 % of students in the EU are taught by digitally confident and supportive teachers; whereas 70 % of teachers in the EU do not consider themselves digitally confident and would like to further develop their ICT skills; whereas 40 % of Europeans aged 16-74 have low or no ICT skills;
- G. whereas open educational resources (OERs) can play a crucial role in facilitating lifelong learning for all learners and in improving the quality of content and the distribution of both formal and informal education providers, and whereas, at the same time, a digitally inadequate education system can hamper the development of learners' knowledge and skills;

⁽¹⁾ OJ C 353 E, 3.12.2013, p. 56.

⁽²⁾ OJ C 258 E, 7.9.2013, p. 55.

⁽³⁾ OJ C 131 E, 8.5.2013, p. 87.

⁽⁴⁾ OJ C 377 E, 7.12.2012, p. 77.

⁽⁵⁾ Not yet published in the Official Journal.

⁽⁶⁾ Not yet published in the Official Journal.

Tuesday 15 April 2014

- H. whereas the EU has still not fully grasped the potential of ICT in terms of cultural and educational wealth and diversity, access to information and the exchange of good practices;
- I. whereas the modernisation of education systems in Europe requires investment in education facilities that are well equipped in terms of information and communication technologies;
- J. whereas, it is therefore vital that broadband access become more widespread, including in the rural, mountain and outlying areas of the Member States;
- K. whereas schools should also train children and young people in the practical and critical use of digital technologies and the internet;

Opportunities and challenges

1. Welcomes the Commission communication which sets out a Union agenda in the field of OERs, and which focuses on the potential of these resources to widen access to and equity in education and further diversify it, and acknowledges the relevance of OERs in an increasingly digital society; believes that the emergence of a European framework for the development of OERs may allow for improvement in the Member States' education systems;
2. Notes that, in order to realise the benefits of OERs, actions leading to universal digital education should be supported, with a focus on good practices and their promotion in various environments;
3. Emphasises that OERs create opportunities for both individuals, such as teachers, students, pupils and learners of all ages, and educational and training institutions to teach and learn in innovative ways; calls on educational institutions to further assess the potential benefits of OERs in the respective educational systems and in view of possibly creating an organisational environment in which such innovation is welcomed, internalised, applied and promoted; calls, in this connection, on the Member States and regions, as part of smart specialisation strategies, to establish innovation and start-up centres of excellence which make full use of the potential of ICT;
4. Deplores the lack of differentiation in the Commission communication between school levels as regards the deployment of new technologies and digital content for learning and teaching purposes; stresses that learners acquire different skills and competences depending on their age, and that consequently curricula and learning methods vary according to school level;
5. Notes that quality assurance plays a crucial role in increasing the trust in and use of OERs; encourages research on and the dissemination of good practices to facilitate the effective use of OERs, investing, in particular, in the areas of methodological experimentation, meta-skills (reflexive, proactive and critical thinking skills) and soft skills; notes that research should also be encouraged with regard to the methods of assessing the skills acquired for such courses which cannot be restricted to peer assessment or automated systems, as occurs in communities of practice;
6. Acknowledges the fact that OERs are generally produced in a limited number of languages and mainly, although not exclusively, by higher education institutions (especially as regards massive open online courses (MOOCs)); encourages education and training institutions at all levels across the Member States, as well as other relevant stakeholders, to produce OERs in their own languages in order to exploit the full potential of digital technology and multilingualism; recalls that the availability, accessibility and innovativeness of materials plays a key role in terms of using e-learning materials in education;
7. Points out that ICT and OERs are currently mainly used in higher education; encourages, where appropriate, their use in primary and secondary education, as well as in vocational education and in other informal learning settings, where student-centred learning combined with ICT also carries huge potential;
8. Notes that proper contextualisation is a critical factor in making educational software effective; points out that this process must be suitably embedded into teaching and learning processes, and must take into account pedagogical and curriculum objectives, tools and individual learning paths;

Tuesday 15 April 2014

9. Stresses the need to facilitate the recognition of knowledge and skills acquired through OERs by means of further dialogue with stakeholders, and calls on the Member States to incorporate appropriate measures into their national qualification frameworks for the validation of such learning;
10. Points to the need to make it easier to obtain recognition for skills acquired abroad, in order to boost and facilitate the use of OERs and MOOCs by pruning bureaucratic structures;
11. Highlights the fact that availability of and access to free, high-quality and suitable online teaching materials is crucial;
12. Stresses the need for the harmonisation of existing limitations and exceptions in copyright for the purpose of illustration in non-commercial teaching, in order to facilitate OERs and distance learning across borders, and to allow European platforms to compete globally by creating economies of scale;
13. Urges the Commission to put forward a proposal to review Directive 2001/29/EC, with the aim of establishing a harmonised and flexible system of copyright and related rights in the EU which is fit for the digital age and acknowledges the public value of access to knowledge;
14. Encourages Member States to explore the predicted potential of OERs for reducing the public and private costs of education, in particular the costs of education materials, without neglecting quality;
15. Notes the importance of ensuring sustainable models for the creation of OERs and MOOCs; calls on the Commission to support further research into the formation, usage and uptake thereof, in dialogue with stakeholders;
16. Acknowledges that the adoption of OERs should be done in a manner that fosters development of 21st century learning solutions, and creates new business opportunities for small and medium-sized innovative European providers of learning solutions;
17. Calls on the Member States to strengthen informal education on online safety and to provide for online safety policies in schools by offering appropriate training to teachers;
18. Calls on the Member States to ensure coordinated and progressive education on internet safety in schools; notes that parents and legal guardians should be regarded as partners in ensuring web safety, and recommends that complementary strategies targeting them be developed, thereby strengthening the role of parental mediation; stresses the fact that these efforts should be aimed at strengthening young people's independence so that they can take ownership of their actions and responsibilities on the web and develop e-skills; insists that the protection of the physical and psychological integrity and privacy of teachers and learners using OERs must be assured;
19. Calls on the Commission to support the exchange of good practices between Member States in the formal and informal education sectors with regard to online safety, the creation of relevant educational content and the formation of public-private partnerships with the aim of involving young people, their parents and teachers and all those who work with young people, including the non-governmental organisations involved in the Safer Internet network;

Skills for teachers and learners

20. Notes that new technologies and OERs allow for a more interactive learning experience and are valuable instruments in placing the learner at the centre of the educational process;
21. Stresses that teachers at all levels of education have a fundamental role in facilitating access to and the use of online learning materials by all learners and in assisting them in acquiring digital skills;
22. Stresses the urgent need for all learners to have the fastest and best possible technical equipment, as well as vital access to broadband internet;

Tuesday 15 April 2014

23. Recalls the crucial importance of high-quality training for teachers and trainers that must be complemented with mandatory career-long professional training focusing on innovative teaching methods and instructing learners about approaches to education ('learning how to learn');
24. Urges the Member States to support teachers in their professional development by offering them modern curricula in their initial education, and by providing them with in-service training geared to equip them with the necessary competences for the use of digitally supported teaching methods;
25. Emphasises, in particular, the proven benefits of European experience abroad for teachers and trainers, for example through the Erasmus+ programme, and calls for a massive expansion of this and other related programmes;
26. Points out that basic literacy and numeracy skills, in addition to meta-skills and soft skills, as well as transversal skills, such as critical thinking and learning to learn, are a prerequisite for developing digital skills and using online educational materials, including OERs, effectively; calls, in this context, on the Commission to further assess the impact of digital and/or online learning materials on the learning performance of learners according to their age and school level;
27. Recognises the importance of traditional ways of teaching and learning, and calls on the Commission to support further research into the question of whether and how OERs and MOOCs can enhance individuals' learning outcomes in addition to, or as an integral part of, traditional teaching methods;
28. Recalls that innovative teaching methods facilitated through ICT and OERs contribute to the development of soft and transversal skills, such as critical thinking, decision-making, communications skills and problem-solving, which are crucial for employability and job market realisation;
29. Stresses that education policies should primarily aim at assisting learners in the development of crucial cognitive and social skills; calls on the Commission to further assess the impact on learners of deploying digital devices and contents for pedagogical purposes while ensuring their physical and psychological integrity;
30. Points out that OERs geared towards the needs of adult learners should be developed so as to ensure greater lifelong learning opportunities for low-skilled European citizens, bearing in mind the fact that many learners have low ICT skills;
31. Underlines the fact that digital skills and knowledge are vital for citizens in an information-driven society that aims to become the most dynamic knowledge-based economy in the world;
32. Notes that digital literacy, in opening up new channels for communication and education, has a positive impact in terms of strengthening social cohesion, personal development, intercultural dialogue and active citizenship;
33. Highlights the fact that ICT and online educational materials, including OERs, can support the teaching and learning of foreign languages at all levels of education and training; stresses that social interaction is a prerequisite for learning a foreign language;
34. Urges the Member States to improve and deepen digital skills also by including coding and programming in their respective curricula, in order to foster economic competitiveness and equip students with the right skills for the job market of the future;

Tuesday 15 April 2014

35. Reiterates that continuous updating of knowledge and skills is essential for successful labour market integration, and notes that OERs can contribute to facilitating the lifelong learning that is necessary in order to remain competitive on the labour market; encourages a more gender-balanced use of ICT with a view to ensuring that women who remain outside the labour market for a given period, for example for maternity or other family care tasks, are also able to benefit from this type of training to update their skills and educate themselves, thereby improving their future re-employment opportunities on the labour market;

36. Points out that public libraries and education centres can offer free access to computers and the internet and training on internet resources;

Widening the reach

37. Stresses the importance of access to education and training and IT equipment for all learners in all age groups, as well as for those with disabilities, those coming from disadvantaged backgrounds, young people currently not in education, employment or training (NEET) and those coming from geographically remote regions, as well as anyone wishing to improve their qualifications;

38. Notes, once again, that not everyone has access to ICTs under equivalent pricing arrangements and in terms of service quality, and that, in general, urban areas are better served than rural areas, thereby creating a digital divide that undermines the notion of equal opportunities for all citizens, wherever they may be in the EU;

39. Stresses the growing importance of adult education, particularly in the context of lifelong vocational training, and calls for the Europe-wide recognition, strengthening and promotion of all adult education organisations;

40. Highlights the advantages of inter-generational learning, and points to the great educational potential offered by digital learning and OERs, also as regards wider access to education and training for all age groups;

41. Acknowledges that new technologies and OERs, in particular MOOCs, have made it possible for education and training institutions to reach thousands of learners in the Union, including in its outermost regions, and around the world; recognises that education and knowledge now travel easily across borders, which increases the potential for international cooperation and helps to promote European educational institutions as centres for innovation and the development of new technologies;

42. Notes that it is important to keep a fair balance between the quality and accessibility of education; highlights the fact that new technologies can be used to ensure that more accessible education does not mean a reduction in the quality of education;

43. Notes that the EU risks falling behind other regions of the world, such as the United States or Asia, where heavy investments are made in research and development, new technologies and OERs; insists that the Union must build on its strength in cultural and linguistic diversity and adapt investments in e-learning material, including OERs, and in new technologies to best support its population;

44. Recalls that new technologies can contribute to the competitiveness of European education on the global stage, offer opportunities for the internationalisation of European higher education, and, as a result, increase Europe's attractiveness as an educational destination;

45. Stresses that OERs can contribute to improving the quality of European education; encourages, in this connection, cooperation with educational institutions around the world, in particular in the United States;

46. Reiterates that successful OER strategies and MOOCs can support internationalisation strategies by improving the quality and visibility of European (higher) education institutions and attracting students and researchers in an increasingly global competition for talent;

Tuesday 15 April 2014

47. Calls on the Member States to promote cooperation and synergies in the field of lifelong learning, in particular to make it as easy as possible to gain access to learning and to adapt and modernise the curricula of educational institutions to the rapidly developing potential and possibilities of digital learning and OERs, in order to address the new challenges of the contemporary world as effectively as possible;

48. Encourages strengthened cooperation between European education and training institutions, and with international organisations and stakeholders, to facilitate a better understanding of new teaching and learning methods and the impact of ICT on education; encourages the development of common platforms for such cooperation;

49. Stresses that the use of new technologies in education should be well targeted to respond to the needs of the job market and overcome the present skills gap; stresses the need for improved communication and cooperation between educational and training institutions and the business sector;

50. Notes that new technologies and e-learning have the added value of providing an international learning experience for those who do not participate in mobility schemes;

51. Points out that digital technologies are not fully exploited in education and training across the Union; fears that this situation may lead to a further fragmentation of teaching and learning approaches; calls on the Member States to apply equity principles to the new markets, given that OERs should remain a tool to broaden access to education and not become a purely economic endeavour;

52. Stresses that digital technology is an important learning tool for citizenship, facilitating the participation of many citizens living in peripheral areas and especially of young audiences, allowing them to benefit fully from freedom of expression and online communication;

The contribution of EU programmes

53. Welcomes the launch of the Open Education Europa portal in all EU languages, providing a single gateway to European OERs, and calls for the portal to be vigorously developed and promoted in the Member States;

54. Notes that an appropriate digital infrastructure based on commonly used, popular technologies is a prerequisite for reaching the highest possible number of learners with OERs;

55. Calls on the Commission to organise an annual European regional planning conference to ensure that all citizens have access to ICT services wherever they may be in the EU;

56. Points out that local and regional authorities have a key role to play in developing infrastructures, disseminating and publicising various measures to a wider public, involving other local stakeholders and disseminating and implementing the relevant European initiatives at national, regional and local level;

57. Calls on the Member States and the local and regional authorities to use the funding available through the European Structural and Investment Funds to overcome the territorial digital divide by improving infrastructure and networks and promoting training in ICT and the effective use thereof, taking into account the needs of educational institutions, in particular in rural and remote regions; notes that the smart and comprehensive use of EU funding requires synergy between the different programmes and instruments, including Erasmus+, Horizon 2020 and the structural and investment funds;

58. Calls on the Commission to encourage the exchange of good practices between Member States and between educational institutions, drawing on existing projects and experiences;

59. Welcomes the Commission initiative to develop indicators to closely monitor the integration of ICT in teaching and training institutions, and to support Union-wide quantitative surveys;

Tuesday 15 April 2014

60. Calls on the Commission to promote and extend the network and action of European Schoolnet;
61. Appreciates that all educational materials drawn up with support from Erasmus+ will be available to the public under open licences; encourages similar practices for other Union programmes, including a broad roll-out of open access under the Horizon 2020 programme;
62. Highlights the fact that Erasmus+ and Horizon 2020 can play an important role in generating OERs through communities of practice, such as that of school teachers using the eTwinning platform; encourages an extension of the use of these platforms to other educational sectors;

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63. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.
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Wednesday 16 April 2014

P7_TA(2014)0429

European Parliament's right of inquiry**European Parliament legislative resolution of 16 April 2014 on a proposal for a regulation of the European Parliament on the detailed provisions governing the exercise of the European Parliament's right of inquiry and repealing Decision 95/167/EC, Euratom, ECSC of the European Parliament, the Council and the Commission (2009/2212(INL))**

(2017/C 443/06)

The European Parliament,

- having regard to the third paragraph of Article 226 of the Treaty on the Functioning of the European Union,
 - having regard to Rules 41 and 48 of its Rules of Procedure,
 - having regard to the report of the Committee on Constitutional Affairs (A7-0352/2011),
1. Adopts as its proposal for a regulation the text adopted on 23 May 2012 ⁽¹⁾;
 2. Invites the Council and the Commission to notify their consent to the proposal;
 3. Invites the Council and the Commission, if they are unable to give their consent to the proposal in its present form, to resume negotiations with the newly elected Parliament, acknowledging the progress made in past negotiations at political level and during the informal contacts at technical level, notably concerning the issue of confidentiality and the handling of classified and other information;
 4. Instructs its President to forward this resolution to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 264 E, 13.9.2013, p. 41.

Wednesday 16 April 2014

P7_TA(2014)0430

Relations between the European Parliament and the national parliaments

European Parliament resolution of 16 April 2014 on relations between the European Parliament and the national parliaments (2013/2185(INI))

(2017/C 443/07)

The European Parliament,

- having regard to the Treaty on European Union (TEU), in particular the preamble thereto and Articles 4(3) (sincere cooperation between the Union and Member States), 5 (conferral of competences and subsidiarity), 10(1) (representative democracy), 10(2) (representation of EU citizens) and 12 (role of national parliaments) thereof,
- having regard to Protocol No 1 on the role of national parliaments in the European Union, in particular the preamble thereto and Title II, on interparliamentary cooperation, thereof, and to Protocol No 2 on the application of the principles of subsidiarity and proportionality, annexed to the Treaty of Lisbon,
- having regard to its resolutions of 12 June 1997 on relations between the European Parliament and the national parliaments ⁽¹⁾, of 7 February 2002 on relations between the European Parliament and the national parliaments in European integration ⁽²⁾, and of 7 May 2009 on the development of the relations between the European Parliament and national parliaments under the Treaty of Lisbon ⁽³⁾,
- having regard to its resolution of 4 February 2014 on ‘EU Regulatory Fitness and Subsidiarity and Proportionality — 19th report on Better Lawmaking covering the year 2011’ ⁽⁴⁾,
- having regard to the final recommendations of 20 December 2011 of the steering group on relations with national parliaments under the Lisbon Treaty,
- having regard to the Commission’s annual reports on relations between the European Commission and national parliaments, in particular the report for 2012 (COM(2013)0565),
- having regard to the conclusions adopted by the Conference of Speakers of EU Parliaments (the EU Speakers’ Conference) at its meetings since the entry into force of the Lisbon Treaty ⁽⁵⁾, in particular those held in Warsaw in 2012 and in Nicosia in 2013,
- having regard to the contributions to, and conclusions of, the meetings of the Conference of Parliamentary Committees for Union Affairs of Parliaments of the European Union (COSAC) since the entry into force of the Lisbon Treaty, in particular the L COSAC meeting in Vilnius in 2013, and to COSAC’s biannual reports ⁽⁶⁾,
- having regard to COSAC’s 20th biannual report, in particular the sections on democratic legitimacy in the EU and the role of parliaments and on political dialogue and the European elections in 2014,
- having regard to the contribution from the national parliaments to the meeting of COSAC chairpersons held at the Greek Parliament in Athens on 26 and 27 January 2014,
- having regard to the guidelines on interparliamentary cooperation adopted by the EU Speakers’ Conference at its meeting of 21 July 2008 in Lisbon,

⁽¹⁾ OJ C 200, 30.6.1997, p. 153.

⁽²⁾ OJ C 284 E, 21.11.2002, p. 322.

⁽³⁾ OJ C 212 E, 5.8.2010, p. 94.

⁽⁴⁾ Texts adopted, P7_TA(2014)0061.

⁽⁵⁾ <http://www.ipex.eu/IPEXL-WEB/euspeakers/getspeakers.do>

⁽⁶⁾ <http://www.cosac.eu/>

Wednesday 16 April 2014

- having regard to the conclusions of the Interparliamentary Conferences for the Common Foreign and Security Policy (CFSP) and the Common Security and Defence Policy (CSDP) of 9 and 10 September 2012 in Paphos (Cyprus), of 24 to 26 March 2013 in Dublin (Ireland) and of 4 to 6 September 2013 in Vilnius (Lithuania), and to the contribution of the Interparliamentary Conference on Economic and Financial Governance of the EU held under Article 13 of the Treaty on Stability, Coordination and Governance (TSCG) on 16 and 17 October 2013 in Vilnius (Lithuania),
 - having regard to its resolutions of 12 December 2013 on constitutional problems of a multitier governance in the European Union ⁽¹⁾ and on relations between the European Parliament and the institutions representing the national governments ⁽²⁾,
 - having regard to the report entitled ‘Towards a genuine economic and monetary union’, presented on 5 December 2012 by Presidents Van Rompuy, Juncker, Barroso and Draghi,
 - having regard to the conclusions of the European Council meetings of 13 and 14 December 2012, of 24 and 25 October 2013 and of 19 and 20 December 2013,
 - having regard to Rule 130 of its Rules of Procedure,
 - having regard to its resolution of 13 March 2014 on the implementation of the Treaty of Lisbon with respect to the European Parliament ⁽³⁾,
 - having regard to Rule 48 of its Rules of Procedure,
 - having regard to the report of the Committee on Constitutional Affairs (A7-0255/2014),
- A. whereas, in accordance with the TEU, the European Union’s current institutional set-up must be viewed as a stage in the process of creating an ever closer union, which was begun when the European Communities were established;
- B. whereas under the principle of sincere cooperation the Union and its Member States assist each other, in full mutual respect, in carrying out tasks flowing from the Treaties, and whereas the Member States facilitate the achievement of the Union’s tasks and refrain from any measures that could jeopardise the attainment of the Union’s objectives;
- C. whereas Article 12 of the TEU, covering the activities of the national parliaments, fleshes out the principle of sincere cooperation by stating that the national parliaments contribute actively to the good functioning of the Union;
- D. whereas the principle of conferral defines the competences of the Union, which are exercised in accordance with the principles of subsidiarity and proportionality, and whereas all the EU institutions, together with the national parliaments, seek to ensure that legislative acts comply with the subsidiarity principle;
- E. whereas democratic legitimacy and accountability must be ensured at all levels at which decisions are taken and implemented, and also in the mutual interactions between those levels;
- F. whereas the Union operates on the basis of representative democracy and a twofold democratic legitimacy stemming from the European Parliament, directly elected by the citizens, and the Member States, as represented in the Council by their governments, which are in turn democratically accountable to their national parliaments and citizens;
- G. whereas the European Parliament and the national parliaments are, in their respective spheres, the pillars of the Union’s twofold democratic legitimacy, the former as the institution in which EU citizens are directly represented and the latter as the national institutions to which the governments represented in the Council are directly accountable;

⁽¹⁾ Texts adopted, P7_TA(2013)0598.

⁽²⁾ Texts adopted, P7_TA(2013)0599.

⁽³⁾ Texts adopted, P7_TA(2014)0249.

Wednesday 16 April 2014

- H. whereas, accordingly, the national parliaments do not form a 'third chamber' of the EU's legislature, but instead serve to hold to account the Union's second chamber, the Council;
- I. whereas it is therefore appropriate to accept this constructive approach from the national parliaments, which is expressed in the communication of such contributions;
- J. whereas the national parliaments should develop strong and coherent EU-related structures with the aim of enhancing links with the European institutions and gaining further expertise on issues pertaining to European affairs;
- K. whereas, at the current stage of integration, the national parliaments have their own special role to play in bolstering 'European awareness' in the Member States and bringing citizens closer to the EU;
- L. whereas interparliamentary cooperation can play an essential role in driving the European integration process forward by allowing exchanges of information, joint examination of issues, mutually beneficial dialogue and smoother transposition of EU legislation into national law;
- M. whereas following the establishment of the Interparliamentary Conference for the Common Foreign and Security Policy (CFSP) and the Common Security and Defence Policy (CSDP) and of the Interparliamentary Conference on Economic Governance, as well as the consolidation of the role of interparliamentary committee meetings as the preferred channel for cooperation, COSAC should remain the forum for a regular exchange of views, information and best practice regarding the practical aspects of parliamentary scrutiny;
- N. whereas the European Parliament should be more closely involved in the 'political dialogue' — in particular the enhanced version engaged in as part of the European semester for economic policy coordination — that the Commission has established with the national parliaments, above all in view of the interdependence between the decisions of the European Parliament and those of the national parliaments;
- O. whereas the changes made to its Rules of Procedure have taken into account the Lisbon Treaty provisions on the role of the national parliaments in the EU;
- P. whereas the role played by the EU Speakers' Conference in interparliamentary cooperation at the current stage should be noted;

I. *National parliaments and the Union's democratic legitimacy*

1. Welcomes the Treaty provisions giving the national parliaments a range of rights and duties allowing them to contribute actively to the good functioning of the Union; sees these rights and duties as covering:
 - (a) active involvement in EU affairs (Treaty ratification powers, participation in Conventions under Article 48 of the TEU, scrutiny of national governments, scrutiny of subsidiarity, ability to oppose legislation under exceptional circumstances, transposition of EU legislation into national law);
 - (b) political dialogue (interparliamentary cooperation and mutual exchange of information with the European institutions, in particular the European Parliament);
2. Points out that the twofold democratic legitimacy of the Union, as a union of citizens and of Member States, is embodied, in the EU legislative process, by the European Parliament and the Council; believes that, if the Member States are to be represented in a unitary, fully democratic manner in the EU, the stances taken by national governments in the Council should take due account of the views of their national parliaments, thereby reinforcing the democratic nature of the Council;
3. Stresses that proper legitimacy and accountability must be ensured at national and EU level by the national parliaments and the European Parliament respectively; recalls the principle, set out in the conclusions of the December 2012 European Council meeting, that 'throughout the process, the general objective remains to ensure democratic legitimacy and accountability at the level at which decisions are taken and implemented';

Wednesday 16 April 2014

4. Commends the national parliaments for taking steps to:
 - (a) improve their guidance and scrutiny procedures with a view to achieving greater consistency;
 - (b) provide ministers and national governments with prior guidance on their work within the Council and the European Council, in accordance with their national constitutional framework;
 - (c) scrutinise the stances taken by ministers and national governments within the Council and the European Council, in accordance with their national constitutional framework;
 - (d) play an effective role in providing guidance on and scrutinising the implementation of directives and regulations;
 - (e) encourage the Council to improve the transparency of its deliberations on legislative acts, in particular during the preparatory stage of the legislative process, in order to reduce the information asymmetry between the European Parliament and the Council;
 - (f) appraise the relations between the committees of the European Parliament and those of the national parliaments;
5. Recognises the role played by the committees of the European Parliament and those of the national parliaments throughout the EU legislative process;
6. Deplores, therefore, the lack of transparency of such deliberations and the lack of balance in the flow of information between the European Parliament and the Council; calls on the Council to apply the same standards of transparency as Parliament, in particular during the drafting of legislative acts;
7. Believes that the lack of transparency of Council deliberations, in particular regarding legislative acts, makes it difficult for governments to be genuinely accountable to their national parliaments;
8. Notes that the thresholds provided for in Article 7(3) of Protocol No 2 have been reached twice to date in the subsidiarity scrutiny process; recalls that the purpose of the early warning mechanism is not to block the European decision-making process, but to improve the quality of EU legislation by ensuring, in particular, that the EU operates within its competences;
9. Takes the view, therefore, that the monitoring of compliance with the subsidiarity principle by the national parliaments and the European institutions should be seen not as an undue restriction, but as a mechanism for guaranteeing the competences of the national parliaments, in that it helps to mould the form and substance of beneficial EU legislative activity;
10. Believes that the early warning mechanism should be viewed and used as one of the tools for ensuring effective cooperation between European and national institutions;
11. Welcomes the fact that in practice this mechanism is also being used as a channel for consultation and cooperative dialogue between the various institutions within the EU's multilevel system;
12. Believes that reasoned opinions delivered by the national parliaments should be viewed by the institutions not least as an opportunity to gain a clearer picture of how best to achieve the objectives set for legislative acts, and calls on the Commission to reply promptly and fully to reasoned opinions and contributions sent in by the national parliaments;

II. *Interparliamentary relations and the European integration process*

13. Reiterates that EU interparliamentary cooperation does not take the place of the normal parliamentary scrutiny exercised by the European Parliament in accordance with the competences conferred on it by the Treaties and by the national parliaments over their governments' EU-related activities; believes that its aim is to:
 - (a) foster the exchange of information and best practice between the national parliaments and the European Parliament, with a view to enabling all of them to exercise more effective scrutiny and contribute more fully, without undermining their respective competences;

Wednesday 16 April 2014

(b) ensure that parliaments are able to exercise their powers in respect of EU matters to the full;

(c) foster the emergence of a genuinely European parliamentary and political culture;

14. Views interparliamentary meetings as places where EU and national policies come together and feed off each other, to the benefit of both; believes that a key function of such meetings is to allow the national parliaments to take account of the European perspective in national debates, and the European Parliament to take account of the national perspective in European debates;

15. Draws attention to the fact that the novel European interparliamentary system is still taking shape and needs to reflect a consensus-based approach in accordance with Title II, Article 9 of Protocol No 1 to the Lisbon Treaty, under which both the European Parliament and the national parliaments are jointly tasked with determining by consensus the organisation and promotion of interparliamentary cooperation within the Union, although any attempt to devise a common framework for interparliamentary cooperation is still premature;

16. Welcomes the actions that have been taken — in accordance with the recommendations of the steering group on relations with the national parliaments — since the entry into force of the Treaty of Lisbon to intensify cooperation between the national parliaments and the European Parliament, in particular as regards the planning of interparliamentary committee meetings, the increase in the number of such meetings (50 since 2010), the forwarding to members of the national parliaments and relevant political bodies of national parliament submissions (reasoned opinions and contributions), the introduction of videoconferences, the promotion of bilateral visits, technical improvements to the InterParliamentary EU information eXchange (IPEX), the increase in the number of collaborative projects carried out under the aegis of the European Centre for Parliamentary Research and Documentation (ECPRD), visits by administrative officials and the exchange of information and of best practice; believes that these actions help to make interparliamentary relations more efficient and more focused, while contributing to parliamentary democratisation;

17. Stresses that interparliamentary meetings need to be organised in close cooperation with the national parliaments in order to enhance their effectiveness and quality; recommends, therefore, their inclusion at the earliest stage possible in drafting the agenda for interparliamentary meetings;

18. Believes that the development of interparliamentary meetings should be based on practical arrangements allowing for the special features of each type of meeting;

19. Commends the effectiveness of interparliamentary committee meetings and calls for closer cooperation between rapporteurs on specific legislative issues;

20. Welcomes the effective meetings between political groups and European political parties as part of the arrangements for EU interparliamentary cooperation; calls for further endorsement of these meetings as an effective means of developing an authentic European political consciousness;

21. Welcomes the role played by IPEX, above all as a platform for the exchange of information on parliamentary scrutiny procedures, notwithstanding the language-related difficulties that may arise; calls, with a view to making the dialogue between parliaments as effective as possible, for the national parliaments to pay particular attention to the principle of multilingualism;

22. Stresses that interparliamentary cooperation must be open and inclusive, and voices its concern about restricted interparliamentary meetings, to which some parliaments are not invited, being organised without proper consultation in order to adopt positions on EU affairs which are not consensus-based;

23. Notes that the ‘political dialogue’, set up under the Barroso Initiative in 2006, and the early warning mechanism are two sides of the same coin; notes the development of wide-ranging relations between the national parliaments and the Commission and the establishment of ‘enhanced political dialogue’ as part of the European semester for economic policy coordination;

III. *Developments and proposals*

24. Proposes that an understanding be developed between the national parliaments and the European Parliament, which could form the basis for efficient cooperation pursuant to Article 9 of Protocol No 1 to the Lisbon Treaty and Rule 130 of its own Rules of Procedure;

Wednesday 16 April 2014

25. Calls for regular, thematically structured and effective meetings between political groups and European political parties to be held in the framework of EU interparliamentary cooperation;
26. Stresses that interparliamentary cooperation must seek at all times to bring the right people together at the right time to address the right issues in a meaningful way, so as to ensure that the decisions taken in the various areas of responsibility benefit from the 'added value' brought by real dialogue and proper debate;
27. Believes that COSAC should remain the forum for a regular exchange of views, information and best practice regarding practical aspects of parliamentary scrutiny;
28. Recalls that with respect to the conference on economic governance, which is based on Article 13 of the Treaty on Stability, Coordination and Governance, an agreement reached by the EU Speakers at their conference in Nicosia in April 2013 provides for a number of arrangements for that conference and for a review of these arrangements, to be completed in 2015 at the Rome EU Speakers' Conference; takes the view, therefore, that any procedure for the adoption of practical arrangements for the conference on economic governance prior to that review would be premature and should therefore be avoided;

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29. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.
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Wednesday 16 April 2014

P7_TA(2014)0431

Implementing measures for the system of own resources ***

European Parliament legislative resolution of 16 April 2014 on the draft Council regulation (EU, Euratom) laying down implementing measures for the system of own resources of the European Union (05600/2014 — C7-0047/2014 — 2011/0184(APP))

(Special legislative procedure — consent)

(2017/C 443/08)

The European Parliament,

- having regard to the draft Council regulation (05600/2014),
 - having regard to the request for consent submitted by the Council in accordance with the fourth paragraph of Article 311 of the Treaty on the Functioning of the European Union and Article 106a of the Treaty establishing the European Atomic Energy Community (C7-0047/2014),
 - having regard to its resolution of 29 March 2007 on the future of the European Union's own resources ⁽¹⁾,
 - having regard to its resolution of 8 June 2011 on investing in the future: a new Multiannual Financial Framework (MFF) for a competitive, sustainable and inclusive Europe ⁽²⁾,
 - having regard to its resolution of 13 June 2012 on the Multiannual Financial Framework and own resources ⁽³⁾,
 - having regard to its resolution of 23 October 2012 in the interest of achieving a positive outcome of the Multiannual Financial Framework approval procedure ⁽⁴⁾,
 - having regard to its resolution of 13 March 2013 on the European Council conclusions of 7-8 February 2013 concerning the Multiannual Financial Framework ⁽⁵⁾,
 - having regard to its resolution of 3 July 2013 on the political agreement on the Multiannual Financial Framework 2014-2020 ⁽⁶⁾,
 - having regard to its resolution of 16 April 2014 on implementing measures for the system of own resources of the European Union ⁽⁷⁾,
 - having regard to the fact that for the first time the Treaty requires Parliament's consent to implementing measures for the system of the Union's own resources,
 - having regard to Rule 81(1), first and third subparagraphs, of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Budgets (A7-0269/2014),
1. Gives its consent to the draft Council regulation;
 2. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 27 E, 31.1.2008, p. 214.

⁽²⁾ OJ C 380 E, 11.12.2012, p. 89.

⁽³⁾ OJ C 332 E, 15.11.2013, p. 42.

⁽⁴⁾ OJ C 68 E, 7.3.2014, p. 1.

⁽⁵⁾ Texts adopted, P7_TA(2013)0078.

⁽⁶⁾ Texts adopted, P7_TA(2013)0304.

⁽⁷⁾ Texts adopted, P7_TA(2014)0434.

Wednesday 16 April 2014

P7_TA(2014)0434

Implementing measures for the system of own resources**European Parliament resolution of 16 April 2014 on implementing measures for the system of own resources of the European Union (2014/2020(INI))**

(2017/C 443/09)

The European Parliament,

- having regard to the draft Council decision (05600/2014),
 - having regard to the Commission proposal for a Council regulation (COM(2011)0740),
 - having regard to the request for consent submitted by the Council in accordance with the third paragraph of Article 311 of the Treaty on the Functioning of the European Union (C7-0047/2014),
 - having regard to its resolution of 29 March 2007 on the future of the European Union's own resources ⁽¹⁾,
 - having regard to its resolution of 8 June 2011 on investing in the future: a new Multiannual Financial Framework (MFF) for a competitive, sustainable and inclusive Europe ⁽²⁾,
 - having regard to its resolution of 13 June 2012 on the Multiannual Financial Framework and own resources ⁽³⁾,
 - having regard to its resolution of 23 October 2012 in the interest of achieving a positive outcome of the Multiannual Financial Framework approval procedure ⁽⁴⁾,
 - having regard to its resolution of 13 March 2013 on the European Council conclusions of 7-8 February 2013 concerning the Multiannual Financial Framework ⁽⁵⁾,
 - having regard to its resolution of 3 July 2013 on the political agreement on the Multiannual Financial Framework 2014-2020 ⁽⁶⁾,
 - having regard to the second subparagraph of Rule 81(1) of its Rules of Procedure,
 - having regard to the report of the Committee on Budgets (A7-0270/2014),
- A. whereas, according to Article 311 TFEU, the Council, acting by means of regulation in accordance with a special legislative procedure, shall lay down implementing measures for the Union's own resources system in so far as this is provided for in the decision laying down the provisions relating to the system of own resources of the Union;
- B. whereas Article 311 TFEU also stipulates that the budget shall be financed wholly from own resources and allows the Council to establish new categories of own resources or abolish an existing category, providing thus the legal basis for an in-depth reform of the own resources system;
- C. whereas Parliament has continuously called for the financing of the EU budget to return to a genuine system of own resources, as stipulated in the Treaty; whereas it has regularly highlighted the shortcomings and limits of the existing system of own resources, the lack of transparency and high complexity of which make it totally incomprehensible to European citizens, who ultimately bear the consequences;

⁽¹⁾ OJ C 27 E, 31.1.2008, p. 214.⁽²⁾ OJ C 380 E, 11.12.2012, p. 89.⁽³⁾ OJ C 332 E, 15.11.2013, p. 42.⁽⁴⁾ OJ C 68 E, 7.3.2014, p. 1.⁽⁵⁾ Texts adopted, P7_TA(2013)0078.⁽⁶⁾ Texts adopted, P7_TA(2013)0304.

Wednesday 16 April 2014

- D. whereas national contributions to the EU budget, based on GNI, which amount nowadays to around 74 % of total EU revenue, cannot be considered as genuine own resources as they simply constitute transfers from national treasuries to the EU budget; whereas the VAT-based resource, which represents around 11 % of total EU revenue, has developed in such way that it is also perceived as a national contribution to the EU budget; whereas this situation has reinforced, over decades, the logic of 'fair return' that also clearly prevailed in the conclusions of the European Council of 7-8 February 2013 on the MFF 2014-2020 and has largely prevented a structural reform of the EU budget;
- E. whereas, because of austerity measures, Member States are reluctant to increase their contributions to the EU budget, despite the undisputed benefits they derive from EU budget-funded programmes, and whereas a system of direct own resources for the EU is the only viable solution;
- F. whereas Parliament has consistently manifested its support for the Commission proposals, presented in June 2011, which — by reducing the share of national contributions to the EU budget to a maximum of 40 %, abolishing the current purely statistical VAT-based contribution and replacing it by a genuine VAT-based EU resource, creating one new and genuine own resource and replacing all rebates and correction mechanisms by a system of lump sums for the period 2014-2020 — took a step in the right direction by bringing the EU budget revenue side into line with the letter and spirit of the Treaty, and which, as such, from the outset gained the support of an overwhelming majority in Parliament;
- G. whereas despite its discontent with the inability of the Council to progress on the reform of the system of own resources, Parliament eventually gave its consent to the MFF 2014-2020 Regulation in November 2013, following the agreement with the Council on a joint declaration on the establishment of the High-Level Group on Own Resources; whereas, on that occasion, the Lithuanian Presidency declared its commitment to organising the inaugural meeting of this Group on 18-19 December 2013; whereas, due to delays within the Council in deciding on its three nominees to this High-Level Group, the meeting is only taking place in April 2014;
- H. whereas the High-Level Group on Own Resources aims to produce a first assessment of the current system's shortcomings by the end of 2014, with a final outcome in 2016 to be assessed at an interinstitutional conference with the participation of national parliaments; whereas the High-Level Group should examine all aspects of the reform of the own resources system with a view to providing the Commission with the necessary means to assess whether new own-resource initiatives are appropriate in parallel with the post electoral review/revision of the 2014-2020 MFF (to be launched no later than the end of 2016) and to propose a successful reform for the period covered by the post-2020 Multiannual Financial Framework;
1. Welcomes the Council's agreement to lay down implementing measures for the Union's own resources as provided for in the Treaty on the Functioning of the European Union;
 2. Considers it regrettable, however, that the Council has decided to transfer the provisions related to the calculation of the GNI resources back to the Own Resources Decision; takes the view that this represents a missed opportunity to group together all implementing provisions in a single text, and that Article 311 of the Treaty of Lisbon does not provide an objective justification for this split;
 3. Deplores the fact that the Council has not been able to make any progress on the reform of the own resources system on the basis of the legislative proposals put forward by the Commission;
 4. Maintains its call for reform of the own resources system of the European Union in order to make it simple, transparent, fair, visible and understandable to EU citizens, thereby reinforcing the EU citizens' link to the European project while at the same time reducing the burden on Member States' national treasuries;
 5. Places high expectations on the work of the High-Level Group on Own Resources, which it believes offers a unique opportunity to overcome the current blockage of the reform of the system of own resources; welcomes the first meeting of the High-Level Group on 3 April 2014; expects that, despite the considerable and regrettable delay in organising this inaugural meeting, the High-Level Group will still comply with the objectives and the calendar set out in the joint declaration establishing the High-Level Group on Own Resources;
 6. Instructs its President to forward this resolution to the Council, the Commission and the national parliaments.
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Thursday 17 April 2014

P7_TA(2014)0455

Negotiation of the EU-Japan strategic partnership agreement

European Parliament resolution of 17 April 2014 containing the European Parliament's recommendation to the Council, the Commission and the European External Action Service on the negotiations of the EU-Japan Strategic Partnership agreement (2014/2021(INI))

(2017/C 443/10)

The European Parliament,

- having regard to the first bilateral summit held in the Hague in 1991 and to the adoption of a joint declaration on EC-Japan relations,
- having regard to the 10th bilateral summit held in Brussels in 2001 and the adoption of the EU-Japan action plan entitled 'Shaping our common future', including the objectives of promoting peace and security, strengthening the economic and trade partnership, coping with global and societal challenges, and bringing together people and cultures,
- having regard to the negotiations authorised by the Council on 29 November 2012 and opened in Brussels on 25 March 2013 on an EU-Japan strategic partnership agreement,
- having regard to the negotiations launched on 25 March 2013 on an EU-Japan free trade agreement,
- having regard to the 21st EU-Japan summit held in Tokyo on 19 November 2013,
- having regard to the Guidelines on the EU's Foreign and Security Policy in East Asia, which were approved by the Council on 15 June 2012,
- having regard to its resolutions of 3 February 2009 on Second Strategic Energy Review ⁽¹⁾ and of 24 March 2011 on the situation in Japan, particularly the state of alert at the nuclear power stations ⁽²⁾,
- having regard to its resolution of 7 October 2010 on the EU strategic objectives for the 10th Meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD), to be held in Nagoya (Japan) from 18 to 29 October 2010 ⁽³⁾,
- having regard to its resolution of 16 February 2012 on the death penalty in Japan ⁽⁴⁾,
- having regard to its resolution of 11 May 2011 on EU-Japan trade relations ⁽⁵⁾,
- having regard to its resolution of 10 December 2013 containing the European Parliament's recommendation to the Council, the Commission and the European External Action Service on the negotiations for an EU-Canada Strategic Partnership Agreement ⁽⁶⁾,
- having regard to the catastrophic earthquake and subsequent tsunami which devastated significant parts of Japan's coast on 11 March 2011 and led to the destruction of the Fukushima nuclear power plant,
- having regard to Rules 90(4) and 48 of its Rules of Procedure,
- having regard to the report of the Committee on Foreign Affairs (A7-0244/2014),

⁽¹⁾ OJ C 67 E, 18.3.2010, p. 16.

⁽²⁾ OJ C 247 E, 17.8.2012, p. 20.

⁽³⁾ OJ C 371 E, 20.12.2011, p. 14.

⁽⁴⁾ OJ C 249 E, 30.8.2013, p. 63.

⁽⁵⁾ OJ C 377 E, 7.12.2012, p. 19.

⁽⁶⁾ Texts adopted, P7_TA(2013)0532.

Thursday 17 April 2014

- A. whereas Japan has been an EU strategic partner since 2003;
- B. whereas the EU and Japan share the special responsibility for fostering peace, stability and prosperity in a rapidly changing world;
- C. whereas the EU and Japan already cooperate in a number of fields such as customs cooperation and legal assistance in criminal matters, science and technology, internet security, academic and research cooperation, the peaceful use of nuclear energy, business community contacts and the promotion of people-to-people links;
- D. whereas the EU and Japan share the values of democracy, the rule of law and the promotion of human rights, all of which should form the core part of any agreement between the two parties, aiming to provide a solid framework for that relationship;
- E. whereas Japan's contribution to international security and stability has increased, with the country being a Proactive Contributor to Peace, based on the principle of international cooperation;
- F. whereas Japan and the North Atlantic Treaty Organisation (NATO) signed their first joint political declaration in April 2013, and referred to crisis management, disaster relief efforts, peace support operations, cyberdefence and maritime security as possible areas of cooperation;
- G. whereas Japan is also an active member of the Asian Development Bank (ADB), the African Development Bank (AFDB), the Inter-American Development Bank (IADB), the United Nations Economic and Social Commission for Asia and the Pacific (UNESCAP), and many other specialised UN agencies, as well as the Asia-Europe Meeting (ASEM) and the Asia Cooperation Dialogue (ACD); whereas Japan is also a member of the World Trade Organisation (WTO) since its establishment in 1995, and is a member of the Organisation for Economic Cooperation and Development (OECD), the European bank for Reconstruction and Development (EBRD), the International bank for Reconstruction and Development (IBRD), the Group of Eight (G8) and the Group of Twenty (G20);
- H. whereas tensions exist between Japan and its neighbours China, Russia and South Korea over islands in East Asia's maritime areas;
- 1. Addresses the following recommendations to the Council, the Commission and the European External Action Service:

On the strategic partnership agreement negotiations

- (a) to further elevate EU-Japan relations through the timely conclusion of the negotiations on a comprehensive strategic partnership agreement; to define a genuine strategic dimension for the agreement that highlights the unique aspects of EU-Japan relations;
- (b) to aim at providing a long-standing framework for a closer relationship contributing considerably to the deepening of political, economic and cultural relations with tangible results for the citizens of both regions, and to pay special attention to the global coordination of economic policies;
- (c) to increase significantly the number and coverage of bilateral cooperation and sectoral dialogues;

Political dialogue

- (d) to reaffirm shared values, common goals and responsibilities for the promotion of global peace, stability, parliamentary democracy, sustainable development and a strong multilateral system; to continue working together towards the strengthening and reform of the United Nations, including the Security Council; to recognise that the increasingly multipolar world is characterised by the growing political significance of a multitude of regional and national players, including the EU and Japan, and to demand enhanced cooperation and coordination in the international arena;

Thursday 17 April 2014

- (e) to deepen and enhance cooperation on political, security and peace matters, including information sharing, the non-proliferation, disarmament and elimination of weapons of mass destruction, cybersecurity and the fight against international crime, such as the trafficking of humans and drugs, piracy and terrorism;
- (f) to commit, as the leading donors of global development assistance, to closer cooperation and coordination in developing policies and interventions in pursuit of the Millennium Development Goals, where the aspect of human security is essential;
- (g) to explore the scope of enhancing cooperation on global security issues, including on crisis management and peacekeeping efforts;
- (h) to cooperate on civilian crisis management, civil protection, response to natural and man-made disasters, humanitarian assistance and post-crisis reconstruction initiatives; to strengthen bilateral and international cooperation in disaster risk reduction;
- (i) to express the great concern of the Member States over the devastating consequences of the Fukushima nuclear catastrophe; to urge the Japanese Government to inform the international community as precisely and comprehensively as possible of available data on the situation at the reactor site and on the levels of pollution;
- (j) to facilitate jointly collaboration in other multilateral arena, such as the UN, the G8, the G20, the World Trade Organisation (WTO) and the International Monetary Fund (IMF); to make joint efforts to promote global economic recovery, job creation and multilateral trade rules;
- (k) to increase concrete cooperation on security-related projects in strategic regions, such as the Middle East, Africa and Central Asia, building upon successful cooperation to date;
- (l) to cooperate on the implementation of the Rio + 20 UN conference decisions to achieve sustainable development;

Regional dialogues

- (m) to support the integration of the Association of Southeast Asian Nations (ASEAN) and to stress the role of the ASEAN Regional Forum and the East Asia Summit in promoting mutual understanding in Asia and also bringing dialogue partners from outside the region, including the EU;
- (n) to emphasise the fact that Japan's relationship with its neighbours is pivotal for stability and security in East Asia and global security in general;
- (o) to recall that stability and détente in East Asia is also in the best interest of Europe; to encourage all parties concerned to settle the tensions in the East China Sea through peaceful dialogue based on international law and conventions; to refrain from any use, or threat of use, of force and agree on de-escalating measures of engagement in the event of unforeseen incidents; to highlight the importance of confidence-building and preventive diplomacy; to stress the fact that the freedom of international navigation is critical to international trade and must be respected;
- (p) to continue to work towards long-lasting peace and security in a nuclear weapons-free Korean peninsula, and to urge the Democratic People's Republic of Korea (DPRK) to abandon all existing nuclear programmes;

Human rights and fundamental freedoms

- (q) to reaffirm the shared values of respect for human rights, democracy, fundamental freedoms, good governance and the rule of law, and to work together for the global promotion and protection of these values;
- (r) to enter into a dialogue with the Japanese Government on a moratorium on capital punishment with a view to its eventual abolition;
- (s) to promote gender equality as a crucial element of democracy;

Thursday 17 April 2014

- (t) to negotiate a provision in the agreement including reciprocal conditionality and political clauses on human rights and democracy, reconfirming the mutual commitment to these values; to adopt appropriate safeguards to ensure the stability of the agreement and that such a provision cannot be abused by either side; to insist that such conditionality should form part of the Strategic Partnership Agreement with Japan, in the spirit of the EU's common approach on the matter;

Economic, environmental, scientific and cultural cooperation

- (u) to incorporate an extensive framework on cooperation in science, technology, business and research so as to enhance the potential for innovation; to cooperate in finding innovative solutions to questions of transport;
- (v) to explore possibilities for closer cooperation on satellite navigation systems;
- (w) to intensify bilateral trade and cooperation on policies promoting safe, secure and sustainable energy, energy efficiency, renewable energies, nuclear safety regulatory frameworks and nuclear facility stress tests, energy research including the International Thermonuclear Experimental Reactor (ITER) project and carbon capture;
- (x) to further cooperate in finding an urgent, comprehensive and sustainable global response to climate change, including through deep cuts in global greenhouse gas emissions by all parties;
- (y) to cooperate in the sustainable management of fish stocks;
- (z) to promote cooperation on global governance and research into rare earth and other critical raw materials;
- (aa) to stress that cyberspace is important in promoting the freedom of expression and equitable social development;
- (ab) to promote public awareness and visibility of both parties in each other's territory; to intensify bilateral cultural, academic, youth, people-to-people and sports exchanges;
- (ac) to exchange experiences and best practices on responding to the needs of an aging and active society;
- (ad) to address health as a particular area of cooperation and a joint endeavour by establishing means to combine and exchange the best available medical knowledge, including biotechnology, in order to respond to the health challenges of aging societies;

Other provisions

- (ae) to consult Parliament regarding the provisions on parliamentary cooperation;
 - (af) to include clear benchmarks and binding deadlines for the implementation of the strategic partnership agreement and to provide for monitoring mechanisms, including regular reports to Parliament;
2. Instructs its President to forward this resolution containing the European Parliament's recommendation to the Council, the Commission, the European External Action Service and the Government and National Diet of Japan.
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Thursday 17 April 2014

P7_TA(2014)0456

Religious freedoms and cultural diversity**European Parliament resolution of 17 April 2014 on EU foreign policy in a world of cultural and religious differences (2014/2690(RSP))**

(2017/C 443/11)

The European Parliament,

- having regard to Articles 2 and 21 of the Treaty on European Union (TEU) and to the Treaty on the Functioning of the European Union (TFEU),
- having regard to the Charter of the United Nations,
- having regard to the European Convention on Human Rights and to the Charter of Fundamental Rights of the European Union, in particular Articles 10 and 22 thereof,
- having regard to the UN Convention on the Elimination of All Forms of Discrimination against Women,
- having regard to the International Covenant on Economic, Social and Cultural Rights,
- having regard to the International Covenant on Civil and Political Rights,
- having regard to the UNESCO Convention on the Protection and the Promotion of the Diversity of Cultural Expressions,
- having regard to the UN resolutions on freedom of religion or belief and on the elimination of all forms of intolerance and of discrimination based on religion or belief, in particular General Assembly resolution A/RES/67/179 of 20 December 2012 and Human Rights Council resolution A/HRC/22/20/L.22 of 22 March 2013,
- having regard to the EU Strategic Framework and Action Plan on Human Rights and Democracy (11855/2012), adopted by the Foreign Affairs Council on 25 June 2012,
- having regard to the Council conclusions of 20 November 2008 on the promotion of cultural diversity and intercultural dialogue in the external relations of the Union and its Member States,
- having regard to the European Agenda for Culture (COM(2007)0242), which aims to promote awareness of cultural diversity and EU values, dialogue with civil society and exchanges of good practices,
- having regard to its recommendation to the Council of 2 February 2012 on a consistent policy towards regimes against which the EU applies restrictive measures ⁽¹⁾,
- having regard to its resolution of 12 May 2011 on the cultural dimensions of the EU's external actions ⁽²⁾,
- having regard to its recommendation to the Council of 13 June 2013 on the draft EU Guidelines on the Promotion and Protection of Freedom of Religion or Belief ⁽³⁾ and to the EU Guidelines on the Promotion and Protection of Freedom of Religion or Belief, adopted by the Foreign Affairs Council on 24 June 2013,
- having regard to its resolution of 11 December 2012 on a Digital Freedom Strategy in EU Foreign Policy ⁽⁴⁾,
- having regard to Rule 110(2) of its Rules of Procedure,

⁽¹⁾ OJ C 239 E, 20.8.2013, p. 11.

⁽²⁾ OJ C 377 E, 7.12.2012, p. 135.

⁽³⁾ Texts adopted, P7_TA(2013)0279.

⁽⁴⁾ Texts adopted, P7_TA(2012)0470.

Thursday 17 April 2014

- A. whereas the EU is founded on the principles of human rights, the rule of law and democracy enshrined in the Charter of Fundamental Rights of the European Union and has the will and a legal and moral duty to promote and defend these values in its external relations with all other countries;
- B. whereas Article 21 TEU recognises that the Union's action on the international scene is to be guided by 'democracy, the rule of law, the universality and indivisibility of human rights and fundamental freedoms, respect for human dignity, the principles of equality and solidarity and respect for the principles of the United Nations Charter and international law';
- C. whereas the notion of cultural and religious differences has often led to conflict between different groups of people and has been exploited by leaders and regimes to further their own goals, thereby fuelling conflict;
- D. whereas an understanding of religious and cultural diversity which enables inclusion, mutual respect and an understanding of different mentalities is a firm means of fostering tolerance and reconciliation in post-conflict situations and a help in encouraging human rights and democracy;
- E. whereas, in this era of globalisation, nations, states and civilisations are actively interacting with each other, and the rules and norms which guide the functioning of economic and political systems are becoming more closely linked and are facing common challenges such as climate change, terrorism and poverty, while at the same time reflecting national identities and cultural differences, a proper understanding of which is crucial to international dialogue based on tolerance;
- F. whereas in all civilisations the national cultural heritage, which forms the basis of the cultural identity of citizens, is highly valued;

Principles of EU foreign policy

- 1. Affirms that respect for cultural diversity and tolerance vis-à-vis different concepts and beliefs, combined with action to combat all forms of extremism and fight inequalities, remains a necessary integral part of the successful construction of a peaceful international order based on universally shared democratic values;
- 2. Reiterates its conviction that when defending its own interests in the world the Union must always base its policies on the promotion of the fundamental values on which it is founded (democracy, the rule of law and human rights, social justice and the fight against poverty) and on respect for other countries;
- 3. Insists that the protection of persons belonging to vulnerable groups such as ethnic or religious minorities, the promotion of women's rights and their empowerment, representation and participation in economic, political and social processes, and the fight against all forms of violence and discrimination based on gender or sexual orientation must be among the EU's goals in foreign relations;
- 4. Considers that access to education in all its forms, especially through the memory of past events, history and the promotion of cultural exchange, is indispensable in understanding and respecting religion and the cultural heritage;
- 5. Calls for the EU to promote the ratification and implementation of key international human rights treaties, including those on women's rights and all non-discrimination agreements, core labour rights conventions and regional human rights instruments; expects a swift ratification of the European Convention on Human Rights following the final ruling of the Court of Justice of the European Union;
- 6. Calls for the EU to promote the ratification and implementation of the UNESCO Convention on the Protection and Promotion of the Diversity of Cultural Expression;
- 7. Stresses that the EU, which has achieved concrete results in the past in its fight against the death penalty, should take a more decisive stand, and calls on the institutions and the Member States to maintain and step up their political commitment to this cause with a view to seeing the death penalty abolished worldwide once and for all;

Thursday 17 April 2014

8. Considers that stable and modern democracies with a functioning rule of law are a tool of peace, international cooperation and willingness to constructively tackle global issues, and that it is in the interest of the EU to actively promote a political culture of freedom, tolerance and openness, the separation of state and religion, and the development of democratic institutions throughout the world;
9. Notes in particular that the transition towards democracy in numerous states throughout the world in the past two decades, and more recently the events of the uprisings in the Arab world, have shown that the aspirations for democracy, social justice, human dignity and equal participation are a universal driving force within and across diverse cultural and religious backgrounds and should not be viewed solely as a Western concern;
10. Considers that the notion of cultural and religious differences has repeatedly been instrumentalised to justify blatant violations of human rights by authoritarian regimes and radical non-state actors;
11. Rejects essentialist visions of cultures as fixed entities; believes that globalisation and the growing interaction between people from different cultural and religious backgrounds can lead to the development and strengthening of a common core of universal values;
12. Recalls that respecting and defending smaller and minority cultures and promoting their ability to express themselves peacefully in accordance with human rights is a way to avoid a vision of cultural differences as a confrontation between irreconcilable blocks and to promote peace and stability;
13. Stresses that inclusive education should play a prominent role in development policy, crisis management and post-conflict stabilisation;
14. Emphasises that respect for religious freedoms is an important external policy principle, contributing to more sustainable international relations and promoting cooperation between nations on a basis of humanity, tolerance and mutual recognition;
15. Repudiates the advocacy and dissemination of fundamentalist religious tenets aimed at eroding or violating the rights of particular communities;
16. Expresses its concern at the proliferation of intolerance and strongly deplores acts of violence against religious communities, including Christians, Muslims, Jews and Bahá'ís who are being denied fundamental human rights solely because of their faith in various countries; strongly condemns, in particular, the numerous attempts to close or destroy churches, mosques, synagogues, temples and other places of worship worldwide;
17. Emphasises the importance of cultural diplomacy, cultural cooperation and educational and cultural exchange in communicating the values that make up European culture and in advancing the interests of the EU and its Member States; stresses the need for the EU to act as a coherent world player with a global perspective and global responsibility;

The EU's role in the UN system and in multilateral fora

18. Recognises that the current structure of the UN system, in particular that of the Security Council, should reflect more adequately the diversity of global actors;
19. Notes, however, that the EU and its Member States have been able to find common ground for dialogue and cooperation towards achieving common solutions with UN member states which go beyond cultural and religious differences; notes also that the tensions and deadlocks that hamper the development of such solutions stem from the opposition of states and parties involved in conflicts to such agreements on strategic grounds rather than on the basis of conflicting moral values;
20. Highlights the importance of coordinating fora aimed at promoting dialogue and mutual understanding between cultures and religions; is of the opinion, nevertheless, that the effectiveness of these fora should be assessed and that means of leveraging their reach should be considered;

Thursday 17 April 2014

21. Recognises the value of parliamentary diplomacy and highlights the work of the parliamentary assemblies of international organisations for the promotion of intercultural and interreligious dialogue; welcomes, in this connection, such initiatives as the recommendation of the Parliamentary Assembly of the Union for the Mediterranean (March 2012, Rabat) to draft a 'Mediterranean Charter of Values';

Challenges of religious influence in the international political arena

22. Notes with concern that, besides the threat that terrorist networks represent for the Union and for the rest of the world, extremist religious groups which use violence as a means of promoting hatred and intolerance and influencing societies and legislation with a view to restricting people's human rights and fundamental freedoms undermine the very principles that the Union promotes in its foreign and development policies and operate with the support, whether open or covert, of certain states;

23. Considers that the EU should be more assertive in its support for the promotion and protection of human rights and social and political rights by civil society, as well as for more open and inclusive interpretations of religious dogma in countries whose governments promote or condone intolerant views of religion and culture;

24. Notes that, in many non-European countries, even where diverse religious expressions are tolerated, secularism and atheistic or agnostic views are nevertheless often subject to legal or social discrimination and that atheists are facing threats, pressure and danger and should be afforded the same protection as religious or other minorities by EU programmes and policies; points out that freedom of religion and conscience implies the right to both religious belief and practice and to the absence thereof, the right to choose or promote religious beliefs as an integral part of freedom of expression, and the right to change or abandon one's belief; expects all of these aspects to be present in the EU's initiatives for intercultural dialogue;

25. Proposes that the religious leaders of the three Abrahamic religions (Judaism, Christianity and Islam) engage in interreligious dialogue, in a spirit of unity and tolerance for all their own different organised expressions;

Credibility, coherence and consistency of EU policy

26. Considers that the effectiveness of EU action rests on its exemplariness and consistency between internal practice and external action;

27. Calls on all Member States to repeal any existing laws which contradict the fundamental freedom of religion and conscience and freedom of expression;

28. Stresses the importance of the EU promoting respect for freedom of expression, freedom of religion or belief, freedom of the press and freedom of access to media and new information technologies in its external actions and actively protecting and promoting people's digital freedoms;

29. Calls for a coherent EU policy on human rights based on common fundamental standards and a constructive, results-oriented approach; stresses that, when faced with human rights violations, the EU should make use of the full range of instruments at its disposal, including sanctions;

30. Reaffirms its support for the inclusion in all EU agreements with third countries of reciprocal conditionality and political clauses on human rights and democracy, as a common reaffirmation of the mutual commitment to these values and regardless of the state of protection of human rights in a given country, with appropriate safeguards to ensure that the suspension mechanism cannot be abused by either side;

Recommendations to the European External Action Service and to the Commission

31. Calls on the EEAS and the EU Delegations worldwide to further engage with third countries and regional organisations in the promotion of intercultural and interreligious dialogue;

32. Expects that in their political statements EU representatives will make it clear that intolerant interpretations of any religion or faith that allow violence and repression against the followers of other beliefs are incompatible with the EU's values and universal human rights and must be opposed with the same assertiveness as any repressive political regime;

Thursday 17 April 2014

33. Calls on the EU to make culture an even stronger part of political dialogue with partner countries and regions around the world, promoting cultural exchanges and systematically integrating culture into development programmes and projects; stresses, in this connection, the need to streamline the Commission's internal operations within the various DGs which focus on external relations (foreign policy, enlargement, trade and development), education, culture and the digital agenda;

34. Stresses the importance of providing EU staff with appropriate training to this end and underlines the relevant work of many organisations such as the Anna Lindh Foundation and the KAICIID Dialogue Centre in Vienna;

35. Recognises that the internet and communication technologies are key enablers in facilitating freedom of expression, pluralism, exchange of information, education, human rights, development, freedom of assembly, democracy and intercultural and interreligious interaction and inclusion, thereby fostering tolerance and understanding; urges the Commission, therefore, to implement the recommendations set out in the Report on a Digital Freedom Strategy in EU Foreign policy;

36. Highlights the multiple possibilities afforded by new technologies in promoting intercultural and interreligious dialogue and EU principles and values; encourages all Heads of EU Delegations to make full use of digital diplomacy tools through their active and consistent presence in the social media; calls on the EEAS to explore the possibilities of new virtual programmes;

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37. Instructs its President to forward this resolution to the Council, the Commission, the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy, the EU Special Representative for Human Rights and the governments of the Member States.

Thursday 17 April 2014

P7_TA(2014)0457

Eastern Partnership countries and in particular destabilisation of eastern Ukraine

European Parliament resolution of 17 April 2014 on Russian pressure on Eastern Partnership countries and in particular destabilisation of eastern Ukraine (2014/2699(RSP))

(2017/C 443/12)

The European Parliament,

- having regard to its previous resolutions on the European Neighbourhood Policy, on the Eastern Partnership (EaP) and on Ukraine, with particular reference to those of 27 February 2014 on the situation in Ukraine ⁽¹⁾ and of 13 March 2014 on the invasion of Ukraine by Russia ⁽²⁾,
 - having regard to its position adopted at first reading on 3 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the reduction or elimination of customs duties on goods originating in Ukraine ⁽³⁾,
 - having regard to the conclusions of the extraordinary meeting of the Foreign Affairs Council on Ukraine of 3 March 2014 and to the conclusions of the Foreign Affairs Council meetings of 17 March and 14 April 2014,
 - having regard to the statement of the Heads of State or Government on Ukraine at the European Council of 6 March 2014,
 - having regard to the European Council's conclusions on Ukraine of 20 March 2014,
 - having regard to the conclusions of the Vilnius Summit held on 28 and 29 November 2013,
 - having regard to the resolution of the Parliamentary Assembly of the Council of Europe of 9 April 2014 on 'recent developments in Ukraine: threats to the functioning of democratic institutions',
 - having regard to the UN General Assembly resolution of 27 March 2014 entitled 'Territorial integrity of Ukraine' ⁽⁴⁾,
 - having regard to the joint statement made by the G7 leaders in The Hague on 24 March 2014,
 - having regard to Rule 110(2) and (4) of its Rules of Procedure,
- A. whereas an illegal and illegitimate referendum was organised on 16 March 2014 in the Autonomous Republic of Crimea and the city of Sevastopol and was conducted under the control of Russian troops; whereas, despite the international condemnation of the referendum, the Russian authorities and lawmakers proceeded swiftly with the annexation of the Ukrainian peninsula, against international law;
- B. whereas limited numbers of pro-Russian demonstrations have taken place in eastern and southern Ukraine over the last few days; whereas pro-Russian separatists, led in most cases by Russian special forces, stormed local administration buildings in Kharkiv, Luhansk and Donetsk; whereas these elements, under the leadership of a group called 'the Russian Sector', occupied the local government building in Donetsk, proclaimed the creation of a sovereign 'People's Republic of Donetsk' independent from Kyiv, and announced a referendum on the secession of the region, to be held no later than 11 May 2014;
- C. whereas on 12 and 13 April 2014 police stations and government buildings in Slovyansk, Kramatorsk, Krasny Lyman, Mariupol, Yenakiyev and other towns in the Donetsk region were attacked and seized by well-armed, unidentified masked gunmen, believed to be led by Russian special forces, in a series of coordinated raids; whereas at least one officer died and several were injured during the clashes;

⁽¹⁾ Texts adopted, P7_TA(2014)0170.

⁽²⁾ Texts adopted, P7_TA(2014)0248.

⁽³⁾ Texts adopted, P7_TA(2014)0285.

⁽⁴⁾ A/RES/68/262.

Thursday 17 April 2014

- D. whereas any further escalation of violent destabilisation in eastern and southern Ukraine risks being used by Russia as a false pretext for further aggression by military means, prevention of the presidential elections, and forced federalisation as a precursor to the partition of Ukraine;
- E. whereas Russia is still maintaining large numbers of combat-ready troops along the Ukrainian-Russian border, despite having promised a withdrawal in order to ease the tensions; whereas there is a serious possibility that Russia could try to repeat the 'Crimea scenario';
- F. whereas Russia continues to violate its international obligations, such as those stemming from the UN Charter, the Helsinki Final Act, the Statute of the Council of Europe and, in particular, the 1994 Budapest Memorandum on security guarantees for Ukraine;
- G. whereas the EU has adopted an economic package in support of Ukraine that also includes macro-financial aid and autonomous trade measures; whereas Ukraine is about to finalise an agreement with the International Monetary Fund on an aid plan; whereas the conditions attached to this agreement have so far been kept confidential;
- H. whereas the social and economic situation of the country is further deteriorating, owing inter alia to Russian destabilisation and trade restrictions; whereas widespread poverty remains one of the most acute socioeconomic problems in Ukraine; whereas according to a recent UN report the poverty rate in Ukraine is now around 25 %, with 11 million people earning less than local social standards;
- I. whereas on 21 March 2014 the EU and Ukraine signed the political provisions of the Association Agreement (AA), undertaking to sign the remainder of the agreement, which includes the Deep and Comprehensive Free Trade Area (DCFTA), as soon as possible;
- J. whereas strong international diplomatic action at all levels and a negotiated process are needed to de-escalate the situation, ease tensions, prevent the crisis from spiralling out of control and secure a peaceful outcome; whereas the EU must respond effectively so as to allow Ukraine and all other eastern neighbouring countries to fully exercise their sovereignty and territorial integrity free from undue external pressure;
- K. whereas, immediately after Crimea was annexed, the Supreme Soviet of the separatist region of Transnistria in Moldova sent an official request to the Russian Federation to consider annexing Transnistria;
- L. whereas Russia is still occupying the Georgian regions of Abkhazia and Tskhinvali / South Ossetia, in violation of the fundamental norms and principles of international law; whereas ethnic cleansing and forcible demographic changes have taken place in the areas under the effective control of the occupying force, which bears the responsibility for human rights violations in these areas;
- M. whereas Russia increased gas prices for Ukraine from USD 268 to USD 486 per thousand cubic metres from 1 April 2014, unilaterally ending the discount Ukraine received as part of the Kharkiv Accords governing the lease of the Sevastopol naval base, and, in the last few days, has banned Ukrainian dairy products from entering Russian territory; whereas the Russian Federation has also arbitrarily applied unilateral trade restrictions on products from Georgia and Moldova;
- N. whereas Russia's annexation of the Crimean peninsula represents, beyond any doubt, a grave violation of international law which undermines trust in international instruments, including the agreements on disarmament and on non-proliferation of nuclear weapons; whereas a new arms race could lead to further escalation; whereas it is imperative to prevent such a dangerous situation, which could easily spiral out of control;
1. Condemns in the strongest possible terms the escalating destabilisation and provocations in eastern and southern Ukraine; rejects any preparation for illegal 'Crimea-like' referendums; warns that the increasing destabilisation and sabotage caused by pro-Russian armed, trained and well-coordinated separatists led by Russian special forces could be used as a false pretext for Russia to intervene militarily, prevent the presidential elections and force federalisation as a precursor to the partition of Ukraine;

Thursday 17 April 2014

2. Expresses its gravest concern over the fast-deteriorating situation and bloodshed in eastern and southern Ukraine; urges Russia to immediately withdraw its presence in support of violent separatists and armed militias who have seized government buildings in Slovyansk, Donetsk and other cities, to cease all provocative actions designed to foment unrest and further destabilise the situation, to remove troops from the eastern border of Ukraine, and to work towards a peaceful resolution of the crisis by political and diplomatic means; expresses its full support for and solidarity with the Government of Ukraine as it seeks to re-establish authority in the occupied cities, welcomes the restrained and measured manner in which the Ukrainian Government has dealt with the current phase of the crisis so far, and recalls that the Ukrainian authorities have the full right to use all necessary measures, including the right to self-defence as defined in Article 51 of the UN Charter; warns Russia against using Ukraine's legitimate right to defend its territorial integrity as a pretext to launch a full-scale military invasion;
3. Strongly reiterates its support for the sovereignty, territorial integrity and political independence of Ukraine and of all Eastern Partnership countries; looks upon Russia's acts of aggression as a grave violation of international law and its own international obligations stemming from the UN Charter, the Helsinki Final Act, the Statute of the Council of Europe and the 1994 Budapest Memorandum on security guarantees, as well as bilateral obligations deriving from the 1997 Bilateral Treaty on Friendship, Cooperation and Partnership;
4. Stresses that no attacks, intimidation or discrimination whatsoever against Russian or ethnic Russian citizens or other minorities have been reported recently in Ukraine, as confirmed by credible international monitors such as the UN, the Organisation for Security and Cooperation in Europe (OSCE) and the Council of Europe;
5. Is convinced that Russia's assertion of the right to use all means to protect Russian minorities in third countries, as proclaimed by President Putin in his speech of 18 March 2014, is not supported by international law and contravenes fundamental principles of international conduct in the 21st century, while also threatening to undermine the post-war European order; calls on the Federation Council to immediately withdraw its mandate to use force on Ukrainian soil;
6. Reiterates the necessity for the EU and its Member States to speak to Russia with one united voice; considers that the current situation requires the Council to strengthen the second phase of sanctions and be ready for the third phase (economic sanctions), which must be applied immediately; reiterates, furthermore, its call on the Council to swiftly apply an arms and dual-use technology embargo;
7. Calls for measures against Russian companies and their subsidiaries, particularly in the energy sector, as well as Russian investments and assets in the EU, and for all agreements with Russia to be reviewed with a view to their possible suspension;
8. Urges the EU to support Ukraine in international bodies, particularly international judicial bodies, should Ukraine decide to bring cases against Russia for violation of its sovereignty and territorial integrity;
9. Stresses the urgent need for Russia to engage in a constructive dialogue with the current legitimate Government of Ukraine, and supports the active engagement of the EU in diplomatic efforts to de-escalate the crisis; looks forward to the quadripartite meeting between the EU High Representative, the US Secretary of State and the Foreign Ministers of Russia and Ukraine, and hopes that this can contribute to reducing tension and paving the way for a comprehensive and lasting diplomatic solution to the crisis; stresses, however, that Ukraine's future choices can only be made by the Ukrainian people themselves through a democratic, inclusive and transparent process;
10. Points out that the suspension of the voting rights of the Russian delegation by the Parliamentary Assembly of the Council of Europe, together with the resolution adopted by the UN General Assembly condemning Russia for the annexation of Crimea, are unequivocal signs of the Russian Federation's growing isolation at international level that should be given all due consideration by the Russian authorities if Russia wants to remain a credible international player;
11. Calls for the introduction of economic, trade and financial restrictions in respect of Crimea and its separatist leadership; takes the view that these restrictions should be implemented rapidly on the basis of the Commission's analysis of the legal consequences of Crimea's annexation;

Thursday 17 April 2014

12. Reiterates its concern over the fate of the Tatar community in Crimea and the safety and access to rights of persons belonging to the Ukrainian-speaking community; stresses the responsibility of the Russian Federation, under the Fourth Geneva Convention, to protect all civilians in the occupied territories;
13. Welcomes the deployment of an OSCE Special Monitoring Mission tasked with gathering information about atypical military activity and provocative actions aimed at destabilising the situation, as well as monitoring human and minority rights in Ukraine, and calls for its expansion; regrets, however, the fact that the mission has not secured access to Crimea, where various human rights violations, including cases of violence against journalists and their families, have taken place; regrets the fact that attacks on journalists are now also being reported in eastern Ukraine;
14. Calls, furthermore, for an in-depth election observation mission from the OSCE Office for Democratic Institutions and Human Rights (ODHIR), and also from Parliament and the EU, to monitor the elections comprehensively; calls for the presidential elections on 25 May 2014 to be conducted in full compliance with international standards; rejects any external pressure to delay these elections;
15. Welcomes the Ukrainian Government's intention to hold early parliamentary elections;
16. Welcomes, in principle, the idea of holding a nationwide referendum on the future status and territorial set-up of Ukraine, as suggested by acting President Oleksandr Turchynov in his televised address of 14 April 2014;
17. Welcomes the recent resolution of the Ukrainian parliament calling for the immediate disarmament of all illegal self-defence forces, and looks forward to its implementation;
18. Welcomes the Council's readiness to assist Ukraine in the field of civilian security-sector reform and provide support for the police and the rule of law, and to examine all options, including a possible CSDP mission, as well as the possibility of an EU monitoring mission;
19. Expresses its strong support for Ukraine and its people in these difficult times; welcomes the signing of the political chapters of the Association Agreement and the subsequent adoption of the unilateral trade measures; calls for the signing of the full AA/DCFTA as soon as possible and before the expiry of the unilateral trade measures;
20. Welcomes the announcement by the Ukrainian Government of an ambitious economic and social reform agenda, and highlights the vital importance of its swift implementation in order to stabilise and overcome the country's critical financial situation; welcomes the decision of the international financial institutions and the EU to provide Ukraine with substantial short- and long-term financial aid; recalls the need to organise and coordinate an international donor conference, which should be convened by the Commission and take place as soon as possible;
21. Supports the conditionality laid down by the EU regarding much-needed structural reforms that will help create more favourable conditions for sustainable economic growth, improve the management of public finances, develop the social safety net and tackle corruption; calls for transparency in the spending of EU funds and effective monitoring by the Commission;
22. Draws attention to the serious economic and social situation in the country; calls for measures to accompany the structural reforms with the aim of alleviating the current situation with regard, in particular, to the most vulnerable sections of the population;
23. Encourages Ukraine to continue to move ahead with its course of political reform, in particular constitutional reform, which should be the subject of a broad, in-depth discussion among all components of Ukrainian society; welcomes the will of the Ukrainian Government to implement its commitments to ensure the representative nature of governmental structures, reflecting regional diversity, to ensure the full protection of the rights of persons belonging to national minorities, to align the country's anti-discrimination legislation with EU standards, to investigate all human rights violations and acts of violence and to fight extremism;
24. Welcomes the Commission's decision to create a Support Group for Ukraine which will work on the implementation of the 'European Agenda for Reform';

Thursday 17 April 2014

25. Supports the efforts of the Ukrainian Government, working in close cooperation with the OSCE and the Council of Europe, to ensure due respect for the legitimate rights of the Russian-speaking population and other cultural, national and linguistic minority groups, in line with the provisions of the European Charter for Regional or Minority Languages and the Framework Convention for the Protection of National Minorities;

26. Reiterates its call for the setting-up of an independent commission to investigate the Kyiv shootings and the tragic events on Maidan, with the inclusion of a strong international component and under the supervision of the Council of Europe International Advisory Panel; welcomes the appointment of a third party to that panel and the holding of its first meeting on 9 April 2014;

27. Welcomes the signing of the political provisions of the AA and expects the quick implementation of the autonomous trade preferences adopted by the EU to bridge the gap until the signing of the remainder of the agreement, which includes the DCFTA;

28. Welcomes the initial measures adopted by the Commission to enable Ukraine to tackle an energy crisis should Russia cut gas supplies to the country, and urges the Council and the Commission to assist and support Kyiv in its efforts to resolve the long-standing gas dispute with Moscow; stresses the urgent need for a strong common energy security policy (an Energy Union), with the aim of reducing the EU's dependency on Russian oil and gas, including the diversification of energy supply, the full implementation of the Third Energy Package and the possibility of suspending gas imports when necessary; takes the view that the South Stream pipeline should not be built, and that other sources of supply should be made available; is convinced that EU assistance to Ukraine in securing reverse-flow supply through further diversification, enhanced energy efficiency and effective interconnections with the EU will strengthen Ukraine against political and economic pressures; recalls, in this connection, the strategic role of the Energy Community, of which Ukraine holds the presidency in 2014;

29. Calls on the Council to authorise the Commission immediately to speed up visa liberalisation with Ukraine, so as to advance along the path of introducing a visa-free regime, following the example of Moldova; calls, in the meantime, for the immediate introduction of temporary, very simple, low-cost visa procedures at EU and Member State level;

30. Stresses that the Russian concerns as regards the EU association process of Ukraine and the other Eastern neighbours must be adequately addressed and explained, so as to ease fears of new geopolitical dividing lines on the European continent; points out that each country has every right to make its own political choices, but that the EU's engagement with the Eastern partners aims to spread prosperity and increase political stability, from which the Russian Federation will also ultimately gain;

31. Reiterates that the AAs with Ukraine and the other EaP countries do not constitute the final goal in their relations with the EU; points out in this connection that, pursuant to Article 49 of the TEU, Georgia, Moldova and Ukraine — like any other European state — have a European perspective and may apply to become members of the Union provided that they adhere to the principles of democracy, respect fundamental freedoms and human and minority rights and ensure the rule of law;

32. Calls on the Council to sign the AAs/DCFTAs between the EU and its Member States and Moldova and Georgia, respectively; expresses its approval of the proposal for a Council decision on the provisional application of the EU–Moldova and EU–Georgia AAs immediately upon signature; urges the General Secretariat of the Council of the European Union to reduce the notification procedures following the signing of the AAs, so that provisional application can take effect as soon as possible after signing; states its intention, in the event of all requirements being met and the AAs subsequently being signed, to proceed with full ratification of the EU–Moldova and EU–Georgia AAs as soon as possible and before the end of the Commission's current term; calls for the allocation to those countries of the additional financial assistance required; calls, furthermore, for a frank and open dialogue with the Russian Federation in order to make every effort to develop synergies aimed at benefiting EaP countries;

Thursday 17 April 2014

33. Expresses particular concern over renewed instability in the separatist region of Transnistria in Moldova; believes that the recent request of 16 April 2014, by the self-proclaimed authorities in Tiraspol for Transnistria to be recognised by Russia as an independent state represents a dangerous and irresponsible step; recalls that the so-called referendum in the Autonomous Territorial Unit of Gagauzia was against the constitution of Moldova and therefore illegal; reiterates its full support for Moldova's territorial integrity and calls on all parties to urgently resume dialogue, under the 5+2 framework, and calls for an enhancement of the EU's status to that of negotiating partner, leading towards a peaceful and sustainable settlement of the issue;

34. Instructs its President to forward this resolution to the Council, the Commission, the governments of the Member States, the Presidents, Governments and Parliaments of Ukraine, Georgia and Moldova, the Council of Europe, the Organisation for Security and Cooperation in Europe and the President, Government and Parliament of the Russian Federation.

Thursday 17 April 2014

P7_TA(2014)0458

EU-Vietnam Free Trade Agreement negotiations

European Parliament resolution of 17 April 2014 on the state of play of the EU-Vietnam Free Trade Agreement (2013/2989(RSP))

(2017/C 443/13)

The European Parliament,

- having regard to the Organisation for Economic Cooperation and Development (OECD) Guidelines on Multinational Enterprises and the International Labour Organisation (ILO) Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy,
- having regard to the Ministerial Declaration of the Fourth Session of the WTO Ministerial Conference, adopted on 14 November 2001 in Doha, and in particular to paragraph 44 thereof on Special and Differential Treatment (SDT),
- having regard to the Cooperation Agreement of 1995 between the EC and the Socialist Republic of Vietnam (hereinafter 'Vietnam'), and the new Partnership and Cooperation Agreement signed on 27 June 2012,
- having regard to the Commission communication of 4 October 2006 entitled 'Global Europe: Competing in the World. A contribution to the EU's Growth and Jobs Strategy' (COM(2006)0567),
- having regard to its resolution of 12 July 2007 on the TRIPS Agreement and access to medicines ⁽¹⁾,
- having regard to its resolution of 22 May 2007 on Global Europe — external aspects of competitiveness ⁽²⁾,
- having regard to the Council's negotiating directives of 23 April 2007 authorising the Commission to negotiate a free trade agreement with countries of the Association of Southeast Asian Nations (ASEAN),
- having regard to the Vietnam Country Strategy Paper (2007-2013) ⁽³⁾,
- having regard to its previous resolutions on Vietnam, in particular that of 1 December 2005 on the human rights situation in Cambodia, Laos and Vietnam ⁽⁴⁾, and that of 18 April 2013 on Vietnam, in particular freedom of expression ⁽⁵⁾,
- having regard to its resolution of 25 November 2010 on human rights and social and environmental standards in international trade agreements ⁽⁶⁾,
- having regard to its resolution of 6 April 2011 on the future European international investment policy ⁽⁷⁾,
- having regard to the Commission communication of 9 November 2010 entitled 'Trade, Growth and World Affairs — Trade Policy as a core component of the EU's 2020 strategy' (COM(2010)0612),
- having regard to its resolution of 27 September 2011 on a New Trade Policy for Europe under the Europe 2020 Strategy ⁽⁸⁾,
- having regard to its resolution of 13 December 2011 on trade and investment barriers ⁽⁹⁾,

⁽¹⁾ OJ C 175 E, 10.7.2008, p. 591.

⁽²⁾ OJ C 102 E, 24.4.2008, p. 128.

⁽³⁾ http://eeas.europa.eu/sp/index_en.htm#V

⁽⁴⁾ OJ C 285 E, 22.11.2006, p. 129.

⁽⁵⁾ Texts adopted, P7_TA(2013)0189.

⁽⁶⁾ OJ C 99 E, 3.4.2012, p. 31.

⁽⁷⁾ OJ C 296 E, 2.10.2012, p. 34.

⁽⁸⁾ OJ C 56 E, 26.2.2013, p. 87.

⁽⁹⁾ OJ C 168 E, 14.6.2013, p. 1.

Thursday 17 April 2014

- having regard to the Commission communication of 21 February 2012 entitled ‘Trade and Investment Barriers — Report 2012’ (COM(2012)0070),
 - having regard to the Commission’s statement to the April 2014 plenary on the EU-Vietnam FTA,
 - having regard to Rule 110(2) of its Rules of Procedure,
- A. whereas the rule-based multilateral trading system, established through the World Trade Organisation (WTO), is the most suitable framework for regulating and promoting open and fair trade, and whereas multilateral negotiations do not preclude bilateral WTO+ agreements, which can be complementary to them;
- B. whereas the Commission’s negotiating directives for the EU-Vietnam FTA are attached to the Council’s authorisation of 23 April 2007 to enter into negotiations for a Free Trade Agreement with countries of the Association of Southeast Asian Nations (ASEAN) and follow on the endorsement by the Council of the scoping paper which outlines the common objectives of both negotiating parties, namely to intensify existing bilateral trade relations; recalls that the initial objective was to negotiate an FTA with the ASEAN region; supports therefore the possibility of negotiating fully comprehensive agreements with countries of the ASEAN region (as building blocks towards the ultimate objective of negotiating a region-to-region FTA in the future);
- C. whereas the official launch of the EU-Vietnam FTA negotiations took place on 26 June 2012 in Brussels, and whereas on 8 November 2013, after the fifth round of negotiations, the two negotiating parties committed to joint efforts with a view to concluding the negotiations by the end of 2014;
- D. whereas the EU-Vietnam trade relationship is embedded in the framework of the Partnership and Cooperation Agreement signed on 27 June 2012, which ensures an effective framework for bilateral trade and investment relations;
- E. whereas the EU and Vietnam have a well-developed bilateral Human Rights Dialogue; whereas all efforts should be made in that framework to help prevent a deterioration of human rights protection in Vietnam; whereas human rights should be treated as an essential element of EU trade policy; whereas the EU is committed, under its Strategic Framework and Action Plan on Human Rights and Democracy, to include human rights in its impact assessments, as and when they are carried out, including for trade agreements that have significant economic, social and environmental impacts;
- F. whereas Vietnam experienced a prosperous decade with uninterrupted GDP growth of around 8 % per year which culminated with its accession to the WTO on 11 January 2007, and whereas the country has since been adversely affected by the global economic downturn, which has led to a sharp decline in export growth, a drop-off in foreign direct investment (FDI) inflows and a fall in remittances from overseas;
- G. whereas over the past ten years the EU has maintained a negative trade balance with Vietnam, as illustrated again by the figures for the second quarter of 2013, which show total trade to the value of EUR 13,4 billion, with the EU’s imports from Vietnam amounting to EUR 10,5 billion, while EU exports to Vietnam were worth EUR 2,8 billion; whereas this represents a sharp decrease compared to the figures for 2012, for which year total trade amounted to EUR 23,871 billion, made up of EUR 18,520 billion in imports from Vietnam to the EU and EUR 5,351 billion in exports to Vietnam from the EU;
- H. whereas the garment and textile industry not only constitutes Vietnam’s largest single source of formal sector employment, with a direct labour force of more than two million workers, but is also its largest export sector; whereas the electronics assembly sector, another leading export manufacturing sector, employs approximately 120 000 workers;
- I. whereas Vietnam has so far only ratified 5 of the 8 core ILO conventions; whereas it has not ratified ILO Convention No 87 on Freedom of Association and Protection of the Right to Organise, No 98 on the Right to Organise and Collective Bargaining, or No 105 on the Abolition of Forced Labour;

Thursday 17 April 2014

- J. whereas Vietnam, a beneficiary of the EU's Generalised System of Preferences, ranks as the EU's 32nd trading partner and its fifth biggest partner within ASEAN, while the EU is Vietnam's second largest trading partner after China, ahead of the USA, and is also Vietnam's largest source of FDI, accounting for 6,5 % of total FDI in the country in 2012; whereas, however, the potential of FDI from Vietnam into the EU remains largely untapped;
- K. whereas both negotiating parties expect to secure significant benefits from the elimination of both tariffs and non-tariff barriers to trade (NTBs), and whereas both parties should aim at achieving a good outcome as regards the liberalisation of trade in services and of establishment, as well as developing a system for the appropriate protection, implementation and enforcement of intellectual property rights, including patents and designs, trade or service marks, copyright and similar rights, and geographical indications including marks of origin for agricultural and foodstuff products;
- L. whereas both negotiating parties should join forces to ensure and promote legal trade in medicines (both patented medicines and generics) in compliance with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its flexibilities;
- M. whereas both negotiating parties should continue to use trade defence instruments in full compliance with existing WTO rules in order to avoid recourse to the WTO dispute settlement mechanism, and should agree on an effective bilateral safeguard clause or equivalent mechanism to adequately protect their respective industries against injury or threat of injury as a result of a surge in imports, especially in their respective sensitive sectors, which have been identified by each party's impact assessment;
1. Welcomes the ongoing progress in the FTA negotiations, in particular in the chapters on customs and trade facilitation, on technical obstacles to trade and on competition, and the Commission's regular debriefing with Parliament on their state of play; recalls that Parliament's consent to the FTA is mandatory⁽¹⁾, and that the Commission and Council should not propose any provisional application of the FTA before the EP has given its consent;
2. Is of the strong opinion that respect for workers' and trade union rights must be a key feature in all trade agreements the EU signs with third countries; calls on the Vietnamese Government to live up to all its obligations under the core ILO conventions it has ratified and to ratify and implement the outstanding core conventions without further delay; reiterates that workers' and trade union rights must be universal and be applied to all workers, including to those working in the Special Economic Zones;
3. Expects the Council and Commission to fully take into account Parliament's requests as expressed in this resolution before concluding the FTA, which must be compatible with WTO rules and obligations; considers that a successful FTA would allow both negotiating parties to reap a balanced set of benefits and would contribute to creating and safeguarding jobs on both sides;
4. Calls on both negotiating parties to fully respect their WTO commitments in the spirit of trade liberalisation; simultaneously underlines their obligation to eliminate WTO-inconsistent measures and practices so as to achieve an ambitious agreement;
5. Appreciates the positive prospects highlighted in the scoping paper which shows that the FTA would increase overall exports and imports for both the EU and Vietnam and provide opportunities for further FDI flows; calls, therefore, for substantial tariff elimination on the Vietnamese side as regards both the average tariff for non-agricultural market access and the agricultural tariffs;
6. Stresses, however, that the objective for industrial trade should be reciprocal full duty elimination, while respecting a degree of asymmetry also involving suitable transition periods in implementation, and that any possible exception to this objective should be limited and subject to review; believes that the elimination of duties should include sectors that are of importance to either side;

⁽¹⁾ Article 218(6)(a)(v) TFEU.

Thursday 17 April 2014

7. Urges both negotiating parties to respect each other's right to regulate, including on the provision of public services, and to ensure that their respective regulations do not hamper bilateral trade with unjustified NTBs; calls, therefore, on both the EU and Vietnam to develop effective mediation disciplines to prevent the emergence of unjustified regulatory obstacles to trade and to tackle existing obstacles by fostering harmonisation or compliance with international standards;
8. Considers that particular attention should be given by the Commission to ensure that the benefits of the future agreement encompass strong and enforceable verification measures in order to guarantee that the benefits of the agreement will accrue only to EU and Vietnamese producers on a basis of full respect for the preferential rules of origin that would be negotiated; calls also for a simplification of EU rules of origin — without lessening the strictness of the current system — in order to make them easier to apply for economic operators and customs administrations and to allow them to derive the full benefits from tariff elimination;
9. Recognises that Vietnam has offensive interests in the liberalisation of Mode 4 in the General Agreement on Trade in Services (GATS) and the conclusion of Mutual Recognition Agreements recognising the professional qualifications of nationals of Vietnam and of the EU, and that the EU has offensive interests in the liberalisation of market access and national treatment under Mode 1, 2 and 3 in most services; is of the view that addressing the EU's offensive interests is an imperative to permit, under Mode 4, temporary stays of necessary skilled professionals, and facilitate distinguishing such stays from national policies on foreign workers in each party's labour markets;
10. Calls on the EU and Vietnam to agree in the FTA on a fair and equitable treatment of all investors and services providers in the banking, insurance, legal, accounting, transport, and distribution services, including both retail and wholesale sectors; recalls that as regards financial services, it is also essential to ensure adequate policy space to reduce systemic risk, fight money laundering, and provide the highest possible level of consumer protection, as well as to enforce fair competition rules and practices between domestic and foreign investors and service providers, inter alia by reducing, if not fully eliminating, existing equity caps and abolishing restrictions on establishment and licence acquisition; recommends that the Commission negotiates strong and binding provisions on transparency and fair competition so that a level playing field also applies between private businesses and state-owned enterprises (SOEs);
11. Strongly encourages Vietnam to develop appropriate data protection legislation in order to achieve the status of a country with an adequate level of protection, yet without creating obstacles to the use of the flexibilities of the TRIPS Agreement, thereby allowing or enabling the transfer of personal data from the EU on the basis of and in compliance with EU legislation and thus boosting bilateral data flows and trade in related services such as e-commerce;
12. Calls on the Commission and the Vietnamese authorities to negotiate effective and transparent procurement systems so as to ensure fair competition between private and state-owned enterprises in the award of public contracts, and to ensure the broadest possible coverage, to include public-sector undertakings, while duly taking into account mutual sensitivities and needs;
13. Urges the Commission to ensure the reduction and the regular supervision of the use of subsidies and other preferences, such as beneficial conditions provided to SOEs and domestic companies in Vietnam, which distort competition with European companies, in particular in the sectors that are of importance for the export policy of Vietnam; also urges the Commission to negotiate disciplines aimed at ensuring a level playing field between EU and Vietnamese public and private market participants;
14. Considers that particular attention should be paid in the FTA to the development of business opportunities for small and medium-sized enterprises (SMEs) and that investment in and by SMEs should be promoted to help finance market-driven local projects and joint ventures in renewable energy and trade in environmental goods and technologies; calls for European investors to be provided with a more transparent and predictable legislative framework in Vietnam, and for fair conditions of competition to be guaranteed between Vietnamese and European undertakings;
15. Urges both negotiating parties to secure a good outcome in the FTA as regards the liberalisation of trade in manufacturing by ensuring effective implementation and enforcement of intellectual property rights, including patents and designs, trademarks, copyright and similar rights for a range of manufactured goods;

Thursday 17 April 2014

16. Considers that the FTA should respect sensitivities linked to trade in agricultural and fisheries products, but that this should not prevent the mutual opening of markets in sectors of complementarity, and emphasises that new market access must be subject to the thorough enforcement of intellectual property protection, also covering geographical indications, including marks of origin for agricultural and foodstuff products, as well as sanitary and phytosanitary measures (SPS), in the interests of producers and consumers; insists that nothing in the agreement must hamper access to affordable generic medicines;

17. Asks for transparent and effective state-to-state dispute settlement arrangements, and, where applicable, provisions on investor-to-state dispute resolution to be included in the FTA, so as to ensure due investment protection and deter investors from filing frivolous claims; takes the view that any mechanism for settling disputes between investors and states should, as far as possible, be based on the rules of the UN Commission on International Trade Law (UNCITR) or of the International Centre for the Settlement of Investment Disputes (ICSID), or else on any bilaterally agreed rules based on international norms and conventions, and should have a suitable legal framework and be subject to strict transparency criteria;

18. Calls for it to be ensured that an investment agreement does not curtail progress in the ratification and full implementation of international human rights agreements, ILO conventions and multilateral environmental agreements (MEAs) by both parties;

19. Prefers the inclusion of animal welfare standards in the FTA's SPS chapter or in a standalone chapter with equivalent enforceable provisions;

20. Expects the FTA to include a binding and enforceable sustainable development chapter reflecting the EU's and Vietnam's common commitment to promote respect for, compliance with, and enforcement of international human rights agreements, the eight core ILO conventions, and key MEAs such as the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), with measures in the event of infringement providing for the involvement of independent civil society organisations representing economic, social, and environmental stakeholders in the monitoring of FTA negotiations and the implementation and monitoring of the sustainable development chapter, as well as encouraging enterprises to take up CSR practices, taking account of internationally agreed principles and instruments such as those of the OECD Guidelines for Multinational Enterprises and the UN guiding principles on business and human rights, as well as the UN Principles for Responsible Investment and Reporting, and also to address outstanding issues such as the welfare of both farm and wild animals;

21. Asks that such a sustainable development chapter be covered by the institutional and legal link to be established between the FTA and the Partnership and Cooperation Agreement (PCA), to include the possibility of suspension of the FTA in case of severe human rights abuses;

22. Calls on the Commission to apply an approach based on conditionality, so as to offer the signing of the FTA in exchange for concrete progress on human rights and other fundamental rights;

23. Commends the socio-economic progress made by Vietnam as part of its Doi Moi reform, and supports the country's continued efforts for further societal improvements; salutes, therefore, Vietnam's candidature, as endorsed by ASEAN, for membership of the United Nations Human Rights Council for the term 2014-2016, as well as the decision of the Vietnamese Government of 27 August 2013 to submit an aide-memoire containing voluntary pledges and commitments to contribute to the promotion and protection of human rights, thus fostering sustainable development on its territory and in relation to its partners; urges the Vietnamese Government to consistently follow up on its pledges and commitments to effectively prevent and correct any human rights violations and deteriorations of fundamental freedoms;

24. Stresses that human rights, democracy and security are essential elements of the overall relationship between the EU and Vietnam; calls, therefore, on both sides to ensure that dialogue on pending issues is actively pursued, with particular reference to the freedom of speech of individual citizens, freedom of the media, and religious freedom;

Thursday 17 April 2014

25. Urges the Commission to carry out as soon as possible a Human Rights Impact Assessment, as requested by Parliament in its resolution of 25 November 2010 on human rights and social and environmental standards in international trade agreements⁽¹⁾, with a view to ensuring 'comprehensible trade indicators based on human rights and on environmental and social standards', and in line with the Report of the UN Special Rapporteur on the right to food;
26. Instructs its President to forward this resolution to the Council, the Commission, the parliaments of the Member States and the Government and Parliament of Vietnam.
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⁽¹⁾ OJ C 99 E, 3.4.2012, p. 31.

Thursday 17 April 2014

P7_TA(2014)0459

Commission follow-up to the ‘TOP TEN’ Consultation of SMEs on EU Regulation

European Parliament resolution of 17 April 2014 on the ‘top ten’ consultation process and lightening the burden of EU regulation on SMEs (2013/2711(RSP))

(2017/C 443/14)

The European Parliament,

- having regard to the European Charter for Small Enterprises, adopted by the European Council at its meeting in Feira on 19 and 20 June 2000,
- having regard to Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ⁽¹⁾,
- having regard to the Commission report of 23 November 2011 entitled ‘Minimising regulatory burden for SMEs — Adapting EU regulation to the needs of micro-enterprises’ (COM(2011)0803),
- having regard to the Commission communication of 23 February 2011 entitled ‘Review of the “Small Business Act” for Europe’ (COM(2011)0078),
- having regard to the Commission communication of 3 March 2010 entitled ‘Europe 2020 — A strategy for smart, sustainable and inclusive growth’ (COM(2010)2020),
- having regard to the Commission proposal of 30 November 2011 for a regulation of the European Parliament and of the Council establishing a Programme for the Competitiveness of Enterprises and small and medium-sized enterprises (2014-2020) (COM(2011)0834),
- having regard to the European Council conclusions of 14 and 15 March 2013 and the Competitiveness Council conclusions of 26 and 27 September 2013,
- having regard to the Commission communication of 18 June 2013 entitled ‘Commission follow-up to the “TOP TEN” Consultation of SMEs on EU Regulation’ (COM(2013)0446),
- having regard to Commission communication of 7 March 2013 entitled ‘Smart Regulation — Responding to the needs of small and medium-sized enterprises’ (COM(2013)0122) and the accompanying staff working document entitled ‘Monitoring and Consultation on Smart Regulation for SMEs’ (SWD(2013)0060),
- having regard to the Commission communication of 2 October 2013 entitled ‘Regulatory Fitness and Performance (REFIT): Results and Next Steps’ (COM(2013)0685),
- having regard to its resolution of 23 October 2012 on ‘Small and Medium Size Enterprises (SMEs): competitiveness and business opportunities’ ⁽²⁾,
- having regard to its resolution of 5 February 2013 on improving access to finance for SMEs ⁽³⁾
- having regard to Rules 115(5) and 110(2) of its Rules of Procedure,

A. whereas enhancing support for the competitiveness, sustainability and employment potential of small and medium-sized enterprises (SMEs) is a horizontal effort that cuts across different policy areas;

⁽¹⁾ OJ L 124, 20.5.2003, p. 36.

⁽²⁾ OJ C 68 E, 7.3.2014, p. 40.

⁽³⁾ Texts adopted, P7_TA(2013)0036.

Thursday 17 April 2014

- B. whereas SMEs suffer disproportionately from unnecessary burdens as their capacity is limited, and whereas the EU legislators have therefore committed to the 'think small first' principle;
- C. whereas, 20,7 million SMEs employ over 65 % of the existing private-sector workforce and whereas SMEs are among the most innovatory enterprises, with the best performance in terms of job creation and economic growth;
- D. whereas, according to a Eurobarometer survey, 74 % of Europeans believe that the EU generates too much red tape;
- E. whereas almost one third of the administrative burden deriving from EU legislation stems primarily from disproportionate and inefficient national implementation, meaning that up to EUR 40 billion could be saved if the Member States transposed EU legislation more efficiently;
- F. whereas enterprises can generate employment provided that the right conditions are met, including administrative simplification, access to finance, skills, knowledge and qualified manpower and support for their innovative efforts;
- G. whereas SMEs are often at a competitive disadvantage compared with large industrial players in terms of taxation, standardisation, public procurement, intellectual property, research and innovation financing;
- H. whereas the Commission has scrapped 5 590 legal requirements in the past five years, reducing costs for business by more than EUR 27 billion;
- I. whereas the Commission is pursuing regulatory and administrative effectiveness via its REFIT programme, impact assessments, competitiveness proofing, fitness checks, the 'top ten' consultation process, the SME scoreboard and the SME test;
- J. whereas, as highlighted by the European Council, regulation at Union level is necessary in order to ensure that EU policy goals, including the proper functioning of the single market, are attained;
- K. whereas Parliament has declared on a number of occasions, for example in its aforementioned resolution of 23 October 2012, that simplification of EU regulations should not interfere with fundamental EU requirements relating to health and safety at work, fundamental EU workers' rights or fundamental principles of EU environmental legislation;
- L. whereas most of the 'top ten' legislative measures identified in the Commission communication on this subject were already under way when the communication was issued; whereas some of the legislative proposals had already been presented at the time of the 'top ten' consultation, and whereas some of them are now already closed;
- M. whereas administrative obstacles prevent SMEs from fully exploiting the benefits of the single market;
- N. whereas this resolution will not comment on the individual follow-up actions, as that will be done separately, but instead focus on the working method applied by the Commission;
1. Welcomes the Commission's 'top ten' initiative as part of the REFIT exercise and takes note of the promise that this is not a one-off effort but should be a regular part of an ongoing screening procedure; stresses, however, that the Commission should accelerate its efforts to address the concerns about regulatory burden raised by SMEs during the consultation process; stresses also that the 'top ten' approach must not replace a systematic, horizontal policy approach to minimising the administrative burden stemming from EU regulation, or undermine the objectives and effectiveness of the legislation in question;
 2. Underlines the need, therefore, for the 'think small first' principle to better inform Union policies as regards innovation, growth, internationalisation, productivity, bureaucracy reduction, the quality of human resources, and social responsibility;

Thursday 17 April 2014

3. Welcomes also, in this connection, the commitment by the Commission to adopt 'smart regulation' as an integral part of the decision-making cycle and specifically to regard REFIT as a rolling programme that will be updated annually;
4. Calls on the Commission, as a matter of urgency, to step up its efforts to ensure that SMEs, especially innovative ones, are encouraged to flourish through administrative simplification and the provision of targeted support in all policy areas;
5. Calls on the Commission to conduct SME tests transparently and properly when developing legislation; believes that exempting micro-enterprises by default is not the right approach, and supports the development of adapted solutions and lighter regimes for SMEs where it can be demonstrated that they do not foster fragmentation or hinder SMEs' access to the internal market;
6. Calls on the Commission to simplify excessive administrative formalities, while at the same time retaining necessary provisions that ensure safety, health and protection at work or require companies to provide their staff with a suitable working environment;
7. Urges the Commission and the Member States to ensure easy access to funding and markets and to reduce the regulatory burden, which constitutes one of the greatest obstacles to the creation and development of small and medium-sized enterprises;
8. Considers it very important for the Member States to implement Directive 2011/7/EU on combating late payment in commercial transactions, which states that, with regard to commercial transactions between enterprises and public authorities, the contractual payment period must not exceed the limits laid down in Article 4(3) thereof, unless otherwise expressly agreed in the contract and provided that this is objectively justified in the light of the particular nature or features of the contract and in any event does not exceed 60 calendar days;
9. Welcomes the fact that from now on the Commission will integrate the SME scoreboard into an annual REFIT scoreboard; considers this to be a step in the right direction if it further embeds SME requirements into the wider regulatory simplification exercise, without undermining the effectiveness of legislation or adding additional layers of bureaucracy; asks the Commission to streamline these instruments via a comprehensive impact assessment; stresses, however, that this amalgamation should not in any way dilute the specific attention accorded to SMEs by the Commission in its processes;
10. Underlines the fact that the planned annual scoreboard should effectively record legislative and implementation-related progress at EU and national level with regard to SMEs; believes that this scoreboard will help SMEs to assess the costs of the administrative burden stemming from legislation at EU or national level, and allow for easier monitoring, thus facilitating constructive participation by SMEs in future consultations;
11. Stresses, however, that any *ex post* evaluation would be easier if the *ex ante* assessments were carried out properly and took all dimensions into account; believes that the impact assessment culture of all the European institutions should be improved, in particular where SMEs and self-employed people are affected by EU legislative proposals; calls on the Commission to assess the added value of granting more independence and powers to the impact assessment board; recommends, furthermore, that Parliament make greater use of its impact assessment and SME testing facilities, e.g. before introducing substantial changes to Commission proposals; calls on the Commission to publish an annual statement of the total net cost to business of new proposals;
12. Believes that burdens arising from new proposals should be offset by reductions of at least a similar size;
13. Invites the Commission and the Member States to develop a web-based application enabling the administration concerned to indicate whether, and to what extent, SMEs are affected by upcoming legislation, along the lines of the German *Mittelstandsmonitor*, which indicates by means of a simple traffic light system whether SMEs are very likely (red), likely (yellow) or unlikely (green) to be affected by upcoming legislation;
14. Welcomes the Council's request, in its conclusions of 14 and 15 March 2013, for further action to reduce the overall regulatory burden at both EU and national level;

Thursday 17 April 2014

15. Considers it regrettable that SMEs have not, as yet, managed to tap into the potential of the single market, and recalls that only 25 % of SMEs in the EU-27 are exporters; calls on the Commission and the Member States to work together to improve the integration of the single market, and to do more to share best practice in relation to simple paperwork and achieve better regulatory cooperation across the Member States; welcomes the conclusion of the Doha Development Agenda (DDA) at the ninth WTO ministerial conference of December 2013 and hopes the agreement will facilitate greater opportunities for trade, particularly for SMEs; welcomes, in this connection, the Commission's intention to propose a standard VAT declaration and believes that any standardisation of VAT declaration forms should be no more complicated than the most simple form it replaces;

16. Encourages the Member States to mirror the REFIT and 'top ten' exercises being undertaken at EU level and to ensure that the administrative and regulatory burden is also eased for SMEs at national level; stresses, further, that Member States can be particularly effective in reducing the regulatory burden on SMEs by avoiding gold-plating when transposing European directives into national legislation; urges the Member States to use the option of reducing unnecessary burden for SMEs in those areas in which legislation allows it;

17. Stresses that Member States can be particularly effective in alleviating the administrative burden on SMEs and avoiding overregulation when transposing European directives into national law; urges the Member States to ease formalities for SMEs where this is authorised under EU legislation;

18. Welcomes the introduction of the SME test, while regretting the fact that only a few Member States have included it in their national decision-making processes;

19. Recalls its position on general exemptions of micro-enterprises from EU legislation, as laid down in its aforementioned resolution of 23 October 2012, according to which exemptions should only be applied where a proper SME test is able to demonstrate, on a case-by-case basis, that the specific needs of micro-enterprises cannot be addressed by means of adapted solutions or lighter regimes; stresses that exemptions for micro-enterprises often carry the risk that SMEs may be subject to a patchwork of national laws which foster fragmentation and hinder their access to the internal market;

20. Welcomes the fact that the Commission has extended the mandate of the High Level Group on Administrative Burdens (HLGAB) until October 2014, as requested by Parliament in its aforementioned resolution of 23 October 2012 and as provided for by the COSME programme;

21. Notes the conclusion from the SMEs' responses to the 'top ten' consultation process that the Working Time Directive is complex and inflexible and in many cases requires SMEs to acquire specialised legal assistance which is costly; calls on the Commission to produce its detailed impact assessment as a matter of urgency;

22. Recommends that, in order to reduce the burdens arising from health and safety legislation, where possible a light-touch regulatory regime should be employed for low-risk companies;

23. Recommends that REACH fee rates for SMEs and micro-enterprises be proportionate;

24. Asks the Commission to accelerate all processing of REACH applications and, in particular, to fast-track applications from SMEs and micro-enterprises; invites the Commission to provide SMEs and micro-enterprises with suitable guidance to help them submit successful applications;

25. Considers the 'top ten' consultation process to be a useful exercise, and its results to constitute an important signal from SMEs and the organisations representing them; calls on the Commission to continue this exercise on a regular basis through Eurobarometer; notes, however, a significant imbalance in the geographical distribution of responses to the 'top ten' consultation process; invites the Commission to carry out an *ex post* evaluation of the reasons behind such an imbalance, so as to ensure that the information collected is not skewed by a lack of awareness or other factors that may have distorted the feedback collected;

26. Expects the next Commission to maintain responsibility for 'smart regulation' as one of the competences of the President's office, and encourages it to enhance the role of the SME envoys; urges the Commission, accordingly, to ensure that national SME organisations form part of the recently established network of SME envoys and that the SME Assembly is duly informed of EU initiatives;

Thursday 17 April 2014

27. Insists that the next Commission should establish a European objective of a 30 % reduction in the costs to SMEs generated by administrative and regulatory burdens by 2020;
 28. Warns of the risks to local and regional competitiveness and individual entrepreneurship if efforts to reduce gold-plating result instead in an increase in maximum harmonisation or one-size-fits-all legislation;
 29. Instructs its President to forward this resolution to the Council and the Commission.
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Thursday 17 April 2014

P7_TA(2014)0460

Pakistan: recent cases of persecution**European Parliament resolution of 17 April 2014 on Pakistan: recent cases of persecution (2014/2694(RSP))**

(2017/C 443/15)

The European Parliament,

- having regard to its previous resolutions on human rights and democracy in Pakistan, in particular those of 12 March 2014 on Pakistan's regional role and political relations with the EU ⁽¹⁾, of 10 October 2013 on recent cases of violence and persecution against Christians, notably in Peshawar ⁽²⁾, of 10 March 2011 on Pakistan, in particular the murder of Shahbaz Bhatti ⁽³⁾, of 20 January 2011 on the situation of Christians in the context of freedom of religion ⁽⁴⁾ and of 20 May 2010 on religious freedom in Pakistan ⁽⁵⁾,
 - having regard to Article 18 of the Universal Declaration of Human Rights of 1948,
 - having regard to Article 18 of the International Covenant on Civil and Political Rights of 1966,
 - having regard to the statements by EU Vice-President / High Representative Catherine Ashton regarding the attack on the Christian community in Peshawar of 23 September 2013 and regarding the assassination of Shahbaz Bhatti of 2 March 2011,
 - having regard to the UN Declaration on the Elimination of all Forms of Intolerance and of Discrimination based on Religion and Belief of 1981,
 - having regard to the reports of the UN Special Rapporteur on freedom of religion or belief,
 - having regard to the report of the UN Special Rapporteur on freedom of religion or belief and the report of the UN Special Rapporteur on the independence of judges and lawyers (Addendum: Mission to Pakistan), of 4 April 2013,
 - having regard to its resolution of 11 December 2013 on the Annual Report on Human Rights and Democracy in the World 2012 and the European Union's policy on the matter ⁽⁶⁾, which condemns the persecution of Christians and other religious minorities,
 - having regard to the EU-Pakistan five-year engagement plan of March 2012, which contains priorities such as good governance and dialogue on human rights, as well as the closely related 2nd EU-Pakistan Strategic Dialogue of 25 March 2014,
 - having regard to the Council conclusions on Pakistan of 11 March 2013 that reiterate the EU's expectations regarding the promotion of and respect for human rights and condemn all acts of violence, including against religious minorities ⁽⁷⁾,
 - having regard to Rules 122(5) and 110(4) of its Rules of Procedure,
- A. whereas a Christian couple, Shafqat Emmanuel and Shagufta Kausar, was sentenced to death on 4 April 2014 for allegedly sending a text message insulting the Prophet Mohammed; whereas the couple denied responsibility and declared that the phone from which the text originated was lost a while before the message was sent;

⁽¹⁾ Texts adopted, P7_TA(2014)0208.

⁽²⁾ Texts adopted, P7_TA(2013)0422.

⁽³⁾ OJ C 199 E, 7.7.2012, p. 179.

⁽⁴⁾ OJ C 136 E, 11.5.2012, p. 53.

⁽⁵⁾ OJ C 161 E, 31.5.2011, p. 147.

⁽⁶⁾ Texts adopted, P7_TA(2013)0575.

⁽⁷⁾ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/foraff/135946.pdf

Thursday 17 April 2014

- B. whereas Sawan Masih, a Pakistani Christian from Lahore, was sentenced to death on 27 March 2014 for blasphemy against the Prophet Mohammed; whereas the announcement of allegations against Masih sparked fierce rioting in Joseph Colony, a Christian neighbourhood in the city of Lahore, in which many buildings, including two churches, were burnt down;
 - C. whereas Asia Bibi, a Christian woman from Punjab, was arrested in June 2009 and received a death sentence in November 2010 on charges of blasphemy; whereas her appeal has finally reached the high court in Lahore after several years; whereas for the two first hearings in January and March 2014 the presiding judges appeared to be on leave;
 - D. whereas in 2012, the 14-year-old Christian girl Rimsha Masih, who was wrongfully accused of desecrating the Quran, was acquitted after being found to have been framed and the person responsible was arrested; whereas, however, she and her family had to leave the country;
 - E. whereas Christians, who represent about 1,6 % of the population in the Islamic Republic of Pakistan, suffer from prejudice and sporadic bouts of mob violence; whereas the majority of Pakistani Christians lead a precarious existence, often fearful of allegations of blasphemy, a subject which can provoke outbursts of public violence; whereas several other Christians are currently in prison on blasphemy charges;
 - F. whereas Mohammad Asghar, a UK citizen with a mental illness living in Pakistan, was arrested after allegedly sending letters to various officials claiming he was a prophet, and was sentenced to death in January 2014;
 - G. whereas another UK citizen, 72-year-old Masood Ahmad, a member of the Ahmaddiya religious community, was only recently released on bail after having been arrested in 2012 on charges of citing from the Quran, which is considered as blasphemy in the case of Ahmaddis who are not recognised as Muslims and are forbidden to 'behave as Muslims' under Section 298-C of the criminal code;
 - H. whereas five Hindu temples have been attacked in different parts of Sindh (in Tharparkar, Hyderabad and Larkana) over the past months and three Hindu boys have been accused of blasphemy and are currently under arrest in Badin (Sindh), as they had spray-painted some signs on the occasion of Holi (the Hindu festival of colour);
 - I. whereas members of the Shia Hazara community in particular are now victims of killings and forced migration on a daily basis due to the upsurge in sectarian violence in Pakistan; whereas more than 10 000 Hindus have also reportedly fled the province as abductions-for-ransom have become routine over the last three years;
 - J. whereas Pakistan's blasphemy laws make it dangerous for religious minorities to express themselves freely or engage openly in religious activities; whereas there has been global concern for a number of years about the application of these laws because accusations are often motivated by score-settling, economic gain or religious intolerance, and they foster a culture of vigilantism, giving mobs a platform for harassment and attacks; whereas Pakistan has been requested by UN Human Rights mechanisms to repeal the blasphemy laws, or at the very least, to put safeguards in place immediately, to prevent abuse of the law to victimise citizens, who often come from minority communities;
 - K. whereas hundreds of honour killings were reported in 2013 alone; whereas these represent only the most visible form of aggression against women, given the consistently high rate of domestic violence and forced marriage;
 - L. whereas Pakistan plays an important role in fostering stability in southern Asia and should therefore lead by example in strengthening the rule of law and human rights;
 - M. whereas the European Union recently granted GSP+ status to Pakistan, subject to the implementation of applicable human rights conventions;
1. Expresses its deep concern at the sharp increase in sectarian violence and religious intolerance towards minorities and attacks on places of worship, including Christian churches, and the continuing repression of women in Pakistan;

Thursday 17 April 2014

2. Is worried about the effects that such violence has on the future development of Pakistani society as a whole in view of the socioeconomic challenges facing the country; stresses that it is in Pakistan's long-term interest for all its citizens to experience greater security;
3. Expresses its deep concern that the controversial blasphemy laws are open to misuse which can affect people of all faiths in Pakistan; expresses its particular concern that use of the blasphemy laws, which were publicly opposed by the late Minister Shahbaz Bhatti and by the late Governor Salman Taseer, is currently on the rise and targets Christians and other religious minorities in Pakistan;
4. Reminds the Pakistani authorities of their obligation under international law to respect freedom of expression and the freedom of thought, conscience, religion and belief; calls on the Pakistani authorities to release prisoners who are convicted on the grounds of blasphemy, and to overrule the death sentences on appeal; calls on the Pakistani authorities to guarantee the independence of the courts, the rule of law and due process in line with international standards on judicial proceedings; calls furthermore on the Pakistani authorities to provide sufficient protection to all those involved in blasphemy cases, including by shielding judges from outside pressure, by protecting the accused and their families and communities from mob violence, and by providing solutions for those who are acquitted but cannot go back to their places of origin;
5. Strongly condemns the application of the death penalty under any circumstances; calls on the Government of Pakistan as a matter of urgency to turn the de facto moratorium on the death penalty into the effective abolition of the death penalty;
6. Calls on the Government of Pakistan to carry out a thorough review of the blasphemy laws and their current application — as contained in Sections 295 and 298 of the Penal Code — for alleged acts of blasphemy, especially in light of the recent death sentences; encourages the government to withstand pressure from religious groups and some opposition political forces to maintain these laws;
7. Appeals to the government to speed up the madrasa reforms by establishing a basic curriculum that meets international standards, with special emphasis on removing hate material from the curricula and introducing community and religious tolerance teaching into the basic syllabus; calls on the Commission to follow up on previous demands for the revision of EU-financed textbooks containing hate speech;
8. Urgently appeals to the Government and Parliament of Pakistan to introduce reforms to the formal justice system in order to discourage recourse to informal structures such as jirgas and panchayats, and to substantially increase the financial and human resources of the judiciary, in particular at the level of courts of first instance;
9. Strongly condemns all acts of violence against religious communities as well as all kinds of discrimination and intolerance on the grounds of religion and belief; calls on the Government of Pakistan to intervene to protect victims of religiously motivated mob violence, and notably to ban public hate speech, and encourages all Pakistanis to work together to promote and ensure tolerance and mutual understanding; urges the Pakistani authorities to prosecute those responsible for incitement and false accusations of blasphemy;
10. Recalls that freedom of religion and minority rights are guaranteed by Pakistan's constitution; welcomes the measures taken in the interest of religious minorities by the Government of Pakistan since November 2008, such as establishing a five per cent quota for minorities in the federal job sector, recognising non-Muslim public holidays and declaring a National Minorities Day;
11. Urges the Pakistani government, however, to increase efforts aimed at better inter-religious understanding, to actively address religious hostility by societal actors, to combat religious intolerance, acts of violence and intimidation, and to act against the perception of impunity;
12. Is deeply concerned about the plight of minority women and girls who often suffer twice over, notably through the practice of forced conversion and targeted sexual violence; urges the Pakistani authorities to improve protection, prosecution and reparations;

Thursday 17 April 2014

13. Stresses that the right to freedom of thought, conscience and religion is a fundamental human right; expresses its concern at the recent tendency in Pakistan to curb the freedom of thought, expression and information by blocking and controlling much frequented internet services; calls on the Government to stop censorship of the internet and to revise both the draft anti-terrorism and draft NGO legislation, which would massively curtail the independence and freedom of operation of NGOs and could lead to the breakdown of work by internationally connected NGOs in Pakistan;
 14. Stresses the important role Pakistan plays in fostering stability in the whole region; encourages Pakistan to play a constructive role in promoting a secure Afghanistan and therefore urges the Pakistani Government to strengthen respect for fundamental human rights in its own country as well as in the whole region;
 15. Instructs its President to forward this resolution to the Council, the Commission, the Vice-President of the European Commission / High Representative of the Union for Foreign Affairs and Security Policy, the EU Special Representative for Human Rights, the governments and parliaments of the Member States, the Secretary-General of the UN, the UN Human Rights Council, and the Government and Parliament of Pakistan.
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Thursday 17 April 2014

P7_TA(2014)0461

Syria: situation of certain vulnerable communities**European Parliament resolution of 17 April 2014 on Syria: situation in certain vulnerable communities (2014/2695(RSP))**

(2017/C 443/16)

The European Parliament,

- having regard to its previous resolutions on Syria, in particular that of 6 February 2014 on the situation in Syria ⁽¹⁾,
 - having regard to the Council conclusions on Syria of 14 April 2014 and 20 January 2014,
 - having regard to the statements of Vice-President / High Representative Catherine Ashton of 15 March 2014 on the 3rd anniversary of the Syrian uprising, and of 8 April 2014 in reference to the killing of Father Van der Lugt, SJ, in Homs, Syria,
 - having regard to the Universal Declaration of Human Rights of 1948,
 - having regard to the Geneva Conventions of 1949 and the additional protocols thereto,
 - having regard to the International Covenant on Civil and Political Rights of 1966,
 - having regard to the UN Declaration on the Elimination of all Forms of Intolerance and of Discrimination based on Religion and Belief of 1981,
 - having regard to UN Security Council resolution 2139 of 22 February 2014,
 - having regard to the report of the Independent International Commission of Inquiry on the Syrian Arab Republic of 12 February 2014,
 - having regard to the statement of the spokesperson for UN Secretary-General Ban Ki-moon on Syria of 7 April 2014,
 - having regard to the statement of UN Emergency Relief Coordinator and Under-Secretary-General for Humanitarian Affairs Valerie Amos on Syria of 28 March 2014,
 - having regard to the European Convention on Human Rights of 1950, and the Charter of Fundamental Rights of the European Union of 2000,
 - having regard to the Rome Statute of the International Criminal Court,
 - having regard to Rules 122(5) and 110(4) of its Rules of Procedure,
- A. whereas the ongoing violent crisis in Syria has resulted in a humanitarian catastrophe of a scale unprecedented in recent history, with more than 150 000 people, most of them civilians, killed, more than 6,5 million people internally displaced, and more than 2,6 million Syrian refugees, mainly in Lebanon, Turkey, Jordan, Iraq and Egypt; whereas ethnic and religious minorities find themselves in a particularly vulnerable situation in this crisis;
- B. whereas the Syrian population has traditionally been composed of a rich diversity of ethnic and religious communities, respectively including Arabs, Arameans, Armenians, Assyrians, Circassians, Kurds and Turkmens, and Muslims, Christians and Druze, as well as other groups; whereas none of the religious or ethnic communities in Syria has been spared by the three-year old conflict, which is increasingly taking on a sectarian dimension;
- C. whereas these communities have always been part of Syrian society, contributing to its development and advancement inter alia through their engagement in the education, health, and culture sectors; whereas they therefore have an important role to play in the democratisation of Syria and need to be represented in any consultation on the country's future and in any reconciliation process;

⁽¹⁾ Texts adopted, P7_TA(2014)0099.

Thursday 17 April 2014

- D. whereas until recently most of these communities had tried to avoid taking sides in the conflict, as many may recognise the need for a change of regime in Syria but also fear that, if the government is overthrown, they will be targeted by Sunni jihadist rebels, calling for the establishment of an Islamic state, or others;
- E. whereas the Assad regime has deliberately triggered a dynamic of sectarian polarisation as its survival strategy, which has inflamed the latent and hitherto largely repressed communal tensions; whereas the increasing presence and infiltration of Islamist extremists and jihadists on all sides in the conflict has created legitimate concerns among minority communities in the country; whereas the deepening Sunni-Shiite cleavage in Syria is also affecting inter-communal relations in neighbouring countries;
- F. whereas Dutch Jesuit Father Frans van der Lugt, who had been living in Syria for many decades and was well known for refusing to leave the besieged city of Homs, was beaten and shot dead by gunmen on 7 April 2014; whereas the UN Secretary-General has condemned this inhumane act of violence against a man who stood by the people of Syria amid sieges and growing difficulties; whereas other Christians remain in the monastery where Father van der Lugt was killed and the international community is worried about their safety, as it is worried about the safety of the many civilians still trapped in the city of Homs, which continues to be under siege;
- G. whereas Father Paolo Dall'Oglio has been missing since July 2013, and Bishop Boulos Yazigi of the Greek Orthodox Church and Bishop John Ibrahim of the Assyrian Orthodox Church were seized in April 2013 from their car by gunmen outside the northern city of Aleppo; whereas their fate is still unknown;
- H. whereas the fights between regime forces and rebel fighters, including elements linked to Al-Qaeda, at the end of March 2014 led to the evacuation of the vast majority of the population of Kassab, an Armenian town on the Syrian-Turkish border; whereas there are contradicting reports about the number of victims of these events;
- I. whereas the latest reports from Syria show that rebels from the Al-Qaeda-linked al-Nusra Front have captured a number of Christian and Kurdish villages on the Turkish border, such as the Kurdish town of Ayn-Al-Arab/Kobane;
- J. whereas Palestine refugees remain a particularly vulnerable group in the crisis in Syria; whereas many of them live in besieged areas, in particular in Yarmouk Camp, which continues to be under heavy attack by regime forces and various armed groups, leading to inhuman suffering of the 18 000 Palestinians staying in this area; whereas almost all of the 540 000 Palestine refugees in Syria are in need of assistance today, with more than half of them being internally displaced within the country, and are facing major obstacles or increasing restrictions when trying to flee to Egypt, Jordan or Lebanon;
- K. whereas women and children continue to suffer from aggression, sexual and gender-based violence, abuse and the lack of basic goods and services in the ongoing crisis in Syria; whereas there are a disproportionately high number of women and children among Syrian refugees; whereas nearly 3 million children have dropped out of school in Syria since 2011, while at least 500 000 registered child refugees are not enrolled in schools in neighbouring countries;
- L. whereas human rights defenders, intellectuals, religious figures, journalists and civil society activists continue to be victims of the violent crisis in Syria; whereas 2011 Sakharov Prize winner Razan Zaitouneh, who was kidnapped together with her husband and two other human rights activists more than four months ago in Douma, continues to be held at an unknown location;
- M. whereas political and religious leaders have a duty at all levels to combat extremism and terrorism and to promote mutual respect among individuals and religious and ethnic groups;
- N. whereas international humanitarian and human rights law prohibits the targeting of individuals or groups based on religious or ethnic identity, as well as attacks against civilians not taking part in hostilities; whereas such actions may constitute war crimes and crimes against humanity; whereas UN Security Council resolution 2139 stressed the need to end impunity for violations of international humanitarian law and violations and abuses of human rights, and reaffirmed that those who had committed or were otherwise responsible for such violations and abuses in Syria must be brought to justice;

Thursday 17 April 2014

1. Expresses its profound dismay at the unprecedented level of human suffering and loss of life, and expresses its solidarity with the families of all innocent victims in the Syrian conflict; strongly condemns the violations of human rights and international humanitarian law by the Assad regime and by pro-government militia; condemns any human rights abuses and violations of international humanitarian law by armed groups opposing the regime; strongly condemns the increasing number of terrorist attacks carried out by extremist organisations and individuals in the country;
2. Is convinced that a lasting solution to the current crisis in Syria can only be achieved through a Syrian-led, inclusive political process with the backing of the international community; deplores the fact that peace talks are currently failing due to the regime's obstruction of these talks, and urgently requests that all the parties involved and the international community put all their efforts into working towards new talks, which will bring this massacre to an end; stresses the importance of the participation and contribution of all parts of Syrian society, including ethnic and religious minorities, in this process, and underlines the crucial role of minorities in preserving the unique cultural heritage and the tradition of intercultural, interethnic and interreligious coexistence in Syria, with the aim of creating a vibrant society for future generations of Syrians;
3. Reiterates that the rights of minorities are inextricably linked to respect for other fundamental human rights and freedoms, such as the right to liberty, security, equality and freedom of expression;
4. Strongly condemns the recent attacks against certain religious and ethnic communities in Syria, notably the Christians, Armenians and Kurds, and calls on all the parties involved to stop all actions aimed at inciting interethnic and interconfessional conflict; stresses that all actors involved in the conflict have a duty to protect all the different minorities present in the country; recognises, however, that the attacks against certain vulnerable communities are only one aspect of the Syrian civil war;
5. Condemns in the strongest possible terms the killing of Father Frans Van der Lugt, an inhumane act of violence against a man who stood by the people of Syria amid sieges and growing difficulties; pays tribute to his work, which extended beyond the besieged city of Homs and continues to help hundreds of civilians with their everyday survival needs;
6. Urges all parties to the conflict to adhere strictly to international humanitarian and human rights law, and calls for the protection of all vulnerable communities, inter alia by allowing humanitarian access and lifting all sieges of populated areas, including the Old City of Homs; reiterates its call for the establishment of safe havens along the Turkish-Syrian border, and possibly within Syria, and for the creation of humanitarian corridors by the international community;
7. Condemns the attack against the Armenian town of Kassab; supports all efforts at local level to avoid and combat sectarian violence in rebel-held areas and in Kurdish-majority areas; urges current and future Syrian authorities to provide reliable and efficient protection for vulnerable communities in the country and to ensure their safe and secure return to their homes, as well as ensuring that the perpetrators of the attacks against them are brought to justice and tried by due process;
8. Calls again for special attention to be given to the vulnerable situation of Palestine refugees in Syria, and particularly the inhuman living conditions of Palestinians staying in Yarmouk Camp; reiterates its call to all the parties involved in the conflict to allow the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA) and other international aid organisations unhindered access to this camp, as well as to all other besieged areas in the country, in order to alleviate the extreme suffering of the local population; commends the work of UNRWA in Syria and calls for increased international support for its activities;
9. Calls on the international community and the EU to pay special attention to the suffering and needs of women and children in the Syrian crisis; calls for zero tolerance regarding the killing, abduction and recruitment of children in particular, as well as for humanitarian aid capacities in the field of support to traumatised victims to be strengthened;
10. Recalls the pressing need to release all political detainees, civil society activists, humanitarian aid workers, religious figures (including Father Paolo Dall'Oglio, Greek Orthodox Bishop Boulos Yazigi and Assyrian Orthodox Bishop John Ibrahim), journalists and photographers held by the regime or by rebel fighters, and to grant independent monitors access to all places of detention; urges once again the EU and its Member States to make all possible efforts to achieve the release of 2011 Sakharov Prize winner Razan Zaitouneh and of all other human rights activists in Syria, including internet activist Bassel Safadi Khartabil;

Thursday 17 April 2014

11. Remains convinced that there can be no sustainable peace in Syria without accountability for the crimes committed during the conflict, including for those based on religious or ethnic grounds; reiterates its call for the referral of the situation in Syria to the International Criminal Court and supports all initiatives in this direction; commends the work of the Independent International Commission of Inquiry on the Syrian Arab Republic and of other international actors collecting and preserving a large volume of testimony on serious crimes committed by the regime and by some rebel groups in Syria, and calls for action in order to bring perpetrators to justice;

12. Expresses its grave concern at the profound consequences of the fragmentation of Syria for the stability and security of the region, particularly in Lebanon and Iraq; is deeply concerned about the high number of Syrian refugees in the neighbouring countries, especially in Lebanon, where, according to the UNHCR, the number has now passed the 1 million mark, not including the tens of thousands who have not registered with the agency, while 12 000 people are fleeing Syria for Lebanon each week; is deeply concerned also about the continued refugee outflow affecting Jordan, Turkey, Iraq and Egypt; encourages the European Union and its Member States to continue providing substantial humanitarian assistance to the populations affected by the Syrian conflict;

13. Instructs its President to forward this resolution to the Vice-President / High Representative, the Council, the Commission, the governments and parliaments of the Member States, the Secretary-General of the United Nations, the UN-Arab League Special Envoy to Syria, the Government and Parliament of Egypt, the Government and Parliament of Iraq, the Government and Parliament of Jordan, the Government and Parliament of Lebanon, the Government and Parliament of Turkey, the Secretary-General of the Cooperation Council for the Arab States of the Gulf, and all the parties involved in the conflict in Syria.

Thursday 17 April 2014

P7_TA(2014)0462

Situation in North Korea**European Parliament resolution of 17 April 2014 on the situation in North Korea (Democratic People's Republic of Korea) (2014/2696(RSP))**

(2017/C 443/17)

The European Parliament,

- having regard to the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, the Convention on the Rights of the Child and the Convention on the Elimination of All Forms of Discrimination against Women, to all of which the Democratic People's Republic of Korea (DPRK) is a party,
 - having regard to the 1984 Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment,
 - having regard to its resolutions of 14 March 2013 on nuclear threats and human rights in the Democratic People's Republic of Korea ⁽¹⁾, of 24 May 2012 on the situation of North Korean refugees ⁽²⁾ and of 8 July 2010 on North Korea ⁽³⁾,
 - having regard to the statements by the spokesperson for the Vice-President of the Commission / High Representative of the Union for Foreign Affairs and Security Policy, Catherine Ashton, of 19 August 2013 on the recent inter-Korean agreements and of 5 June 2013 concerning the expulsion of nine North Koreans from Laos, and to the statement by Catherine Ashton of 13 March 2013 on nuclear threats and human rights in North Korea,
 - having regard to the declaration by the DPRK of 13 March 2013 that it had ended the 1953 armistice and 'is not restrained by the North-South declaration on non-aggression',
 - having regard to the UN Human Rights Council resolutions of 26 March 2014 and 21 March 2013 and the UN General Assembly resolution of 18 December 2013 on the situation of human rights in the Democratic People's Republic of Korea,
 - having regard to the Commission of Inquiry on human rights in the Democratic People's Republic of Korea which was established on 21 March 2013 by the UN Human Rights Council,
 - having regard to Rules 122(5) and 110(4) of its Rules of Procedure,
- A. whereas the UN Commission of Inquiry (CoI) investigated 'the systematic, widespread and grave violations of human rights' in North Korea and released a report on 7 February 2014;
- B. whereas the professional, thorough and inclusive working methods applied by the CoI can serve as an example for the work of future fact-finding missions requested by the UN Human Rights Council where governments refuse all cooperation, as has been the case with the DPRK;
- C. whereas the DPRK, upon the establishment of the CoI, stated that it would 'totally reject and disregard it', refused it permission to visit the country and failed to cooperate in any way; whereas the DPRK regime has not cooperated in general with the UN and has rejected all UN Human Rights Council and General Assembly resolutions regarding human rights in North Korea; whereas it has failed to cooperate with the UN Special Rapporteur on the situation of human rights in the country and has rejected all assistance from the UN High Commissioner for Human Rights;
- D. whereas the EU-DPRK human rights dialogue was suspended by the DPRK in 2003;

⁽¹⁾ Texts adopted, P7_TA(2013)0096.

⁽²⁾ OJ C 264 E, 13.9.2013, p. 94.

⁽³⁾ OJ C 351 E, 2.12.2011, p. 132.

Thursday 17 April 2014

- E. whereas the CoI has come to the conclusion that ‘systematic, widespread and gross human rights violations have been and are being committed by the DPRK, and in many instances, the violations found constitute crimes against humanity based on State policies’ and do not have ‘any parallel in the contemporary world’;
 - F. whereas these crimes against humanity entail extermination, murder, enslavement, torture, imprisonment, rape, forced abortions and other sexual violence, persecution on political, religious, racial and gender grounds, the forcible transfer of populations, the enforced disappearance of persons and the inhumane act of knowingly causing prolonged starvation; whereas these crimes against humanity are ongoing in the DPRK because the policies, institutions and patterns of impunity remain in place;
 - G. whereas the CoI’s report concludes that ‘the unspeakable atrocities’ that have been committed against the hundreds of thousands of past and present inmates of the prison camps ‘resemble the horrors of camps that totalitarian States established during the twentieth century’;
 - H. whereas the report demonstrates that in the DPRK the state claims absolute control over every aspect of its citizens’ lives, and an absolute monopoly over information, movement inside and outside the country and over social life (the Songbun class system);
 - I. whereas the government has even been extending its repressive acts beyond the state’s borders, with the systematic abduction of, and denial of repatriation to, well over 200 000 people from other countries, many of whom have subsequently suffered enforced disappearance;
 - J. whereas discrimination and violence against women is widespread, including public beatings and sexual assault on women by public officials; whereas women and girls are vulnerable to trafficking and forced sex work;
1. Notes with extreme concern the findings of the UN CoI and supports its recommendations;
 2. Reiterates its strong condemnation of the decade-long state repression exercised in a systematic manner by the present and past Supreme Leaders of the DPRK and the administration, and calls on the DPRK to put an immediate end to the grave, widespread and systematic human rights violations perpetrated against its own people;
 3. Underlines the fact that the violations described, many of which constitute crimes against humanity, have been taking place for far too long under the observing eyes of the international community, and appeals to the EU Member States and all members of the UN General Assembly to move the suffering of the North Korean population to the forefront of the political agenda and to ensure that the CoI’s recommendations are followed up;
 4. Is convinced that the time has come for the international community to take concrete action to end the perpetrators’ impunity; demands that those most responsible for the crimes against humanity committed in the DPRK be held accountable, brought before the International Criminal Court and subjected to targeted sanctions;
 5. Asks the European External Action Service (EEAS) to ensure that the implementation of the CoI’s recommendations be a standing item on the agenda for human rights dialogues and other meetings with third countries, in particular the dialogues with Russia and China; asks the EEAS and the EU Special Representative for Human Rights, furthermore, to ensure that all EEAS ambassadors are briefed about the CoI’s report and understand that they are tasked with ensuring worldwide support for UN Security Council action as recommended by the CoI;
 6. Calls on the Government of the DPRK to fulfil its obligations under the human rights instruments to which it is a party, and to cooperate fully with humanitarian organisations, independent human rights monitors and the UN Special Rapporteur on the situation of human rights in the DPRK, inter alia by providing access to the country;

Thursday 17 April 2014

7. Calls on the EEAS and the Member States to support the UN High Commissioner for Human Rights in establishing special structures to ensure accountability for the crimes committed, through the continued collection of evidence and documentation;
 8. Calls on the DPRK immediately and permanently to stop public and secret executions and to abolish the death penalty; calls, furthermore, on the DPRK to put an end to extrajudicial killings, enforced disappearances and collective punishment, to close all prison camps, to release political prisoners and to allow its citizens to travel freely, both within and outside the country; calls on the DPRK to allow free expression and press freedom for national and international media, and uncensored access to the internet for its citizens;
 9. Urges the Government of the DPRK to hand over all information on third-country nationals suspected to have been abducted by North Korean state agents during the past decades, and to return those abductees still being held to their home countries immediately;
 10. Expresses its particular concern at the continuing severity of the food situation in the country and its impact on the economic, social and cultural rights of the population; calls on the Commission to maintain existing humanitarian aid programmes and channels of communication with the DPRK, and to secure the safe delivery of such aid to the target population groups; calls on the DPRK authorities to ensure access for all citizens to food and humanitarian assistance on the basis of need, in accordance with humanitarian principles; calls, furthermore, on the DPRK to invest its resources in improving the appalling living conditions of its people instead of in the further build-up of its military arsenal and nuclear programme;
 11. Calls on all UN members, and in particular the People's Republic of China, to come to the aid of North Korean citizens who manage to escape from the country, by granting them the right to stay, together with legal protection and basic services equivalent to those afforded to their own citizens, and — imperatively — to refrain from cooperating in any way with the DPRK administration in the extradition or repatriation of North Korean citizens;
 12. Welcomes any humanitarian project between the two Koreas — such as reunions of separated South and North Korean families — that can concretely ease the suffering of the population, and calls on both governments to increase the number of initiatives of this type;
 13. Calls on the UN, as proposed by the CoI, to convene a high-level political conference between the parties to the Korean War with the aim of concluding a final peaceful settlement of the war and establishing a procedure for intensifying cooperation, along similar lines to the Helsinki process, for example;
 14. Instructs its President to forward this resolution to the Council, the Commission, the Government of the DPRK, the Vice-President of the Commission / High Representative of the Union for Foreign Affairs and Security Policy, the EU Special Representative for Human Rights, the parliaments of the Member States, the UN Secretary-General, the UN Human Rights Council, the members of the UN Commission of Inquiry on human rights in the DPRK, including the Special Rapporteur, the Government and Parliament of the Republic of Korea, the Government and Parliament of the Russian Federation, the Government and Parliament of Japan and the Government of the People's Republic of China.
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Tuesday 15 April 2014

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN PARLIAMENT

P7_TA(2014)0348

Request for defence of the parliamentary immunity of Alexander Mirsky

European Parliament decision of 15 April 2014 on the request for defence of the immunity and privileges of Alexander Mirsky (2014/2026(IMM))

(2017/C 443/18)

The European Parliament,

- having regard to the request by Alexander Mirsky of 14 February 2014, announced in plenary on 24 February 2014, for the defence of his immunity and privileges in connection with civil proceedings pending before the Civil Division of the Senate of the Supreme Court of the Republic of Latvia (hereinafter referred to as 'the Supreme Court') (ref. C17129611),
- having regard to Article 8 of Protocol No 7 on the Privileges and Immunities of the European Union, and Article 6(2) of the Act of 20 September 1976 concerning the election of the Members of the European Parliament by direct universal suffrage,
- having regard to the judgments of the Court of Justice of the European Union of 12 May 1964, 10 July 1986, 15 and 21 October 2008, 19 March 2010 and 6 September 2011 ⁽¹⁾,
- having regard to the verbatim report of the proceedings of the plenary sitting of 4 April 2011,
- having regard to Rule 5(2) and to Rules 6a and 7 of its Rules of Procedure,
- having regard to the report of the Committee on Legal Affairs (A7-0273/2014),

A. whereas a Member of the European Parliament, Alexander Mirsky, has requested the defence of his parliamentary immunity in connection with civil proceedings pending before the Supreme Court of the Republic of Latvia; whereas the proceedings in question relate to the decision of the Civil Division of the Riga District Court (hereinafter referred to as 'the Riga District Court') to require Alexander Mirsky to retract a statement made in a speech at the European Parliament on 4 April 2011 and to pay LVL 1 000 in non-material compensation to the benefit of the allegedly prejudiced applicants;

⁽¹⁾ Judgment of the Court of Justice of 12 May 1964, *Wagner v Fohrmann and Krier*, 101/63, ECLI:EU:C:1964:28; judgment of the Court of Justice of 10 July 1986, *Wybot v Faure and others*, 149/85, ECLI:EU:C:1986:310; judgment of the General Court of 15 October 2008, *Mote v Parliament*, T-345/05, ECLI:EU:T:2008:440; judgment of the Court of Justice of 21 October 2008, *Marra v De Gregorio and Clemente*, C-200/07 and C-201/07, ECLI:EU:C:2008:579; judgment of the General Court of 19 March 2010, *Gollnisch v Parliament*, T-42/06, ECLI:EU:T:2010:102; judgment of the Court of Justice of 6 September 2011, *Patriciello*, C-163/10, ECLI: EU: C:2011:543.

Tuesday 15 April 2014

- B. whereas, according to Article 8 of Protocol No 7 on the Privileges and Immunities of the European Union, Members of the European Parliament may not be subject to any form of inquiry, detention or legal proceedings in respect of opinions expressed or votes cast by them in the performance of their duties;
- C. whereas in the exercise of its powers in respect of privileges and immunities, Parliament acts to uphold its integrity as a democratic legislative assembly and to secure the independence of its Members in the performance of their duties;
- D. whereas the Court of Justice has clarified that Article 8 of the Protocol, in the light of its objective of protecting the freedom of speech and independence of Members of the European Parliament and in the light of its wording, which expressly refers to votes cast as well as to opinions expressed by the Members, is in essence intended to apply to statements made by those Members within the very precincts of the European Parliament ⁽¹⁾;
- E. whereas immunity under Article 8 of the Protocol must, to the extent that it seeks to protect the freedom of expression and independence of Members of the European Parliament, be considered as an absolute immunity barring any judicial proceedings in respect of an opinion expressed or a vote cast in the exercise of parliamentary duties ⁽²⁾;
- F. whereas the immunity from legal proceedings enjoyed by Members of the European Parliament includes immunity from civil proceedings;
- G. whereas the request by Alexander Mirsky relates to legal proceedings instituted against him in connection with statements made during a one-minute speech at the plenary sitting of 4 April 2011; whereas it is uncontested that Alexander Mirsky was a Member of the European Parliament at the time of the statements in question;
- H. whereas the Jūrmala Town Court has correctly acknowledged that Alexander Mirsky enjoyed the immunity accorded to the Members of the European Parliament by Article 8 of the Protocol and thus rejected the applicants' claim; whereas, conversely, the Riga District Court has completely ignored the applicability of that provision; whereas a national court has a duty to apply EU primary law;
- I. whereas the legal proceedings brought against Alexander Mirsky are still pending before the Supreme Court of the Republic of Latvia and the final judgment may be in his favour; whereas, however, should the judgment of the Riga District Court be confirmed by the Supreme Court, this would amount to an infringement of EU primary law by the Latvian authorities;
- J. whereas, further to the judgment of the Riga District Court, there has, in fact, been a breach of the privileges and immunities of Alexander Mirsky; whereas, in particular, the circumstances of the case in point constitute a restriction on an opinion expressed in the performance of his parliamentary duties;
1. Decides to defend the immunity and privileges of Alexander Mirsky;
 2. Calls on the Commission to intervene with the Latvian authorities in order to enforce EU primary law — notably, Article 8 of Protocol No 7 on the privileges and immunities of the European Union — and, if necessary, to initiate a Union law infringement procedure under Article 258 of the Treaty on the Functioning of the European Union;
 3. Instructs its President to forward this decision and the report of its competent committee immediately to the Commission, the relevant authorities of the Republic of Latvia and Alexander Mirsky.

⁽¹⁾ Case C-163/10 *Patriciello*, cited above, paragraph 29.

⁽²⁾ Joined Cases C-200/07 and C-201/07 *Marra v De Gregorio and Clemente*, cited above, paragraph 27.

Tuesday 15 April 2014

P7_TA(2014)0396

Voting in the context of procedures concerning the immunity of Members (interpretation of the Rules of Procedure)

European Parliament decision of 15 April 2014 concerning voting in the context of procedures concerning the immunity of Members (interpretation of Rules 166, 167(1) and 195(3)) (2014/2028(REG))

(2017/C 443/19)

The European Parliament,

- having regard to the letter of 9 April 2014 from the Chair of the Committee on Constitutional Affairs,
- having regard to Rule 211 of its Rules of Procedure,

1. Decides to append the following interpretation to Rules 166, 167(1) and 195(3):

‘Rule 166, Rule 167(1) and Rule 195(3) on voting by roll call do not apply to the reports provided for in Rule 6b(2) and Rule 7(3), (6) and (8) in the context of procedures relating to the immunity of a Member.’

2. Instructs its President to forward this decision to the Council and the Commission, for information.

Wednesday 16 April 2014

P7_TA(2014)0408

Amendment of Parliament's Rules of Procedure with regard to parliamentary questions**European Parliament decision of 16 April 2014 on amendment of Parliament's Rules of Procedure with regard to parliamentary questions (2013/2083(REG))**

(2017/C 443/20)

The European Parliament,

- having regard to the letter from its President of 13 February 2013,
 - having regard to Rules 211 and 212 of its Rules of Procedure,
 - having regard to the report of the Committee on Constitutional Affairs (A7-0123/2014),
1. Decides to amend its Rules of Procedure as shown below;
 2. Decides that the amendments shall enter into force on the first day of the first part-session of the eighth parliamentary term;
 3. Decides that the ballot system established by the amendments for determining the Members allowed to put a question shall be assessed after a trial period of one year from the beginning of the eighth parliamentary term;
 4. Instructs its President to forward this decision to the Council and the Commission, for information.

Amendment 1**Parliament's Rules of Procedure****Rule 116***Present text*

1. Question Time with the Commission shall be held at each part-session **at times decided by Parliament on a proposal from** the Conference of Presidents.
2. **No Member may put more than one question to the Commission at any given part-session.**
3. **Questions shall be submitted in writing to the President, who shall rule on their admissibility and on the order in which they are to be taken. The questioner shall be notified immediately of this decision.**
4. **The detailed procedure** shall be **governed by guidelines** laid down in an annex to these Rules of Procedure⁽¹⁷⁾.

Amendment

1. Question Time with the Commission shall be held at each part-session **for a duration of 90 minutes on one or more specific horizontal themes to be decided upon by** the Conference of Presidents **one month in advance of the part-session.**
2. **The Commissioners invited to participate by the Conference of Presidents shall have a portfolio related to the specific horizontal theme or themes on which questions are to be put to them. The number of Commissioners shall be limited to two per part-session, with the possibility of adding a third being dependent on the specific horizontal theme or themes chosen for the Question Time.**
3. **Question time** shall be **conducted in accordance with a ballot-system the details of which are** laid down in an annex to these Rules of Procedure⁽¹⁷⁾.

Wednesday 16 April 2014

Present text

5. In accordance with guidelines established by the Conference of Presidents, specific question hours may be held with the Council, with the President of the Commission, with the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy and with the President of the Eurogroup.

⁽¹⁷⁾ See Annex II.

Amendment

4. In accordance with guidelines established by the Conference of Presidents, specific question hours may be held with the Council, with the President of the Commission, with the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy and with the President of the Eurogroup.

⁽¹⁷⁾ See Annex II.

Amendment 2

Parliament's Rules of Procedure

Rule 117 — paragraph 1

Present text

1. Any Member may put questions for written answer to the President of the European Council, the Council, the Commission or the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy in accordance with **guidelines** laid down in an annex to these Rules of Procedure⁽¹⁸⁾. The content of questions shall be the sole responsibility of their authors.

⁽¹⁸⁾ See Annex III.

Amendment

1. Any Member may put questions for written answer to the President of the European Council, the Council, the Commission or the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy in accordance with **criteria** laid down in an annex to these Rules of Procedure⁽¹⁸⁾. The content of questions shall be the sole responsibility of their authors.

⁽¹⁸⁾ See Annex III.

Amendment 3

Parliament's Rules of Procedure

Rule 117 — paragraph 2

Present text

2. Questions shall be submitted **in writing** to the President **who shall forward them to the addressees**. Doubts concerning the admissibility of a question shall be settled by the President. The questioner shall be notified of **his** decision.

Amendment

2. Questions shall be submitted to the President. Doubts concerning the admissibility of a question shall be settled by the President. **The President's decision shall be based not exclusively on the provisions of the annex referred to in paragraph 1 but on the provisions of these Rules of Procedure in general.** The questioner shall be notified of **the President's** decision.

Amendment 4

Parliament's Rules of Procedure

Rule 117 — paragraph 2 a (new)

Present text

Amendment

2a. Questions shall be submitted in electronic format. Each Member may submit a maximum of five questions per month.

Wednesday 16 April 2014

Present text

Amendment

By way of exception, additional questions may be submitted in the form of a paper document tabled and signed personally by the Member concerned in the relevant service of the Secretariat.

After a period expiring one year from the beginning of the eighth parliamentary term, the Conference of Presidents shall carry out an assessment of the regime in respect of additional questions.

Amendment 7

Parliament's Rules of Procedure

Rule 117 — paragraph 4 — subparagraph 3

Present text

Amendment

Members shall indicate which type of question they are submitting. The final decision shall be taken by the President.

deleted

Amendment 8

Parliament's Rules of Procedure

Rule 117 — paragraph 5

Present text

Amendment

5. Questions and answers shall be published *in the Official Journal of the European Union*.

5. Questions and answers shall be published *on Parliament's website*.

Amendment 9

Parliament's Rules of Procedure

Rule 118 — paragraph 1

Present text

Amendment

1. Any Member may put questions for written answer to the European Central Bank in accordance with *guidelines* laid down in an annex to these Rules of Procedure ⁽¹⁹⁾.

1. Any Member may put *a maximum of six* questions *per month* for written answer to the European Central Bank in accordance with *criteria* laid down in an annex to these Rules of Procedure ⁽¹⁹⁾. *The content of questions shall be the sole responsibility of their authors.*

⁽¹⁹⁾ See Annex III.

⁽¹⁹⁾ See Annex III.

Wednesday 16 April 2014

Amendment 10

Parliament's Rules of Procedure

Rule 118 — paragraph 2

Present text

2. Such questions shall be submitted in writing to the Chair of the committee responsible, who shall **forward** them to the European Central Bank.

Amendment

2. Such questions shall be submitted in writing to the Chair of the committee responsible, who shall **notify** them to the European Central Bank. **Doubts concerning the admissibility of a question shall be settled by the Chair. The questioner shall be notified of the Chair's decision.**

Amendment 11

Parliament's Rules of Procedure

Rule 118 — paragraph 3

Present text

3. **The** questions and answers shall be published **in the Official Journal of the European Union.**

Amendment

3. Questions and answers shall be published **on Parliament's website.**

Amendment 12

Parliament's Rules of Procedure

Annex II

Present text

Conduct of Question Time **under Rule 116**

A. Guidelines

1. Questions shall be admissible only where they

— are concise and are drafted so as to permit a brief answer to be given;

— fall within the competence and sphere of responsibility of the addressee and are of general interest;

— concern in particular, in the case of specific questions to the Council, the exercise of its functions in defining, coordinating and implementing Union policies, or concern its powers relating to appointment procedures or the operation of the institutions, agencies and bodies of the European Union or a revision of the Treaties,

Amendment

Conduct of Question Time **with the Commission**

1. **Members who put a question to one of the Commissioners shall be chosen by means of a ballot system in the following way:**

— **a ballot box shall be placed at the entrance to the Chamber one hour before the start of Question Time;**

— **Members wishing to put a question write their name on a form and place it in the ballot box;**

— **Members wishing to put a question may submit no more than one form;**

— **the President opens Question Time and closes the ballot box;**

Wednesday 16 April 2014

Present text

Amendment

— do not require extensive prior study or research by the institution concerned;

— are clearly worded and relate to a specific matter;

— do not contain assertions or opinions;

— do not relate to strictly personal matters;

— are not aimed at procuring documents or statistical information;

— are interrogatory in form.

2. A question shall be inadmissible if the agenda already provides for the subject to be discussed with the participation of the institution concerned, or if it relates to the exercise of the Council's legislative and budgetary functions referred to in Article 16(1), first sentence, of the Treaty on European Union.

3. A question shall be inadmissible if an identical or similar question has been put down and answered during the preceding three months, or to the extent that it merely seeks information on the follow-up to a specific resolution of Parliament of a kind which the Commission has already provided in a written follow-up communication, unless there are new developments or the author is seeking further information. In the first case a copy of the question and the answer shall be given to the author.

Supplementary questions

4. Each Member may follow up the reply with a supplementary question to any question and may put in all two supplementary questions.

5. Supplementary questions shall be subject to the rules of admissibility laid down in these Guidelines.

6. The President shall rule on the admissibility of supplementary questions and shall limit their number so that each Member who has put down a question may receive an answer to it.

— the President draws one ballot at a time and calls on the chosen Member to put his or her question to the competent Commissioner.

2. The Member shall be given one minute in which to formulate the question and the Commissioner two minutes in which to reply. That Member may put a supplementary question of 30 seconds duration, having a direct bearing on the main question. The Commissioner shall then be given two minutes in which to give a supplementary reply.

3. Questions and supplementary questions must be directly related to the specific horizontal theme chosen. The President may rule on the admissibility.

Wednesday 16 April 2014

Present text

Amendment

The President shall not be obliged to declare a supplementary question admissible, even if it satisfies the foregoing conditions of admissibility, if:

- a) it is likely to upset the normal conduct of Question Time, or*
- b) the main question to which it relates has already been adequately covered by other supplementary questions, or*
- c) it has no direct bearing on the main question.*

Answers to questions

7. The institution concerned shall ensure that answers are concise and are relevant to the subject of the question.

8. If the content of the questions concerned permits it, the President may decide, after consulting the questioners, that the institution concerned should answer them together.

9. A question may be answered only if the questioner is present or has notified the President in writing, before Question Time begins, of the name of a substitute.

10. If neither the questioner nor a substitute is present, the question shall lapse.

11. If a Member tables a question, but neither that Member nor a substitute is present at Question Time, the President shall remind the Member in writing of his or her responsibility to be present or substituted. If the President has to send such a letter three times in the space of any twelve-month period, the Member concerned shall lose the right to table questions at Question Time for a six-month period.

12. Questions that remain unanswered for lack of time shall be answered in accordance with Rule 117(4), first subparagraph, unless their authors request the application of Rule 117(3).

13. The procedure for answers in writing shall be governed by Rule 117(3) and (5).

Time limits

14. Questions shall be tabled at least one week before Question Time begins. Questions not tabled within this time limit may be taken during Question Time with the consent of the institution concerned.

Wednesday 16 April 2014

Present text

Amendment

Questions declared admissible shall be distributed to Members and forwarded to the institutions concerned.

B. Recommendations

(extract from resolution of Parliament of 13 November 1986)

The European Parliament,

1. Recommends stricter application of the guidelines for the conduct of Question Time under Rule 43⁽²⁷⁾, and in particular of point 1 of those guidelines concerning admissibility;

2. Recommends more frequent use of the power conferred on the President of the European Parliament by Rule 43(3)⁽²⁸⁾ to group questions for Question Time according to subject; considers, however, that only the questions falling within the first half of the list of questions tabled for a given part-session should be subject to such grouping;

3. Recommends, as regards supplementary questions, that as a general rule the President should allow one supplementary question from the questioner and one or at most two supplementaries put by Members belonging preferably to a different political group and/or Member State from the author of the main question; recalls that supplementary questions must be concise and interrogatory in form and suggests that their duration should not exceed 30 seconds;

4. Invites the Commission and the Council, pursuant to point 7 of the guidelines, to ensure that answers are concise and relevant to the subject of the question.

⁽²⁷⁾ Now Rule 116.

⁽²⁸⁾ Now Rule 116(3).

Amendment 13

Parliament's Rules of Procedure

Annex III — title

Present text

Amendment

Guidelines for questions for written answer under Rules 117 and 118

Criteria for questions for written answer under Rules 117 and 118

Wednesday 16 April 2014

Amendment 14
Parliament's Rules of Procedure
Annex III — paragraph 1 — indent 2

Present text

— fall within the **competence** and sphere of responsibility of the addressee and be of general interest;

Amendment

— fall **exclusively** within the **limits of the competences of the institutions as laid down in the relevant Treaties** and **within the** sphere of responsibility of the addressee, and be of general interest;

Amendment 15
Parliament's Rules of Procedure
Annex III — paragraph 1 — indent 3 a (new)

Present text

Amendment

— **not exceed 200 words;**

Amendment 16
Parliament's Rules of Procedure
Annex III — paragraph 1 — indent 5 a (new)

Present text

Amendment

— **not contain more than three sub-questions.**

Amendment 17
Parliament's Rules of Procedure
Annex III — paragraph 2

Present text

2. **If a question does not comply with these guidelines**, the Secretariat shall provide **the author** with advice on how **the question may be drafted in order to be admissible**.

Amendment

2. **Upon request**, the Secretariat shall provide **authors** with advice on how **to comply in an individual case with the criteria laid down in paragraph 1**.

Wednesday 16 April 2014

Amendment 18**Parliament's Rules of Procedure****Annex III — paragraph 3***Present text*

3. If an identical or similar question has been put and answered during the preceding six months, or to the extent that a question merely seeks information on the follow-up to a specific resolution of Parliament of a kind which the Commission has already provided in a written follow-up communication, the Secretariat shall transmit a copy of the previous question and answer to the author. The renewed question shall not be forwarded to the addressee unless the **author invokes new significant developments or is seeking further information.**

Amendment

3. If an identical or similar question has been put and answered during the preceding six months, or to the extent that a question merely seeks information on the follow-up to a specific resolution of Parliament of a kind which the Commission has already provided in a written follow-up communication, the Secretariat shall transmit a copy of the previous question and answer to the author. The renewed question shall not be forwarded to the addressee unless the **President so decides in the light of significant new developments and in response to a reasoned request by the author.**

Amendment 19**Parliament's Rules of Procedure****Annex III — paragraph 4***Present text*

4. If a question seeks factual or statistical information that is already available to Parliament's **library, the latter shall inform the Member, who may withdraw the question.**

Amendment

4. If a question seeks factual or statistical information that is already available to Parliament's **research services, it shall not be forwarded to the addressee but to those services, unless the President decides otherwise upon request by the author.**

Amendment 20**Parliament's Rules of Procedure****Annex III — paragraph 5***Present text*

5. Questions concerning related matters may be answered together.

Amendment

5. Questions concerning related matters may be **merged into a single question by the Secretariat and** answered together.

Wednesday 16 April 2014

P7_TA(2014)0409

Amendment of Rule 90 of Parliament's Rules of Procedure on international agreements

European Parliament decision of 16 April 2014 on amendment of Rule 90 of Parliament's Rules of Procedure on international agreements (2013/2259(REG))

(2017/C 443/21)

The European Parliament,

- having regard to the letters of 29 January 2013 from the Chair of the Committee on Foreign Affairs and of 13 February 2013 from the Chair of the Committee on International Trade, to the Chair of the Committee on Constitutional Affairs,
 - having regard to Rules 211 and 212 of its Rules of Procedure,
 - having regard to the report of the Committee on Constitutional Affairs (A7-0253/2014),
1. Decides to amend its Rules of Procedure as shown below;
 2. Points out that the amendments will enter into force on the first day of the next part-session;
 3. Instructs its President to forward this decision to the Council and the Commission, for information.

Amendment 1

Parliament's Rules of Procedure

Rule 90 — paragraph 4

Present text

4. At any stage of the negotiations Parliament may, on the basis of a report from the committee responsible, and after considering any relevant proposal tabled pursuant to Rule 121, adopt recommendations and require them to be taken into account before the conclusion of **the international** agreement **under consideration**.

Amendment

4. At any stage of the negotiations **and from the end of the negotiations to the conclusion of the international agreement**, Parliament may, on the basis of a report from the committee responsible, and after considering any relevant proposal tabled pursuant to Rule 121, adopt recommendations and require them to be taken into account before the conclusion of **that** agreement.

Amendment 2

Parliament's Rules of Procedure

Rule 90 — paragraph 5

Present text

5. **When the negotiations are completed, but before any agreement is signed, the draft agreement shall be submitted to Parliament for its opinion or consent. In the case of the consent procedure Rule 81 shall apply.**

Amendment

5. **Requests by the Council for Parliament's consent or opinion shall be referred by the President to the committee responsible for consideration in accordance with Rule 81 or Rule 43(1).**

Wednesday 16 April 2014

Amendment 3**Parliament's Rules of Procedure****Rule 90 — paragraph 6***Present text*

6. Before the vote **on the consent** is taken, the committee responsible, a political group or at least one-tenth of the Members may propose that Parliament seek an opinion from the Court of Justice on the compatibility of an international agreement with the Treaties. If Parliament approves such a proposal, the vote **on the consent** shall be adjourned until the Court has delivered its opinion ⁽¹⁵⁾.

⁽¹⁵⁾ See also interpretation of Rule 128.

Amendment

6. Before the vote is taken, the committee responsible, a political group or at least one-tenth of the Members may propose that Parliament seek an opinion from the Court of Justice on the compatibility of an international agreement with the Treaties. If Parliament approves such a proposal, the vote shall be adjourned until the Court has delivered its opinion ⁽¹⁵⁾.

⁽¹⁵⁾ See also interpretation of Rule 128.

Wednesday 16 April 2014

P7_TA(2014)0410

Amendment of Parliament's Rules of Procedure so as to allow for the possibility of electronic signatures

European Parliament decision of 16 April 2014 on amendment of Parliament's Rules of Procedure so as to allow for the possibility of electronic signatures (2014/2011(REG))

(2017/C 443/22)

The European Parliament,

- having regard to the letter from the Chair of the Conference of Committee Chairs of 10 December 2013,
 - having regard to Rules 211 and 212 of its Rules of Procedure,
 - having regard to the report of the Committee on Constitutional Affairs (A7-0175/2014),
1. Decides to amend its Rules of Procedure as shown below;
 2. Points out that the amendments will enter into force on the first day of the next part-session;
 3. Instructs its President to forward this decision to the Council and the Commission, for information.

Amendment 1

Parliament's Rules of Procedure

Rule 148a (new)

Present text

Amendment

Rule 148a

Electronic handling of documents

Parliament documents may be prepared, signed and distributed in electronic form. The Bureau shall decide on the technical specifications and on the presentation of the electronic form.

Amendment 2

Parliament's Rules of Procedure

Rule 156 — paragraph 1 — interpretation appearing after subparagraph 2

Present text

Amendment

Amendments may be signed electronically as part of a pilot project involving a limited number of parliamentary committees, on condition, first, that the committees participating in the project have given their agreement and, second, that appropriate measures have been put in place to ensure the authenticity of the signatures.

deleted

Tuesday 15 April 2014

III

(Preparatory acts)

EUROPEAN PARLIAMENT

P7_TA(2014)0340

Non-objection to a delegated act: Fund for European Aid for the Most Deprived**European Parliament decision to raise no objections to Commission delegated regulation of 13 March 2014 supplementing Regulation (EU) No 223/2014 of 11 March 2014 of the European Parliament and of the Council on the Fund for European Aid to the Most Deprived (C(2014)1627 — 2014/2676(DEA))**

(2017/C 443/23)

The European Parliament,

- having regard to Commission Delegated Regulation C(2014)1627,
 - having regard to the Commission's letter of 13 March 2014 asking Parliament to declare that it will raise no objections to the delegated regulation,
 - having regard to the letter from the Committee on Employment and Social Affairs to the Chair of the Conference of Committee Chairs of 18 March 2014,
 - having regard to Article 290 of the Treaty on the Functioning of the European Union,
 - having regard to Regulation (EU) No 223/2014 ⁽¹⁾, and in particular to Articles 32(8), 32(9), 34(7), 34(8), 55(4) and 62(4) thereof,
 - having regard to Rule 87a(6) of its Rules of Procedure,
 - having regard to the fact that no objections have been raised within the period laid down in the third and fourth indents of Rule 87a(6) of its Rules of Procedure, which expired on 3 April 2014,
- A. whereas it has repeatedly stressed that it is essential for the Fund for European Aid to the Most Deprived to become operational without delay;
1. Declares that it has no objections to the delegated regulation;
 2. Instructs its President to forward this decision to the Council and the Commission.

⁽¹⁾ OJ L 72, 12.3.2014, p. 1.

Tuesday 15 April 2014

P7_TA(2014)0341

Resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Bank Resolution Fund *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Bank Resolution Fund and amending Regulation (EU) No 1093/2010 of the European Parliament and of the Council (COM(2013)0520 — C7-0223/2013 — 2013/0253(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/24)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0520),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0223/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Central Bank of 6 November 2013 ⁽¹⁾,
 - having regard to the opinion of the European Economic and Social Committee of 17 October 2013 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 27 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Legal Affairs and the Committee on Constitutional Affairs (A7-0478/2013),
1. Adopts its position at first reading hereinafter set out ⁽³⁾;
 2. Takes note of the Council statement annexed to this resolution;
 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ Not yet published in the Official Journal.

⁽²⁾ OJ C 67, 6.3.2014, p. 58.

⁽³⁾ This position replaces the amendments adopted on 6 February 2014 (Texts adopted P7_TA(2014)0095).

Tuesday 15 April 2014

P7_TC1-COD(2013)0253

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Bank Resolution Fund and amending Regulation (EU) No 1093/2010

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 806/2014.)

Tuesday 15 April 2014

ANNEX TO THE LEGISLATIVE RESOLUTION

Council Statement

The signatories to the Intergovernmental Agreement on the transfer and mutualisation of contributions to the Single Resolution Fund declare that they will strive to complete its process of ratification in accordance with their respective national legal requirements in due time so as to permit the Single Resolution Mechanism to be fully operational by 1 January 2016.

Tuesday 15 April 2014

P7_TA(2014)0343

Technical requirements for inland waterway vessels *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council laying down technical requirements for inland waterway vessels and repealing Directive 2006/87/EC of the European Parliament and of the Council (COM(2013)0622 — C7-0266/2013 — 2013/0302(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/25)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0622),
 - having regard to Article 294(2) and Article 91(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0266/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 21 January 2014 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 31 January 2014 ⁽²⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism (A7-0145/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0302

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council laying down technical requirements for inland waterway vessels and repealing Directive 2006/87/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91(1) thereof,

⁽¹⁾ OJ C 177, 11.6.2014, p. 58.

⁽²⁾ OJ C 126, 26.4.2014, p. 48.

Tuesday 15 April 2014

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) Directive 2006/87/EC of the European Parliament and of the Council ⁽⁴⁾ establishes harmonised conditions for issuing technical certificates for inland waterway vessels throughout the Union's inland waterway network.
- (2) The technical requirements for vessels navigating on the Rhine river are established by the Central Commission for Navigation on the Rhine (CCNR).
- (3) The technical requirements set out in the annexes to Directive 2006/87/EC for the most part incorporate the provisions laid down in the Rhine Vessels Inspection Regulations, in the version approved in 2004 by the CCNR. The conditions and technical requirements for issuing inland navigation certificates under Article 22 of the Revised Convention for Rhine Navigation are updated regularly and are recognised as reflecting current technological developments.
- (4) ~~Maintaining two different set of rules, those for legal frameworks and timeframes for the decision-making procedures, it is difficult to maintain the equivalence between the Union inland navigation certificates issued pursuant to Directive 2006/87/EC and the certificates issued pursuant to Article 22 of the Revised Convention on the Navigation on the Rhine and for the Union inland navigation certificate, does not ensure legal certainty and for Rhine Navigation. Legal certainty is therefore not ensured, and this has a potentially negative impact on navigation safety. [Am. 1]~~
Given the different set of rules, those for legal frameworks and timeframes for the decision-making procedures, it is difficult to maintain the equivalence between the Union inland navigation certificates issued pursuant to Directive 2006/87/EC and the certificates issued pursuant to Article 22 of the Revised Convention on the Navigation on the Rhine and for the Union inland navigation certificate, does not ensure legal certainty and for Rhine Navigation. Legal certainty is therefore not ensured, and this has a potentially negative impact on navigation safety. [Am. 1]
- (5) In order to achieve harmonisation at Union level and to prevent distortions of competition and varying levels of safety the same technical requirements for the whole of the Union's inland waterway network should be applied and updated regularly.
- (6) Since the CCNR has built up significant expertise in **developing and** updating technical requirements for inland navigation vessels, ~~this~~ **that** expertise should be fully used for the inland waterways in the Union. **The Commission's services and the CCNR signed an Administrative Arrangement in 2013 to reinforce their cooperation, particularly as regards the development of technical requirements concerning inland waterway vessels. Within that framework, it has been agreed that a Committee (the Committee for the Elaboration of European Technical Standards (CESTE)) is to be established to draw up technical standards in the field of inland navigation to which reference can be made by the Union and the CCNR in their respective regulations. [Am. 2]**
- (7) Union inland navigation certificates attesting that craft are fully compliant with the technical requirements should be valid on all Union inland waterways.
- (8) The conditions for the issuing of supplementary Union inland navigation certificates by Member States for operations on Zone 1 and 2 waterways (estuaries) and for operations on Zone 4 waterways should be harmonised more closely.

⁽¹⁾ OJ C 177, 11.6.2014, p. 58.

⁽²⁾ OJ C 126, 26.4.2014, p. 48

⁽³⁾ Position of the European Parliament of 15 April 2014.

⁽⁴⁾ Directive 2006/87/EC of the European Parliament and of the Council of 12 December 2006 laying down technical requirements for inland waterway vessels and repealing Council Directive 82/714/EEC (OJ L 389, 30.12.2006, p. 1).

Tuesday 15 April 2014

- (9) In the interests of safety, standards should be harmonised at a high level and in such a way that there is no reduction in safety standards on the Union inland waterways. However, Member States should be allowed, after consulting the Commission, to establish specific provisions concerning additional or reduced technical requirements for certain zones provided that such measures are limited to the specific subjects set out in Annexes III and IV.
- (10) Member States should have the possibility to derogate from the provisions of this Directive in certain cases related to navigable waterways not linked to the inland waterways of other Member States or to certain craft that operate exclusively on a national waterway.
- (11) Member States, after authorisation by the Commission, should also be allowed to derogate from the provisions of this Directive for specific crafts to accommodate alternative approaches, promote innovation or to prevent unreasonable costs.
- (12) The Union inland navigation certificate should be issued to a craft that passes a technical inspection carried out prior to the craft being put into service. This technical inspection should be used to check whether the craft complies with the technical requirements set out in this Directive. The competent authorities of the Member States ~~should~~ **will** be entitled to carry out additional inspections at any time to verify that the craft's physical state matches the Union inland navigation certificates. **[Am. 3]**
- (13) It is appropriate, within certain time limits and depending on the category of craft concerned, to determine the period of validity of Union inland navigation certificates in each specific case.
- (14) Detailed provisions concerning the replacement, renewal, extension of validity and issuance of new Union inland navigation certificates need to be established, within certain limits, in order to maintain a high degree of safety in inland navigation.
- (15) The measures set out in Directive 2009/100/EC of the European Parliament and of the Council ⁽¹⁾ need to remain in force for vessels not covered by this Directive.
- (16) A transitional regime should be applied in the case of craft in service not yet carrying a Union inland navigation certificate when they undergo a first technical inspection under the revised technical requirements established by this Directive.
- (17) Binding administrative instructions should be issued in order to provide detailed rules on the application of the technical requirements in a harmonised manner.
- (18) ~~Changes in~~ **In order to ensure a high level of safety and efficiency for inland navigation and to maintain the equivalence of the inland navigation certificates, the technical requirements need to be taken laid down in the annexes to this Directive should be kept up to date in order to take into account for reasons of safety of scientific and technical progress and technical standards in the field of inland navigation and equivalence of certificates.** In order to do so, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission ~~to adapt~~ **in respect of the adaptation of the annexes to this Directive in line with to scientific and technical progress or with to developments in this area and updates of technical standards** arising from the work of international organisations, in particular the CCNR. ~~It is particularly important that the~~ **The Commission carries should carry out, in an open and transparent manner, appropriate consultations with all relevant stakeholders** during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure ~~a simultaneous, timely and appropriate submission~~ **transmission** of the relevant documents to the European Parliament and to the Council. **[Am. 4]**

⁽¹⁾ Directive 2009/100/EC of the European Parliament and of the Council of 16 September 2009 on reciprocal recognition of navigability licences for inland waterway vessels (OJ L 259, 2.10.2009, p. 8).

Tuesday 15 April 2014

- (18a) ***The Commission should in particular adopt delegated acts to introduce technical requirements for vessels powered by liquefied natural gas (LNG), in order to allow efficient and safe circulation of those vessels in inland waterways. [Am. 5]***
- (19) In order to accommodate alternative approaches, to promote innovation, to prevent unreasonable costs, to provide for an efficient process for issuing certificates or to take account of regional circumstances, implementing powers should be conferred on the Commission as regards the authorisation of certain derogations to the technical requirements for specific craft, to approve classification societies and to approve additional or reduced technical requirements for vessels operating in certain zones which are not linked to the navigable inland waterways of another Member State. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (19a) ***In order to ensure an appropriate framework for coordination and cooperation with international organisations competent for inland waterway navigation, in particular the CCNR, and the development of uniform technical standards for inland navigation to which the Union and international organisations could refer, this Directive should be subject to review, particularly as regards the effectiveness of the measures introduced by it, as well as the mechanisms for cooperation with international organisations competent for inland navigation, with a view to achieving a single, uniform set of technical standards. [Am. 6]***
- (20) Directive 2006/87/EC should therefore be repealed,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Classification of waterways

For the purposes of this Directive, the inland waterways of the Union shall be classified as follows:

- (a) Zones 1, 2, 3 and 4:
- (i) Zones 1 and 2: the waterways listed in Chapter 1 of Annex I;
 - (ii) Zone 3: the waterways listed in Chapter 2 of Annex I;
 - (iii) Zone 4: the waterways listed in Chapter 3 of Annex I.
- (b) Zone R: those of the waterways referred to in point (a) for which certificates are to be issued in accordance with Article 22 of the Revised Convention for Rhine Navigation as that Article is worded when this Directive enters into force.

Article 2

Definitions and scope of application

1. For the purposes of this Directive, the following definitions shall apply:
- (a) 'craft': means a vessel or item of floating equipment;
 - (b) 'vessel': means an inland waterway vessel or sea-going ship;
 - (c) 'tug': means a vessel specially built to perform towing operations;
 - (d) 'pusher': means a vessel specially built to propel a pushed convoy;
 - (e) 'passenger vessel': means a day trip or cabin vessel constructed and equipped to carry more than 12 passengers;

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Tuesday 15 April 2014

- (f) 'floating equipment': means a floating installation carrying working gear such as cranes, dredging equipment, pile drivers or elevators;
- (g) 'recreational craft': means a vessel other than a passenger vessel, intended for sport or pleasure;
- (h) 'water displacement': means the immersed volume of the vessel, in m³;
- (i) 'length (L)': means the maximum length of the hull in m, excluding rudder and bowsprit;
- (j) 'breadth (B)': means the maximum breadth of the hull in m, measured to the outer edge of the shell plating (excluding paddle wheels, rub rails, and similar);
- (k) 'draught (T)': means the vertical distance in m between the lowest point of the hull without taking into account the keel or other fixed attachments and the maximum draught line;
- (l) 'Classification society': means a classification society that has been approved in accordance with the criteria and procedures referred to in Article 9;
- (m) 'Union inland navigation certificate': means a certificate issued to an inland waterway vessel by the competent authority, signifying compliance with the technical requirements of this Directive.

2. This Directive shall apply to the following craft:

- (a) vessels having a length (L) of 20 metres or more;
- (b) vessels for which the product of length (L), breadth (B) and draught (T) is a volume of 100 m³ or more.

3. This Directive shall also apply to the following craft:

- (a) tugs and pushers intended for towing or pushing craft referred to in paragraph 1 or floating equipment or for moving such craft or floating equipment alongside;
- (b) vessels intended for passenger transport which carry more than 12 passengers in addition to the crew;
- (c) floating equipment.

4. This Directive shall not apply to the following craft:

- (a) ferries;
- (b) naval vessels;
- (c) sea-going vessels, including sea-going tugs and pusher craft, which:
 - (i) operate or are based on tidal waters;
 - (ii) operate temporarily on inland waterways, provided that they carry:
 - a certificate proving conformity with the 1974 International Convention for the Safety of Life at Sea (SOLAS), or equivalent, a certificate proving conformity with the 1966 International Convention on Load Lines, or equivalent, and an international oil pollution prevention (IOPP) certificate proving conformity with the 1973 International Convention for the Prevention of Pollution from Ships (MARPOL); or
 - in the case of passenger vessels not covered by all of the Conventions referred to in the first indent, a certificate on safety rules and standards for passenger ships issued in conformity with Directive 2009/45/EC of the European Parliament and of the Council⁽¹⁾; or
 - in the case of recreational craft not covered by all of the Conventions referred to in the first indent, a certificate of the country of which it carries the flag.

⁽¹⁾ Directive 2009/45/EC of the European Parliament and of the Council of 6 May 2009 on safety rules and standards for passenger ships (OJ L 163, 25.6.2009, p. 1.)

Tuesday 15 April 2014

Article 3

Obligation to carry a certificate

1. Craft operating on the Union inland waterways referred to in Article 1 shall carry:
 - (a) when operating on a Zone R waterway:
 - either a certificate issued pursuant to Article 22 of the Revised Convention for Rhine Navigation; or
 - a Union inland navigation certificate attesting full compliance of the craft, without prejudice to the transitional provisions of Annex II, with technical requirements as referred to in Annex II for which equivalency with the technical requirements laid down in application of the Revised Convention for Rhine Navigation has been established according to the applicable rules and procedures;
 - (b) when operating on other waterways, a Union inland navigation certificate, including, where applicable, the specifications referred to in Article 5.
2. The Union inland navigation certificate shall be drawn up following the model set out in Part I of Annex V and shall be issued in accordance with this Directive. The Commission shall be empowered to adopt delegated acts in accordance with Article 24 to amend that model if this becomes necessary in order to take account of scientific and technical progress, to streamline administrative requirements or to take account of developments in this area arising from the work of international organisations, in particular that of the CCNR.

Article 4

Supplementary Union inland navigation certificates

1. All craft carrying a valid certificate issued pursuant to Article 22 of the Revised Convention for Rhine Navigation may, subject to the provisions of Article 5(5) of this Directive, navigate on Union waterways carrying that certificate only.
2. However, all craft carrying the certificate referred to in paragraph 1 shall also be provided with a supplementary Union inland navigation certificate:
 - (a) when operating on Zone 3 and 4 waterways, if they wish to take advantage of the reduction in technical requirements on those waterways;
 - (b) when operating on Zone 1 and 2 waterways, or, in respect of passenger vessels, when operating on Zone 3 waterways that are not linked to the navigable inland waterways of another Member State, if the Member State concerned has adopted additional technical requirements for those waterways, in accordance with Article 5(1), (2) and (3).
3. The supplementary Union inland navigation certificate shall be drawn up following the model set out in Part II of Annex V and shall be issued by the competent authorities on production of the certificate referred to in paragraph 1 and under the conditions laid down by the authorities competent for the waterways concerned. The Commission shall be empowered to adopt delegated acts to amend that model if this becomes necessary in order to take account of scientific and technical progress, to streamline administrative requirements or to take account of developments in this area arising from the work of international organisations, in particular that of the CCNR.

Article 5

Additional or reduced technical requirements for certain zones

1. Member States may, after consulting the Commission, and where applicable subject to the requirements of the Revised Convention for Rhine Navigation, adopt technical requirements additional to those in Annex II for craft operating on Zone 1 and 2 waterways within their territory.
2. In respect of passenger vessels operating on Zone 3 waterways within its territory that are not linked to the navigable inland waterways of another Member State, each Member State may maintain technical requirements additional to those in Annex II. Member States may adopt such new additional technical requirements following the procedure referred to in paragraph 3. The additional requirements may cover only the elements listed in Annex III.

Tuesday 15 April 2014

3. The Member State shall notify the Commission of the proposed additional requirements at least six months before their envisaged date of entry into force and shall inform the other Member States.

The Commission shall approve the additional technical requirements by way of implementing acts adopted in accordance with the advisory procedure referred to in Article 25(2).

4. Compliance with the additional requirements shall be specified in the Union inland navigation certificate referred to in Article 3 or, where Article 4(2) applies, in the supplementary Union inland navigation certificate. Such proof of compliance shall be recognised on Union waterways of the corresponding zone.

5. Where application of the transitional provisions set out in chapter 24a of Annex II would result in a reduction in existing national safety standards, a Member State may disapply those transitional provisions in respect of inland waterway passenger vessels operating on its inland waterways that are not linked to the navigable inland waterways of another Member State. In such circumstances, the Member State may require that such vessels operating on its non-linked inland waterways comply fully with the technical requirements set out in Annex II starting from 30 December 2008.

A Member State using the possibility referred to in the first subparagraph shall inform the Commission and the other Member States of its decision and provide the Commission with details of the relevant national standards applying to passenger vessels operating on its inland waterways.

Compliance with the requirements of a Member State for operating on its non-linked inland waterways shall be specified in the Union inland navigation certificate referred to in Article 3 or, where Article 4(2) applies, in the supplementary Union inland navigation certificate.

6. Craft operating only on Zone 4 waterways shall qualify for the reduced requirements set out in Annex II on all waterways in that zone. Compliance with those reduced requirements shall be specified in the Union inland navigation certificate referred to in Article 3.

7. Member States may, after consulting the Commission, allow a partial application of the technical requirements or set technical requirements which are less stringent than those of Annex II for craft operating exclusively on Zone 3 and 4 waterways within their territory.

The less stringent or partial application of technical requirements may cover only the elements listed in Annex IV. Where the technical characteristics of a craft correspond to the less stringent or partial application of technical requirements, this shall be specified in the Union inland navigation certificate or, where Article 4(2) applies, in the supplementary Union inland navigation certificate.

The Member States shall notify the Commission of the less stringent or partial application of the technical requirements of Annex II at least six months before they come into force and shall inform the other Member States.

Article 6

Derogations

1. Member States may authorise derogations from all or part of this Directive for:

- (a) vessels, tugs, pushers and floating equipment operating on navigable waterways not linked by inland waterway to the waterways of other Member States;
- (b) craft having a dead weight not exceeding 350 tonnes or craft not intended for the carriage of goods and having a water displacement of less than 100 m³, which were laid down before 1 January 1950 and operate exclusively on a national waterway.

Tuesday 15 April 2014

2. Member States may authorise, in respect of navigation on their national waterways, derogations from one or more provisions of this Directive for limited journeys of local interest or in harbour areas. The derogations and the journeys or area for which they are valid shall be specified in the craft's certificate.
3. The Member States shall notify to the Commission the derogations authorised in accordance with paragraphs 1 and 2 and shall inform the other Member States thereof.
4. Any Member State which, as a result of derogations authorised in accordance with paragraphs 1 and 2, has no craft subject to the provisions of this Directive operating on its waterways, shall not be required to comply with Articles 8, 9 and 11.

Article 7

Issuance of Union inland navigation certificates

1. The Union inland navigation certificate shall be issued to craft laid down as from [date of transposition of this Directive] following a technical inspection carried out prior to the craft being put into service and intended to check whether the craft complies with the technical requirements of Annex II.
2. The Union inland navigation certificate shall be issued to craft excluded from the scope of Council Directive 82/714/EEC ⁽¹⁾, but covered by this Directive in accordance with Article 2(2) and (3), following a technical inspection which shall be carried out upon expiry of the craft's current certificate, but in any case no later than 30 December 2018, to check whether the craft complies with the technical requirements of Annex II.

Any failure to meet the technical requirements of Annex II shall be specified in the Union inland navigation certificate. Provided that the competent authorities consider that these shortcomings do not constitute a manifest danger, the craft referred to in the first subparagraph of this Article may continue to operate until such time as those components or areas of the craft which have been certified as not meeting those requirements are replaced or altered, whereafter those components or areas shall meet the technical requirements of Annex II.

3. Manifest danger within the meaning of this Article shall be presumed in particular when requirements concerning the structural soundness of the shipbuilding, the navigation or manoeuvrability or special features of the craft in accordance with the technical requirements referred to Annex II are affected. Derogations as allowed for in the technical requirements of Annex II shall not be identified as shortcomings which constitute a manifest danger.

The replacement of existing parts with identical parts or parts of an equivalent technology and design during routine repairs and maintenance shall not be considered as a replacement within the meaning of this Article.

4. Compliance of a craft with the additional requirements referred to in Article 5(1), (2) and (3) shall, where appropriate, be checked during the technical inspections provided for in paragraphs 1 and 2 of this Article, or during a technical inspection carried out at the request of the craft's owner.

Article 8

Competent authorities

1. Union inland navigation certificates ~~may~~ **shall** be issued by the competent authorities of the Member States. [**Am. 7**]
2. Each Member State shall draw up a list indicating the competent authorities for issuing the Union inland navigation certificates and shall notify the Commission and the other Member States thereof.

⁽¹⁾ Council Directive 82/714/EEC of 4 October 1982 laying down technical requirements for inland waterway vessels (OJ L 301, 28.10.1982, p. 1), (Directive repealed by Directive 2006/87/EC).

Tuesday 15 April 2014

3. Competent authorities shall keep a register of all Union inland navigation certificates they issue in accordance with the model set out in Annex VI. The Commission shall be empowered to adopt delegated acts in accordance with Article 24 to amend that model in order to take account of scientific and technical progress, to streamline administrative requirements or to take account of developments in this area arising from the work of other international organisations, in particular that of the CCNR.

Article 9

Carrying out of technical inspections

1. The technical inspection referred to in Article 7 shall be carried out by the competent authorities. Those authorities may refrain from subjecting the craft in whole or in part to technical inspection where it is evident from a valid attestation, issued by a recognised classification society, that the craft satisfies in whole or in part the technical requirements of Annex II.

2. The Commission shall adopt implementing acts in order to approve a classification society which meets the criteria listed in Annex VII, or to withdraw approval, in accordance with the procedure provided in paragraphs 3 and 4. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 25(2).

3. An application for approval shall be submitted to the Commission by the Member State in which the classification society has its headquarters or a subsidiary authorised to issue attestations that craft satisfies the requirements of Annex II in accordance with this Directive. This application shall be accompanied with all information and documentation needed to check that the criteria for approval are met.

Any Member State can demand that a hearing takes place or that further information or documentation has to be provided.

4. Any Member State can submit to the Commission a request to withdraw the approval if it considers that a classification society no longer meets the criteria provided in Annex VII. The request for withdrawal shall be accompanied with documentary evidence.

5. Until their approval under this Directive, classification societies which are recognised and approved and authorised by a Member State in accordance with Council Directive 94/57/EC⁽¹⁾ shall be considered approved only in respect of vessels which operate exclusively on waterways of that Member State.

6. The Commission shall publish *for the first time by ...* (*), and keep updated, a list of the classification societies approved in accordance with the present Article. [**Am. 8**]

7. Each Member State shall draw up a list indicating its competent authorities for carrying out technical inspections and shall notify the Commission and the other Member States thereof.

8. Each Member State shall comply with the specific requirements as regards inspection bodies and the request for an inspection provided in Annex II.

Article 10

Validity of Union inland navigation certificates

1. The validity period of Union inland navigation certificates issued to newly built vessels in accordance with the provisions of this Directive shall be determined by the competent authority up to a maximum of:

- (a) five years in the case of passenger vessels;
- (b) 10 years in the case of all other craft.

The period of validity shall be entered on the Union inland navigation certificate.

⁽¹⁾ Council Directive 94/57/EC of 22 November 1994 on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations (OJ L 319, 12.12.1994, p. 20).

(*). **One year after the date of entry into force of this Directive.**

Tuesday 15 April 2014

2. In the case of vessels already in operation before the technical inspection, the competent authority shall set the period of validity of the Union inland navigation certificate on a case- by-case basis, in the light of the results of the inspection. However, the validity may not exceed the periods specified in paragraph 1.

3. Each Member State may, in the cases specified in Annex II, issue provisional Union inland navigation certificates. Provisional Union inland navigation certificates shall be drawn up following the model set out in Part III of Annex V. The Commission shall be empowered to adopt delegated acts in accordance with Article 24 to amend that model in order to take account of scientific and technical progress, to streamline administrative requirements or to take account of developments in this area arising from the work of other international organisations, in particular that of the CCNR.

Article 11

Replacement of Union inland navigation certificates

Each Member State shall lay down the conditions under which a valid Union inland navigation certificate which has been lost or damaged may be replaced.

Article 12

Renewal of Union inland navigation certificates

1. The Union inland navigation certificate shall be renewed on expiry of its period of validity in accordance with the conditions laid down in Article 7.

2. For the renewal of Union inland navigation certificates, the transitional provisions provided in chapters 24 and 24a of Annex II shall apply to the craft and under the conditions specified therein.

Article 13

Extension of validity of Union inland navigation certificates

The validity of a Union inland navigation certificate may be exceptionally extended without a technical inspection in accordance with Annex II by the authority which issued or renewed it. The extension shall be indicated on the certificate.

Article 14

Issuance of new Union inland navigation certificates

In the event of major alterations or repairs which affect the structural soundness of the ship, the navigation or manoeuvrability or special features of the craft in accordance with Annex II, that craft shall again undergo, prior to any further voyage, the technical inspection provided for in Article 7. Following this inspection, a new Union inland navigation certificate stating the technical characteristics of the craft shall be issued or the existing certificate shall be amended accordingly. If the certificate is issued in a Member State other than that which issued or renewed the initial certificate, the competent authority which issued or renewed the certificate shall be informed accordingly within one month.

Article 15

Refusal to issue or renew, and withdrawal of, Union inland navigation certificates

1. Any decision refusing to issue or renew a Union inland navigation certificate shall be motivated. The owner of the craft shall be notified and shall be informed about the appeal procedure and its time limits in the Member State concerned.

2. Any valid Union inland navigation certificate may be withdrawn by the competent authority which issued or renewed it if the craft ceases to comply with the technical requirements specified in its certificate.

Tuesday 15 April 2014

Article 16

Additional inspections

1. The competent authorities of a Member State may check at any time whether a craft is carrying a certificate valid under the terms of this Directive and satisfies the requirements set out in such certificate or constitutes a manifest danger for the persons on board, the environment or the safety of the navigation. The competent authorities shall take the necessary measures in accordance with paragraphs 2 to 5.

2. If the authorities find upon such inspection that the certificate is not being carried or that the certificate carried on the craft is invalid, or that the craft does not satisfy the requirements set out in the certificate, but that such invalidity or failure to satisfy the requirements does not constitute a manifest danger, the owner of the craft or his representative shall take all necessary measures to remedy the situation. The authority which issued the certificate or which last renewed it shall be informed within seven days.

3. If, upon making the inspection, the authorities find that the craft constitutes a manifest danger for the persons on board, the environment or the safety of the navigation, they may prevent the craft from proceeding with its voyage until the necessary steps have been taken to remedy the situation.

They may also prescribe measures which will enable the craft to proceed safely, where appropriate on termination of its transport operations, to a place where it will be either inspected or repaired. The authority which issued or last renewed the certificate shall be informed within seven days.

4. A Member State which has prevented a craft from proceeding with its voyage, or has notified the owner of its intention to do so if the defects found are not corrected, shall inform the authority in the Member State which issued or last renewed the certificate, within seven days, of the decision which it has taken or intends to take.

5. Any decision to interrupt the passage of a craft taken in the implementation of this Directive shall state in detail the reasons on which it is based. It shall be notified without delay to the party concerned, who shall at the same time be informed of the appeal procedures available to him under the laws in force in the Member States and of their time limits.

Article 17

Unique European Vessel Identification Number

The competent authority having issued a Union inland navigation certificate shall include in the Union inland navigation certificate the Unique European Vessel Identification Number in accordance with Chapter 2 of Annex II.

Article 18

Equivalences and derogations

1. Member States may require the Commission to adopt implementing acts allowing derogations or recognising the equivalence of technical specifications for a specific craft regarding:

- (a) the use, or presence, on board of a craft of other materials, installations or items of equipment, or the adoption of other design aspects or other arrangements than those included in Annex II;
- (b) the issuance of a Union inland navigation certificate for trial purposes for a limited period incorporating new technical specifications that derogate from the requirements of Part II of Annex II provided those specifications offer equivalent safety;
- (c) the application, by the inspection bodies, of derogations, on a passenger vessel, regarding the areas provided for use by persons with reduced mobility, where the application of the specific requirements laid down in chapter 15 of Annex II is considered difficult in practice or incurs unreasonable costs;
- (d) the use of other extinguishing agents than those referred to in chapter 10 of Annex II;
- (e) the use of permanently installed firefighting systems for protecting objects;
- (f) the application of chapter 24 of Annex II to a craft converted to a length of more than 110 m;

Tuesday 15 April 2014

- (g) derogations from the requirements laid down in chapter 24 and chapter 24a of Annex II following the expiry of the transitional provisions, where those requirements are technically difficult to apply or where their application might require disproportionate costs;
- (h) the recognition of standards concerning systems spraying smaller quantities of water other than those referred to in chapter 10 of Annex II.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 25(2).

2. The equivalences and derogations referred to in points (a) to (g) of paragraph 1 shall be entered in the Union inland navigation certificate by the competent authorities of the Member States. The Commission and the other Member States shall be informed.

3. Pending the adoption of the implementing acts referred to in point (a) of paragraph 1, the competent authorities may issue a provisional Union inland navigation certificate in accordance with Article 10(2).

In that case, the competent authorities shall within one month of the issuance of the provisional Union inland navigation certificate report to the Commission and the other Member States the name and the European Vessel Identification Number of the craft, the nature of the derogation and the State in which the craft is registered or has its home port.

4. The Commission shall publish a register of radar navigation equipment and rate-of-turn indicators approved in accordance with Annex II.

Article 19

Recognition of navigability certificates of craft from third countries

The Union shall enter into negotiations with third countries in order to ensure the mutual recognition of navigability certificates between the Union and third countries.

Pending the conclusion of such agreements, the competent authorities of a Member State may recognise the navigability certificates of craft from third countries for navigation on the waterways of that Member State.

The issuance of Union inland navigation certificates to craft from third countries shall be carried out in accordance with Article 7(1).

Article 20

Continued applicability of Directive 2009/100/EC

For those craft falling outside the scope of Article 2(2) and (3) of this Directive, but falling within the scope of Article 1(a) of Directive 2009/100/EC, the provisions of that Directive shall apply.

Article 21

Transitional provisions concerning the use of documents

Documents falling within the scope of this Directive and issued by the competent authorities of the Member States under Directive 2006/87/EC before the entry into force of this Directive remain valid until they expire.

Article 22

Adaptation of the Annexes

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 24 concerning the adaptations of Annexes I, II, III, IV and VII to scientific and technical progress or to developments in this area arising from the work of international organisations, in particular that of the CCNR to ensure that the two certificates referred to in Article 3(1)(a) are issued on the basis of technical requirements which guarantee an equivalent level of safety, or to take account of the cases referred to in Article 5.

The Commission shall, by 31 December 2017, adopt delegated acts in accordance with Article 24 concerning the introduction, within Chapter 19ba of Annex II, of specific requirements for vessels powered by liquefied natural gas (LNG). [Am. 9]

Tuesday 15 April 2014

The Commission shall be empowered to adopt delegated acts in accordance with Article 24 concerning binding administrative instructions as regards the detailed application of the technical requirements provided in Annex II, in order to ensure a harmonised interpretation of those requirements or take into account best practices developed at Union level or derived from the work of international organisations, in particular that of the CCNR.

When adopting such delegated acts the Commission shall ensure that the technical requirements that have to be fulfilled for the issuance of the Union inland navigation certificate recognised for navigation on the Rhine comply with a level of safety equivalent to that required for the issuing of the certificate referred to in Article 22 of the Revised Convention for Rhine Navigation.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 24 in order to update the references in this Directive to certain provisions of Annex II with a view to taking into account the amendments brought to this Annex.

Article 23

Temporary requirements

The Commission shall be empowered to adopt delegated acts in accordance with Article 24 in order to provide for temporary technical requirements for crafts to allow tests in order to incentivise innovation and technical progress. Such requirements shall be valid for a maximum period of three years.

Article 24

Delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The ~~delegation of power~~ **to adopt delegated acts** referred to in Articles 3, 4, 8, 10, 22 and 23 ~~is~~ **shall be** conferred on the Commission for ~~an indeterminate~~ **a period of time five years** from [date of entry into force of the Directive] ... (*). **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period. [Am. 10]**

3. ~~The European Parliament or the Council may revoke~~ The delegation of power referred to in Articles 3, 4, 8, 10, 22 and 23 **may be revoked** at any time **by the European Parliament or by the Council**. A ~~revocation decision of revocation to revoke~~ shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified ~~in the decision~~ **therein**. It shall not affect the validity of any delegated acts already in force. **[Am. 11. Not concerning all languages]**

4. As soon as it adopts a delegated act, the Commission shall simultaneously notify it to the European Parliament and to the Council.

5. A delegated act adopted ~~under~~ **pursuant to** Articles 3, 4, 8, 10, 22 and 23 shall enter into force only if ~~neither~~ **no objection has been expressed either by** the European Parliament ~~nor~~ **or** the Council ~~objects~~ within ~~2~~ **a period of two** months of ~~the Commission notifying them of the act~~ **notification of that act** to the European Parliament ~~or~~ **and the Council or if, before the expiry of that period, the European Parliament and** the Council ~~may extend this~~ **have both informed the Commission that they will not object. That period by 2 shall be extended by two** months **at the initiative of the European Parliament or of the Council. [Am. 12]**

(*) *Date of entry into force of this Directive.*

Tuesday 15 April 2014

Article 25

Committee procedure

1. The Commission shall be assisted by the Committee established by Article 7 of Council Directive 91/672/EEC⁽¹⁾ (hereinafter referred to as 'the Committee'). That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply. If the Committee's opinion is to be obtained by written procedure, its chair may decide to terminate the procedure without result within the time-limit for delivery of the opinion.

Article 26

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take the measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

Article 26a

Review

The Commission shall submit, before ... (*) and every three years thereafter, a report to the European Parliament and to the Council reviewing the effectiveness of the measures introduced by this Directive, particularly as regards the harmonisation of technical requirements and the development of technical standards for inland navigation. The report shall also review the mechanisms for cooperation with international organisations competent for inland navigation. The report shall, if appropriate, be accompanied by a legislative proposal to further streamline cooperation and coordination in establishing standards to which reference can be made in legal acts of the Union. [Am. 13]

Article 27

Transposition

1. Member States with inland waterways referred to in Article 1 shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive with effect from 1 January 2015. They shall forthwith inform the Commission thereof.

When Member States adopt such provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the national law provisions that they adopt in the field covered by this Directive.

Article 28

Repeal

Directive 2006/87/EC is repealed with effect from 1 January 2015.

References to the repealed Directive shall be construed as references to this Directive.

Article 29

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ Council Directive 91/672/EEC of 16 December 1991 on the reciprocal recognition of national boatmasters' certificates for the carriage of goods and passengers by inland waterway (OJ L 373, 31.12.1991, p. 29).

^(*) ***Three years after the date of entry into force of this Directive.***

Tuesday 15 April 2014

Article 30

Addressees

This Directive is addressed to the Member States that have the inland waterways referred to in Article 1.

Done at

*For the European Parliament**The President**For the Council**The President*

Tuesday 15 April 2014

LIST OF ANNEXES

Annex I List of Union inland waterways divided geographically into Zones 1, 2, 3 and 4

In Annex II, the following Chapter is inserted:

‘CHAPTER 19ba

SPECIFIC REQUIREMENTS APPLICABLE TO VESSELS POWERED BY LIQUEFIED NATURAL GAS (LNG) (left void)’ [Am. 14]

Annex II Minimum technical requirements applicable to craft on inland waterways of Zones 1, 2, 3 and 4

Annex III Subjects for possible additional technical requirements applicable to craft on inland waterways of Zones 1 and 2

Annex IV Subjects for possible reductions of the technical requirements applicable to craft on inland waterways of Zones 3 and 4

Annex V Model for Union inland navigation certificate

Annex VI Model for register of Union inland navigation certificates

Annex VII Classification societies

The annexes are not reproduced in full in this consolidated text. Please consult the Commission proposal COM(2013)0622, Parts 2 and 3.

Tuesday 15 April 2014

P7_TA(2014)0344

Correct application of the law on customs and agricultural matters *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters (COM(2013)0796 — C7-0421/2013 — 2013/0410(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/26)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0796),
 - having regard to Article 294(2) and Articles 33 and 325 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0421/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the Court of Auditors of 25 February 2014 ⁽¹⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection (A7-0241/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0410

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EC) No 515/97 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 33 and 325 thereof,

Having regard to the proposal from the European Commission,

⁽¹⁾ OJ C 94, 31.3.2014, p. 1.

Tuesday 15 April 2014

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the Court of Auditors ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) In order to ensure that Council Regulation (EC) No 515/97 ⁽³⁾ covers all possible movements of goods in relation to the customs territory of the Union, it is appropriate to clarify the definition of customs legislation with regard to the concepts of entry and exit of goods.
- (2) With a view to further enhancing administrative and criminal procedures for dealing with irregularities, it is necessary to ensure that evidence obtained through mutual assistance can be considered as admissible in proceedings before the administrative and judicial authorities of the Member State of the applicant authority.
- (3) The Commission Communication of 8 January 2013 on Customs Risk Management and Security of the Supply Chain recognises an urgent need to improve the quality and availability of data for use in pre-arrival risk analysis, in particular for the effective identification and mitigation of safety and security risks at national and Union levels, within the Common Risk Management Framework established under Article 13(2) of Council Regulation (EEC) No 2913/92 ⁽⁴⁾. The integration of data on container movements in pre-arrival risk management will greatly improve supply chain visibility and will significantly enhance the capacity of the Union and the Member States to target higher-risk consignments for controls, while facilitating the flow of legitimate trade.
- (4) With a view to increasing clarity, consistency, **effectiveness, coherence** and transparency, it is necessary to define in more concrete terms the authorities which should have access to the directories established on the basis of Regulation (EC) No 515/97; for that purpose a uniform reference to competent authorities will be established. **[Am. 1]**
- (5) Data concerning container movements make it possible to identify fraud and risk trends with regard to goods that are moved in and out of the customs territory of the Union. Such data serve to assist in preventing, investigating and prosecuting operations which are or appear to constitute breaches of customs legislation, and to assist the competent authorities in managing customs risks defined in point 25 of Article 4 of Regulation (EEC) No 2913/92. In order to collect and use a set of data as complete as possible, while avoiding potential negative impacts on small and medium-sized enterprises in the freight forwarding sector, it is necessary that public or private sector providers active in the international supply chain submit to the Commission data concerning container movements in so far as they collect such data in electronic formats via their equipment tracking systems or have access to such data.
- (5a) ***The information obtained from the Commission's impact assessment of 25 November 2013 on the amendment of Regulation (EC) No 515/97 in relation to the scale of the problem shows that fraud resulting from false declaration of origin alone may amount to a yearly loss of as much as EUR 100 million for the EU27. In 2011, Member States reported 1 905 cases of detected fraud and other irregularities relating to misdescription of goods amounting to damage of EUR 107,7 million. That figure covers only damage detected by the Member States and the Commission. The actual scale of the problem is substantially higher, since no information is available on an estimated 30 000 cases of potential fraud.*** **[Am. 2]**
- (5b) ***In order to ensure a high level of consumer protection, the Union has a duty to combat customs fraud and thus contribute to the internal market's objective of having safe products with genuine certificates of origin.*** **[Am. 3]**

⁽¹⁾ OJ C 94, 31.3.2014, p. 1.

⁽²⁾ Position of the European Parliament of 15 April 2014.

⁽³⁾ Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters (OJ L 82, 22.3.1997, p. 1).

⁽⁴⁾ Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

Tuesday 15 April 2014

- (6) **Given the increase in the scale of customs fraud, it is crucial to increase detection and prevention simultaneously at national and Union level.** The detection of fraud, identification of risk trends and the implementation of effective risk management procedures depend significantly on the identification and cross-analysis of relevant operational data sets. It is necessary therefore to establish, at European Union level, a directory containing data on import, export and transit of goods including transit of goods within the Member States and direct export. For that purpose, Member States should allow systematic replication of data on import ~~export~~ and transit of goods from the systems operated by the Commission and should supply to the Commission data relating to transit of goods within a Member State ~~and direct export~~ **at the earliest possible date. Each year, the Commission should submit the results obtained from that directory to the European Parliament and to the Council. By ... (*)**, the Commission should carry out assessments in order to appraise the feasibility of extending the data contained in the directory by including data on import and transit of goods by land and air and the necessity of extending the data contained in the directory by including data on export. [Am. 4]
- (7) For the implementation of Article 18b of Regulation (EC) No 515/97, the Commission has created a number of technical systems enabling the provision of technical assistance, training or communication activity and other operational activity to the Member States. Those technical systems need to be explicitly referred to in that Regulation and covered by data protection requirements.
- (8) The introduction of in 2011 of e-Customs, by which documents supporting imports and exports are no longer kept by the customs administrations but by the economic operators, has led to delays in the conduct of European Anti-fraud Office (OLAF) investigations in the customs area, as OLAF needs the intermediation of these administrations to obtain such documents. Moreover, the three-year limitation period applicable to customs documents held by the administration, puts additional constraints to the successful conduct of investigations. In order to accelerate the conduct of investigations in the area of customs the Commission should therefore, **in certain circumstances and following prior notification to the Member States**, have the right to request documents supporting import and export declarations directly from the economic operators concerned. **The economic operators concerned should be informed which type of procedure applies.** Those economic operators should be obliged to provide the Commission with the requested documents **in good time, following advance notification by the Commission to the Member States.** [Am. 5]
- (9) In order to ensure confidentiality **and greater security** of the inserted data, provision should be made for limiting access to inserted data to specific users **and for defined purposes** only. [Am. 6]
- (10) In order to ensure up-to-date information and to secure the transparency and information right of data subjects as enshrined in Regulation (EC) No 45/2001 of the European Parliament and of the Council ⁽¹⁾ and Directive 95/46/EC of the European Parliament and of the Council ⁽²⁾, the possibility of publishing on the internet updates of the lists of competent authorities designated by the Member States and the Commission departments to have access to the Customs Information System (CIS) should be introduced.
- (11) Regulation (EC) No 45/2001 applies to the processing of personal data by Union institutions, bodies, offices and agencies.
- (12) In order to improve consistency of data protection supervision, the European Data Protection Supervisor needs to cooperate closely with the Joint Supervisory Authority established under Council Decision 2009/917/JHA ⁽³⁾, with a view to achieving coordination of the audits of the CIS.

(*) **Two years after the entry into force of this Regulation.**

⁽¹⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

⁽²⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽³⁾ Council Decision 2009/917/JHA of 30 November 2009 on the use of information technology for customs purposes (OJ L 323, 10.12.2009, p. 20).

Tuesday 15 April 2014

- (13) The provisions governing the storage of data in the CIS frequently result in unjustifiable loss of information; this is because Member States do not systematically carry out the yearly reviews due to the administrative burden involved **and the lack of appropriate resources, particularly human resources**. It is therefore necessary to simplify the procedure governing the ~~storage~~ **retention** of data in the CIS by removing the obligation to review data annually and by setting a maximum retention period of 10 years, corresponding to periods provided for the directories established on the basis of this Regulation. **However, this should not apply to the limitation period, as laid down in Article 221 (3) of Regulation (EEC) No 2913/92. The retention** period is necessary due to the long procedures for processing irregularities and because these data are needed for the conduct of joint customs operations and of investigations. Furthermore, to safeguard the rules governing data protection, the European Data Protection Supervisor should be informed about cases where personal data are stored in CIS for a period exceeding five years. [Am. 7]
- (14) In order to further enhance the possibilities for analysis of fraud and facilitate the conduct of investigations, data concerning current investigation files stored in the Files Identification Database (FIDE) should be rendered anonymous, after one year since the last observation, and retained in a form in which identification of the data subject is no longer possible.
- (15) Since the objectives of enhancing customs risk management as defined in points 25 and 26 of Article 4 and Article 13(2) of Regulation (EEC) No 2913/92 laying down the Community Customs Code, and of improving detection, investigation and prevention of customs-related fraud in the Union, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve those objectives.
- (16) Public or private service providers active in the international supply chain who, at the time of the entry into force of this Regulation, are bound by private contract obligations as regards the supply of data on container movements, should be entitled to benefit from a deferred application of Article 18c in order to renegotiate their contracts and ensure that future contracts are compatible with the obligation to provide data to the Commission.
- (17) Regulation (EC) No 515/97 confers powers on the Commission to implement some of the provisions of that Regulation; as a consequence of the entry into force of the Treaty of Lisbon, the powers conferred on the Commission under that Regulation need to be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).
- (18) In order to supplement certain non-essential elements of Regulation (EC) No 515/97 and in particular to create a streamlined and structured directory of CSMs, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the events for which CSMs should be reported, the minimum data elements to be reported in CSMs and the frequency of reporting.
- (19) In order to supplement certain non-essential elements of Regulation (EC) No 515/97 and in particular to specify the information to be inserted into the CIS, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of determining the operations concerning the application of agricultural legislation for which information has to be introduced into the central database of the CIS.
- (20) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Tuesday 15 April 2014

- (21) In order to ensure uniform conditions for implementation of Regulation (EC) No 515/97, implementing powers should be conferred on the Commission in respect of the format of the data and method of transmission of CSMs. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽¹⁾. The examination procedure should be used for the adoption of implementing acts.
- (22) In order to ensure uniform conditions for implementation of Regulation (EC) No 515/97, implementing powers should be conferred on the Commission in respect of the specific elements to be included in the CIS under each of the categories referred to under items (a) to (h) in Article 24. Those powers should be exercised in accordance with Regulation (EU) No 182/2011. The examination procedure should be used for the adoption of implementing acts. The specific elements to be included in the CIS will be based on those listed in the Annex to the Commission Regulation (EC) No 696/98⁽²⁾.
- (23) The European Data Protection Supervisor has been consulted and issued an opinion on 11 March 2014,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 515/97 is amended as follows:

1. In Article 2, paragraph 1 is amended as follows:

- (a) The first indent is replaced by the following:

‘— “customs legislation” means the body of Union provisions and the associated delegated and implementing acts governing the entry, exit, import, export, transit and presence of goods traded between Member States and third countries, and between Member States in the case of goods that do not have Union status within the meaning of Article 28(2) of the Treaty on the Functioning of the European Union (TFEU) or goods subject to additional controls or investigations for the purposes of establishing their Union status.’

- (b) The following indent is added:

‘— “**public or private** service providers active in the international supply chain” means owners, shippers, consignees, freight forwarders, carriers, **producers** and other **involved** intermediaries or persons involved in the international supply chain.’ [Am. 8]

2. Article 12 is replaced by the following:

‘Documents, certified true copies of documents, attestations, all ~~instruments~~ **official acts** or decisions which emanate from the administrative authorities, reports, and any other intelligence obtained by the staff of the requested authority and communicated to the applicant authority in the course of the assistance provided for in Articles 4 to 11 may constitute admissible evidence in administrative and judicial proceedings of the applicant Member State in the same way as if they had been obtained in the Member State where the proceedings take place.’ [Am. 9]

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

⁽²⁾ Commission Regulation (EC) No 696/98 of 27 March 1998 implementing Council Regulation (EC) No 515/97 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters (OJ L 96, 28.3.1998, p. 22).

Tuesday 15 April 2014

2a. The following Article is inserted:

'Article 16a

Documents, certified true copies of documents, attestations, all instruments or decisions which emanate from the administrative authorities, reports, and any other intelligence obtained by staff of one Member State and communicated to another Member State in the course of the assistance provided for in Articles 13 to 15 may constitute admissible evidence in administrative and judicial proceedings of the Member State receiving the information in the same way as if they had been obtained in the Member State where the proceedings take place.' [Am. 10]

2b. In the first subparagraph of Article 18(1), the following indent is added:

'— breaches of customs legislation above a threshold set by the Commission.' [Am. 11]

2c. The concluding phrase of the first subparagraph of Article 18(1) is replaced by the following:

'they shall communicate to the Commission as soon as possible, but in any event not later than within three weeks, either on their own initiative or in response to a reasoned request from the Commission, any relevant information, be it in the form of documents or copies or extracts thereof, needed to determine the facts so that the Commission may coordinate the steps taken by the Member States.' [Am. 12]

2d. The first subparagraph of Article 18(4) is replaced by the following:

'4. Where the Commission considers that irregularities have taken place in one or more Member States, it shall inform the Member State or Member States concerned thereof and that Member State or those Member States shall at the earliest opportunity but in any event not later than three weeks after the information was received carry out an enquiry, at which Commission officials may be present under the conditions laid down in Articles 9 (2) and 11 of this Regulation.' [Am. 13]

3. Article 18a is amended as follows:

(a) Paragraph 1 is replaced by the following:

*'1. Without prejudice to the competences of the Member States, for the purpose of risk management as set out in Article 4, points 25 and 26, and Article 13(2) of Regulation (EEC) No 2913/92, and with a view to assisting the authorities referred to in Article 29 to detect movements of goods that are the object of operations in potential breach of customs and agricultural legislation and means of transport, including containers, used for that purpose, the Commission shall establish and manage a directory of data received from public or private service providers active in the international supply chain. That directory shall be directly accessible to those authorities. **They shall ensure that the information regarding the interests of Member States' service providers contained in that directory shall be used only for the purposes of this Regulation.**'* [Am. 14]

(b) Paragraph 2 is replaced by the following:

'2. In managing that directory, the Commission shall be empowered:

(a) to access or extract and store the contents of the data, by any means or in any form, and to use data for the purposes of an administrative or judicial procedure in compliance with legislation applicable to intellectual property rights. ~~The Commission shall put in place adequate safeguards against arbitrary interference by public authorities including technical and organisational measures and transparency requirements towards the data subjects.~~ Data subjects shall be provided with the right of access and correction in relation to data processed for this purpose; [Am. 15]

Tuesday 15 April 2014

- (b) to compare and contrast data that are accessible in or extracted from the directory, to index them, to enrich them from other data sources and to analyse them in compliance with Regulation (EC) No 45/2001 of the European Parliament and of the Council (*);
- (c) to make the data in this directory available to the authorities referred to in Article 29, using electronic data-processing techniques.

(*) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

- (c) The following ~~paragraphs 5 and 6~~ are **paragraph is** added:

~~5. The European Data Protection Supervisor shall supervise compliance of this directory with Regulation (EC) No 45/2001.~~

~~The Commission shall implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction, accidental loss or unauthorised disclosure, alteration and access or any other unauthorised form of processing. [Am. 16]~~

6. ~~Without prejudice to Regulation (EC) No 45/2001,~~ The Commission may transfer, subject to the agreement of the public or private service providers active in the international supply chain, data referred to in Article 18a(3) to international organisations ~~and/or EU institutions/agencies~~ **including the World Customs Organisation, the International Maritime Organisation, the International Civil Aviation Organisation and the International Air Transport Association, as well as Europol**, which contribute to the protection of the financial interests of the Union and correct application of customs legislation with which the Commission concluded a relevant arrangement or memorandum of understanding. [Am. 17]

Data shall be transferred under this paragraph only for the general purposes of this Regulation ~~also~~ including the protection of the financial interests of the Union, and/or for the purpose of risk management as set out in points 25 and 26 of Article 4 and Article 13(2) of Council Regulation (EEC) No 2913/92 (*). [Am. 18]

~~The arrangement or memorandum of understanding based on which the transfer of data may take place under this paragraph shall include, inter alia, respect~~ data protection principles ~~such as~~, the possibility for data subjects to exercise their rights of access and correction and to seek administrative and judicial redress, as well as an independent oversight mechanism to ensure compliance with the data protection safeguards. [Am. 19]

Data received from public or private service providers active in the international supply chain shall be kept only for the time necessary to achieve the purpose for which they were introduced and may not be stored for more than ten years. If personal data are stored for a period exceeding five years, the European Data Protection Supervisor shall be informed accordingly.

The Commission shall be empowered to adopt delegated acts in accordance with Article 43 in order to amend the list of international organisations and/or Union institutions/agencies which contribute to the protection of the financial interests of the Union and the correct application of customs legislation. [Am. 20]

The Commission shall consult business representatives regarding the development of delegated acts referred to in Article 18a(6). [Am. 21]

(*) Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

Tuesday 15 April 2014

4. Article 18b is amended as follows:

(a) Paragraph 2 is replaced by the following:

'2. The Commission ~~may make~~ **shall ensure that** expertise, technical or logistical assistance, training or communication activity or any other operational support available to the Member States both for the achievement of the objectives of this Regulation and in the performance of Member States' duties in the framework of the implementation of the customs cooperation provided for by Article 87 TFEU. For that purpose, the Commission shall establish appropriate technical systems.' [Am. 22]

~~(b) The following paragraph 3 is added:~~

~~'3. The European Data Protection Supervisor shall supervise compliance of all the technical systems provided under this Article with Regulation (EC) No 45/2001.'~~ [Am. 23]

5. The following Articles are inserted:

'Article 18c

1. ~~The public or private service providers active in the international supply chain referred to in Article 18a(1)~~ **Maritime carriers** that store data on the movement and status of containers or have access to such data shall report to the Commission Container Status Messages ("CSMs"). [Am. 24]

2. The required CSMs shall be reported ~~in either of the following situations:~~ **for containers destined to be brought by vessel into the customs territory of the Union from a third country.**

~~(a) containers destined to be brought by vessel into the customs territory of the Union from a third country;~~ [Am. 25]

~~(b) containers leaving the customs territory of the Union to a third country by vessel.~~ [Am. 26]

3. The required CSMs shall report the events referred to in Article 18f insofar as they are known to the reporting public or private service provider active in the international supply chain **and for which the data have been generated or collected in the electronic container tracking equipment.** [Am. 27]

4. The Commission shall establish and manage a directory of reported CSMs, (the "CSM directory"). **The CSM directory shall form part of the directory referred to in Article 18a and shall not contain personal data.** [Am. 28]

Article 18d

1. Where a container, including containers which will not be discharged in the Union, is destined to be brought by vessel into the customs territory of the Union from a third country, the public or private service providers that are subject to the obligation in Article 18c(1) shall report CSMs for all events taking place from the moment when the container was reported empty before being brought into the customs territory of the Union until the container is again reported empty.

2. In cases where the specific CSMs needed to identify the relevant empty container events are not available in the provider's electronic records in any given case, the provider shall report CSMs for events taking place at least three months prior to physical arrival at the customs territory of the Union until one month after the entry into the customs territory of the Union or until arrival at a destination outside the customs territory of the Union, whichever is sooner.

Tuesday 15 April 2014

Article 18e

1. Where a container is leaving the customs territory of the Union to a third country by vessel, the public or private service providers that are subject to the obligation in Article 18c(1) shall report CSMs for all events taking place from the moment when the container was reported empty in the customs territory of the Union until the container is reported to be empty outside the customs territory of the Union.
2. In cases where the specific CSMs needed to identify the relevant empty container events are not available in the provider's electronic records in any given case, the provider may report CSMs for events taking place during at least three months after exit from the customs territory of the Union.

Article 18f

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 43 laying down the container status events for which CSMs are to be reported in accordance with Article 18c, the minimum data elements to be reported in the CSMs and the frequency of reporting.
 2. The Commission shall adopt, by means of implementing acts, provisions regarding the format of the data in the CSMs and the method of transmission of the CSMs, **and regarding obligations that may pertain to containers that are brought into the Union due to diversions**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43a(2). [Am. 29]
- 2a. Pursuant to Article 18a(1), the Commission shall establish by means of an implementing act the means by which the agreement of service providers shall be obtained prior to the transferral of their filed CSMs to other organisations or bodies. [Am. 30]**
- 2b. The Commission is urged to consult closely with business representatives of the container liner shipping industry concerning the preparation of the delegated and implementing acts referred to in this Article. They may be invited to participate in the relevant committee meetings and expert groups that are to be used to develop such acts. [Am. 31]**

Article 18 g

1. The Commission shall establish and manage a directory containing data on import, ~~export~~ and transit of goods, including transit within a Member State, as set out in Annexes 37 and 38 of Commission Regulation (EEC) No 2454/93 (*), (the 'import, export, transit directory'). The Member States shall authorise the Commission to systematically replicate data relating to import, ~~export~~ and transit from the sources operated by the Commission on the basis of Regulation (EEC) No 2913/92. The Member States shall, **at the earliest possible date**, supply to the Commission data concerning the transit of goods within a Member State ~~and direct export~~. **Information provided on natural and legal persons shall be used for the purposes of this Regulation only.** [Am. 32]
2. The import, export, transit directory shall be used to assist in preventing, investigating and prosecuting operations which are, or appear to constitute, breaches of customs legislation and for the purpose of risk management including risk-based customs controls as defined in points 25 and 26 of Article 4, and Article 13(2) of Regulation (EEC) No 2913/92.
3. The import, export, transit directory shall be accessible exclusively to the Commission departments and to the national authorities referred to in Article 29. Within the Commission and national authorities, only designated analysts shall be empowered to process personal data contained in that directory.

Tuesday 15 April 2014

~~Without prejudice to Regulation (EC) No 45/2001, the Commission may transfer, subject to the agreement of the supplying Member State, selected data obtained in accordance with the procedure specified in paragraph 1 to international organisations and/or EU institutions/agencies including the World Customs Organisation, the International Maritime Organisation, the International Civil Aviation Organisation and the International Air Transport Association, as well as Europol, which contribute to the protection of the financial interests of the Union and correct application of customs legislation and with which the Commission concluded a relevant arrangement or memorandum of understanding. [Am. 33]~~

Data shall be transferred under this paragraph only for the general purposes of this Regulation also including the protection of the financial interests of the Union, and/or for the purpose of risk management as set out in points 25 and 26 of Article 4 and Article 13(2) of Regulation (EEC) No 2913/92.

The arrangement or memorandum of understanding based on which the transfer of data may take place under this paragraph shall include, inter alia, data protection principles such as the possibility for data subjects to exercise their rights of access and correction and to seek administrative and judicial redress, as well as an independent oversight mechanism to ensure compliance with the data protection safeguards.

3a. The Commission shall present, on an annual basis, the results provided by the import, export, transit directory to the European Parliament and the Council, pursuant to Article 51a. [Am. 34]

~~4. Regulation (EC) No 45/2001 shall apply to the processing of personal data by the Commission in the context of data included in this directory. [Am. 35]~~

The Commission shall be considered as data controller within the meaning of Article 2(d) of Regulation (EC) No 45/2001.

~~The import, export, transit directory shall be subject to prior checking by the European Data Protection Supervisor in accordance with Article 27 of Regulation (EC) No 45/2001. [Am. 36]~~

Data contained in the import, export, transit directory shall be kept only for the time necessary to achieve the purpose for which they were introduced and may not be stored for more than ten years. If personal data are stored for a period exceeding five years, the European Data Protection Supervisor shall be informed accordingly.

~~5. The import, export, transit directory shall not include the special categories of data within the meaning of Article 10(5) of Regulation (EC) No 45/2001.~~

~~The Commission shall implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction, accidental loss or unauthorised disclosure, alteration and access or any other unauthorised form of processing. [Am. 37]~~

Article 18h

1. The Commission may, **following a request to a Member State as referred to in paragraph 1a of this Regulation and in accordance with Article 14 of Regulation (EEC) No 2913/92**, obtain directly from the economic operators documents supporting import and export transit declarations **and for which supporting documents have been generated or collected by the economic operators**, with respect to investigations related to the implementation of customs legislation as defined in Article 2(1) **of this Regulation with either the explicit authorisation of a Member State or with the tacit authorisation specified in 18h(1b) of this Regulation. The Commission shall notify all Member States likely to be involved in a subsequent enquiry of the request in parallel with the request being made. The Commission shall provide the Member State where the economic operator is established with a copy of the request in parallel with the request being made. The Commission shall provide copies of the response and of the supporting documents from the economic operator to the Member State where the economic operator is established within one week of receipt of a response. [Am. 38]**

Tuesday 15 April 2014

1a. Following a request from the Commission to a Member State for documents supporting an import or transit declaration, the Member State shall, in accordance with Article 14 of Regulation (EEC) No 2913/92, have three weeks within which to either:

- **answer the request and provide the requested documentation;**
- **notify the Commission that the Member State has requested the documentation from the economic operator;**
- **request, for operational reasons, a further two weeks to fulfil the request; or**
- **decline the request and notify the Commission that the request was impossible to fulfil by means of due diligence, for instance due to the failure of the economic operator to provide the requested information or by a refusal decision taken by a Member State judicial authority in accordance with Article 3 of this Regulation. [Am. 39]**

1b. If the Member State does not:

- **respond with the requested documents;**
- **notify the Commission that the Member State has requested the documents from the economic operator;**
- **request, for operational reasons, a further two weeks to fulfil the request; or**
- **decline the request within the initial three-week period,**

it shall be considered to have given its tacit authorisation for the Commission to request documents supporting an import or transit declaration directly from the economic operator. [Am. 40]

2. Within the time limits obliging economic operators to maintain the relevant documentation, economic operators shall provide the Commission upon request with the information mentioned in paragraph 1 *within three weeks*. [Am. 41]

(*) Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (OJ L 253, 11.10.1993, p. 1).'

5a. Article 21(1) is replaced by the following:

'1. The findings and information obtained in the course of the Community missions referred to in Article 20 of this Regulation, and in particular documents passed on by the competent authorities of the third countries concerned, as well as the information obtained during the course of an administrative enquiry, including by the Commission's services, shall be handled in accordance with Article 45 of this Regulation.' [Am. 42]

6. In Article 23, paragraph 4 is replaced by the following:

'4. The Commission shall be empowered to adopt delegated acts in accordance with Article 43 determining those operations in connection with the application of agricultural regulations which require the introduction of information into the CIS.'

7. In Article 25, paragraph 1 is replaced by the following:

'1. The Commission shall adopt, by means of implementing acts, provisions regarding the items to be included in the CIS relating to each of the categories referred to in Article 24(a) to (h) to the extent that this is necessary to achieve the aim of the System. Personal data may not appear in the category referred to in Article 24(e). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43a(2).'

Tuesday 15 April 2014

8. Article 29 is amended as follows:

(a) Paragraph 1 is replaced by the following:

'1. Access to data included in the CIS shall be reserved ~~exclusively~~ for the national authorities designated by each Member State and the departments designated by the Commission. Those national authorities shall be customs administrations but may also include other authorities competent, according to the laws, regulations and procedures of the Member State in question, to act in order to achieve the aim stated in Article 23(2). [Am. 43]

The supplying CIS partner shall have the right to determine which among those national authorities mentioned above may have access to data that it has included in the CIS.'

(b) Paragraph 2 is replaced by the following:

'2. Each Member State shall send the Commission a list of its designated competent national authorities which have access to the CIS stating, for each authority, to which data it may have access and for what purposes.

The Commission shall inform the other Member States accordingly. It shall also verify the list of the designated national authorities against disproportionate designations and inform all the Member States of the corresponding details concerning the Commission departments authorised to have access to the CIS.

The list of national authorities and Commission departments thus designated shall be published for information by the Commission in the *Official Journal of the European Union* and subsequent updates to the list shall be made public by the Commission on the internet.'

9. In Article 30(3), the third subparagraph is replaced by the following:

'The list of the authorities or departments thus designated shall be made public by the Commission on the internet.'

9a. In Article 30, paragraph 4 is replaced by the following:

'4. Data obtained from the CIS may, with the prior authorization of, and subject to any conditions imposed by, the Member State which included them in the System, be communicated for use by national authorities other than those referred to in paragraph 2, third countries and international or regional organizations and/or Union agencies which contribute to the protection of the financial interests of the Union and correct application of customs legislation. Each Member State shall take special measures to ensure the security of such data when they are being transmitted or supplied to departments located outside its territory.

The provisions referred to in the first subparagraph shall apply mutatis mutandis to the Commission where it has entered the data in the System.' [Am. 44]

10. The title of Chapter 4 is replaced by the following:

'Chapter 4

Storage of data.'

11. Article 33 is replaced by the following:

'Article 33

Data included in the CIS shall be kept only for the time necessary to achieve the purpose for which they were introduced and may not be stored for more than ten years. ~~If personal data are stored for a period exceeding five years, the European Data Protection Supervisor shall be informed accordingly.~~ [Am. 45]

Tuesday 15 April 2014

12. Article 37 is amended as follows:

(a) Paragraph 3a is replaced by the following:

‘3a. This Regulation particularises and complements Regulation (EC) No 45/2001.

The European Data Protection Supervisor shall supervise compliance of the CIS with Regulation (EC) No 45/2001.’

(b) The following paragraph is added:

‘5. The European Data Protection Supervisor shall co-ordinate with the Joint Supervisory Authority, established under Council Decision 2009/917/JHA (*), each acting within the scope of their respective competence, with a view to ensuring coordinated supervision and audits of the CIS.

(*) Council Decision 2009/917/JHA of 30 November 2009 on the use of information technology for customs purposes (OJ L 323, 10.12.2009, p. 20).’

13. Article 38 is amended as follows:

(a) In paragraph 1, point b is deleted.

(b) Paragraph 2 is replaced by the following:

‘2. In particular, both the Member States and the Commission shall take measures:

(a) to prevent any unauthorised person from having access to installations used for the processing of data;

(b) to prevent data and data media from being read, copied, modified or deleted by unauthorised persons;

(c) to prevent the unauthorised entry of data and any unauthorised consultation, modification or deletion of data;

(d) to prevent data in the CIS from being accessed by unauthorised persons by means of data-transmission equipment;

(e) to guarantee that, with respect to the use of the CIS, authorised persons have right of access only to data for which they have competence;

(f) to guarantee that it is possible to check and establish to which authorities data may be transmitted by data-transmission equipment;

(g) to guarantee that it is possible to check and establish *ex post facto* what data have been introduced into the CIS, when and by whom, and to monitor interrogation;

(h) to prevent the unauthorised reading, copying, modification or deletion of data during the transmission of data and the transport of data media.’

(c) Paragraph 3 is replaced by the following:

‘3. The Commission shall verify that the searches carried out were authorized and were carried out by authorised users. ~~At least 1% of all searches made shall be verified.~~ **The level of verification shall depend on the extent of the area to be verified, the severity of the infringement and expected amount of revenue affected, but shall always be equal to 1% or more of searches made.** A record of such searches and verifications shall be entered into the system and shall be used only for the said verifications. It shall be deleted after six months.’ [Am. 46]

Tuesday 15 April 2014

14. Article 41d is amended as follows:

(a) Paragraph 1 is replaced by the following:

'1. The period for which data may be stored shall depend on the laws, regulations and procedures of the Member State supplying them. **The need for the retention of data shall be reviewed by the supplying Member State.** The maximum and non-cumulative periods, calculated from the date of entry of the data in the investigation file, which may not be exceeded are as follows: [Am. 47]

(a) data concerning current investigation files may not be stored for more than three years without any operation in breach of customs and agricultural legislation being observed; data must be anonymised before that time limit if one year has elapsed since the last observation;

(b) data concerning administrative enquiries or criminal investigations in which an operation in breach of customs and agricultural legislation has been established but which have not given rise to an administrative decision, a conviction or an order to pay a criminal fine or an administrative penalty may not be stored for more than six years;

(c) data concerning administrative enquiries or criminal investigations which have given rise to an administrative decision, a conviction or an order to pay a criminal fine or an administrative penalty may not be stored for more than ten years.'

(b) Paragraph 3 is replaced by the following:

'3. The Commission shall ~~anonymise~~ **make anonymous or delete** the data as soon as the maximum storage period provided for in paragraph 1 has elapsed.' [Am. 48]

15. Article 43 is replaced by the following:

'1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in ~~Articles~~ **Article 18a(6), Article 18f(1), Article 18 g(3) and Article 23(4)** shall be conferred on the Commission for an indeterminate period of time from ~~[dd/mm/yyyy] [insert date of entry into force of this Regulation]~~ ... (*). [Am. 49]

3. The power to adopt delegated acts referred to in ~~Articles~~ **Article 18a(6), Article 18f(1), Article 18 g(3) and Article 23(4)** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force. [Am. 50]

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to ~~Articles~~ **Article 18a(6), Article 18f(1), Article 18 g(3) and Article 23(4)** shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.' [Am. 51]

(*) **Date of entry into force of this Regulation.**

Tuesday 15 April 2014

16. The following article is inserted:

‘Article 43a

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 (*).
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

(*) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).’

Article 1a

By ... (*), the Commission shall carry out an assessment of:

- **the necessity of extending the data contained in the directory referred in Article 18a of Regulation (EC) No 515/97 by including data on export, and**
- **the feasibility of extending the data contained in the directory referred in Article 18a of Regulation (EC) No 515/97 by including data on import and transit of goods by land and air. [Am. 52]**

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

For public or private service providers who, at the time of the entry into force of this Regulation, are bound by private contracts that prevent them from fulfilling their obligation stipulated in Article 18c(1) of Regulation (EC) No 515/97, this shall take effect **no earlier than** one year after the ~~Regulation has entered~~ **required delegated and implementing acts referred to in Articles 18f(1) and 18f(2) of Regulation (EC) No 515/97 enter** into force. [Am. 53]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament
The President

For the Council
The President

(*) **Two years after the date of entry into force of this Regulation.**

Tuesday 15 April 2014

P7_TA(2014)0345

**Information in the field of technical regulations and rules on Information Society services
***I**

European Parliament legislative resolution of 15 April 2014 on the amended proposal for a directive of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codified text) (COM(2013)0932 — C7-0006/2014 — 2010/0095(COD))

(Ordinary legislative procedure — codification)

(2017/C 443/27)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2010)0179) and the amended proposal (COM(2013)0932),
 - having regard to Article 294(2) and Articles 114, 337 and 43 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0006/2014),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinions of the European Economic and Social Committee ⁽¹⁾;
 - having regard to the Interinstitutional Agreement of 20 December 1994 — Accelerated working method for official codification of legislative texts ⁽²⁾,
 - having regard to Rules 86 and 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Legal Affairs (A7-0247/2014),
- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the proposal in question contains a straightforward codification of the existing texts without any change in their substance;
1. Adopts its position at first reading hereinafter set out;
 2. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2010)0095

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114, 337 and 43 thereof,

⁽¹⁾ Opinion of 14 July 2010 (OJ C 44, 11.2.2011, p. 142) and opinion of 26 February 2014 (not yet published in the Official Journal).

⁽²⁾ OJ C 102, 4.4.1996, p. 2.

Tuesday 15 April 2014

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinions of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Directive 98/34/EC of the European Parliament and of the Council ⁽³⁾ has been substantially amended several times ⁽⁴⁾. In the interests of clarity and rationality the said Directive should be codified.
- (2) The internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured. Therefore, the prohibition of quantitative restrictions on the movement of goods and of measures having an equivalent effect is one of the basic principles of the Union.
- (3) In order to promote the smooth functioning of the internal market, as much transparency as possible should be ensured as regards national initiatives for the establishment of technical regulations.
- (4) Barriers to trade resulting from technical regulations relating to products may be allowed only where they are necessary in order to meet essential requirements and have an objective in the public interest of which they constitute the main guarantee.
- (5) It is essential for the Commission to have the necessary information at its disposal before the adoption of technical provisions. Consequently, the Member States which are required to facilitate the achievement of its task pursuant to Article 4(3) of the Treaty on European Union (TEU) must notify it of their projects in the field of technical regulations.
- (6) All the Member States must also be informed of the technical regulations contemplated by any one Member State.
- (7) The aim of the internal market is to create an environment that is conducive to the competitiveness of undertakings. Increased provision of information is one way of helping undertakings to make more of the advantages inherent in this market. It is therefore necessary to enable economic operators to give their assessment of the impact of the national technical regulations proposed by other Member States, by providing for the regular publication of the titles of notified drafts and by means of the provisions relating to the confidentiality of such drafts.
- (8) It is appropriate, in the interests of legal certainty, that Member States publicly announce that a national technical regulation has been adopted in accordance with the formalities laid down in this Directive.
- (9) As far as technical regulations for products are concerned, the measures designed to ensure the proper functioning or the continued development of the market include greater transparency of national intentions and a broadening of the criteria and conditions for assessing the potential effect of the proposed regulations on the market.
- (10) It is therefore necessary to assess all the requirements laid down in respect of a product and to take account of developments in national practices for the regulation of products.
- (11) Requirements, other than technical specifications, referring to the life cycle of a product after it has been placed on the market are liable to affect the free movement of that product or to create obstacles to the proper functioning of the internal market.

⁽¹⁾ Opinion of 14 July 2010 (OJ C 44, 11.2.2011, p. 142) and opinion of 26 February 2014 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 15 April 2014.

⁽³⁾ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

⁽⁴⁾ See Annex III, Part A.

Tuesday 15 April 2014

- (12) It is necessary to clarify the concept of a *de facto* technical regulation. In particular, the provisions by which the public authority refers to technical specifications or other requirements, or encourages the observance thereof, and the provisions referring to products with which the public authority is associated, in the public interest, have the effect of conferring on such requirements or specifications a more binding value than they would otherwise have by virtue of their private origin.
- (13) The Commission and the Member States must also be allowed sufficient time in which to propose amendments to a contemplated measure, in order to remove or reduce any barriers which it might create to the free movement of goods.
- (14) The Member State concerned must take account of these amendments when formulating the definitive text of the measure envisaged.
- (15) It is inherent in the internal market that, in particular where the principle of mutual recognition cannot be implemented by the Member States, the Commission adopts or proposes the adoption of binding acts. A specific temporary standstill period has been established in order to prevent the introduction of national measures from compromising the adoption of binding acts by the European Parliament and the Council or by the Commission in the same field.
- (16) The Member State in question must, pursuant to the general obligations laid down in Article 4(3) of the TEU, defer implementation of the contemplated measure for a period sufficient to allow either a joint examination of the proposed amendments or the preparation of a proposal for a legislative act or the adoption of a binding act of the Commission.
- (17) With a view to facilitating the adoption of measures by the European Parliament and the Council, Member States should refrain from adopting technical regulations once the Council has adopted a position at first reading on a Commission proposal concerning that sector.
- (18) It is necessary to envisage a Standing Committee, the members of which are appointed by the Member States, with the task of cooperating in the efforts of the Commission to lessen any adverse effects on the free movement of goods.
- (19) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law of the directives set out in Annex III, Part B,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. For the purposes of this Directive, the following meanings shall apply:
 - (a) 'product', any industrially manufactured product and any agricultural product, including fish products;
 - (b) 'service', any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

For the purposes of this definition:

- (i) 'at a distance' means that the service is provided without the parties being simultaneously present,
- (ii) 'by electronic means' means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means,
- (iii) 'at the individual request of a recipient of services' means that the service is provided through the transmission of data on individual request.

An indicative list of services not covered by this definition is set out in Annex I;

- (c) 'technical specification', a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures.

Tuesday 15 April 2014

The term 'technical specification' also covers production methods and processes used in respect of agricultural products as referred to Article 38(1), second subparagraph of the TFEU, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC of the European Parliament and of the Council ⁽¹⁾, as well as production methods and processes relating to other products, where these have an effect on their characteristics;

- (d) 'other requirements', a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;
- (e) 'rule on services', requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point (b), in particular provisions concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point.

For the purposes of this definition:

- (i) a rule shall be considered to be specifically aimed at Information Society services where, having regard to its statement of reasons and its operative part, the specific aim and object of all or some of its individual provisions is to regulate such services in an explicit and targeted manner,
- (ii) a rule shall not be considered to be specifically aimed at Information Society services if it affects such services only in an implicit or incidental manner;
- (f) 'technical regulation', technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 7, prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider.

De facto technical regulations include:

- (i) laws, regulations or administrative provisions of a Member State which refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to technical specifications or to other requirements or to rules on services, compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions,
- (ii) voluntary agreements to which a public authority is a contracting party and which provide, in the general interest, for compliance with technical specifications or other requirements or rules on services, excluding public procurement tender specifications,
- (iii) technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services; technical specifications or other requirements or rules on services linked to national social security systems are not included.

This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list drawn up and updated, where appropriate by the Commission before, in the framework of the Committee referred to in Article 2.

The same procedure shall be used for amending this list;

⁽¹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Tuesday 15 April 2014

(g) 'draft technical regulation', the text of a technical specification or other requirement or of a rule on services, including administrative provisions, formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made.

2. This Directive shall not apply to:

(a) radio broadcasting services;

(b) television broadcasting services covered by point (e) of Article 1(1) of Directive 2010/13/EU of the European Parliament and of the Council ⁽¹⁾.

3. This Directive shall not apply to rules relating to matters which are covered by Union legislation in the field of telecommunications services, as covered by Directive 2002/21/EC of the European Parliament and of the Council ⁽²⁾.

4. This Directive shall not apply to rules relating to matters which are covered by Union legislation in the field of financial services, as listed non-exhaustively in Annex II to this Directive.

5. With the exception of Article 5(3), this Directive shall not apply to rules enacted by or for regulated markets within the meaning of Directive 2004/39/EC of the European Parliament and of the Council ⁽³⁾ or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

6. This Directive shall not apply to those measures Member States consider necessary under the Treaties for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

Article 2

A Standing Committee shall be set up consisting of representatives appointed by the Member States who may call on the assistance of experts or advisers; its chairman shall be a representative of the Commission.

The Committee shall draw up its own rules of procedure.

Article 3

1. The Committee shall meet at least twice a year.

The Committee shall meet in a specific composition to examine questions concerning Information Society services.

2. The Commission shall submit to the Committee a report on the implementation and application of the procedures set out in this Directive, and shall present proposals aimed at eliminating existing or foreseeable barriers to trade.

3. The Committee shall express its opinion on the communications and proposals referred to in paragraph 2 and may in this connection propose, in particular, that the Commission:

(a) ensure where necessary, in order to avoid the risk of barriers to trade, that initially the Member States concerned decide amongst themselves on appropriate measures;

(b) take all appropriate measures;

(c) identify the areas where harmonisation appears necessary, and, should the case arise, undertake appropriate harmonisation in a given sector.

⁽¹⁾ Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 95, 15.4.2010, p. 1).

⁽²⁾ Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive) (OJ L 108, 24.4.2002, p. 33).

⁽³⁾ Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments amending Council Directives 85/611/EEC and 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC (OJ L 145, 30.4.2004, p. 1).

Tuesday 15 April 2014

4. The Committee must be consulted by the Commission:
 - (a) when deciding on the actual system whereby the exchange of information provided for in this Directive is to be effected and on any change to it;
 - (b) when reviewing the operation of the system provided for in this Directive.
5. The Committee may be consulted by the Commission on any preliminary draft technical regulation received by the latter.
6. Any question regarding the implementation of this Directive may be submitted to the Committee at the request of its chairman or of a Member State.
7. The proceedings of the Committee and the information to be submitted to it shall be confidential.

However, the Committee and the national authorities may, provided that the necessary precautions are taken, consult, for an expert opinion, natural or legal persons, including persons in the private sector.

8. With respect to rules on services, the Commission and the Committee may consult natural or legal persons from industry or academia, and where possible representative bodies, capable of delivering an expert opinion on the social and societal aims and consequences of any draft rule on services, and take notice of their advice whenever requested to do so.

Article 4

Member States shall communicate to the Commission, in accordance with Article 5(1), all requests made to standards institutions to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products as draft technical regulations, and shall state the grounds for their enactment.

Article 5

1. Subject to Article 7, Member States shall immediately communicate to the Commission any draft technical regulation, except where it merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary, where these have not already been made clear in the draft.

Where appropriate, and unless it has already been sent with a prior communication, Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft technical regulation.

Member States shall communicate the draft again under the conditions set out in the first and second subparagraphs of this paragraph if they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

Without prejudice to the provisions of Title VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁽¹⁾, where, in particular, the draft seeks to limit the marketing or use of a chemical substance, preparation or product on grounds of public health or of the protection of consumers or the environment, Member States shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the principles provided for in the relevant part of Section II.3 of Annex XV to Regulation (EC) No 1907/2006.

⁽¹⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Tuesday 15 April 2014

The Commission shall immediately notify the other Member States of the draft and all documents which have been forwarded to it; it may also refer this draft, for an opinion, to the Committee referred to in Article 2 and, where appropriate, to the committee responsible for the field in question.

With respect to the technical specifications or other requirements or rules on services referred to in point (iii) of the second subparagraph of point (f) of Article 1(1), the comments or detailed opinions of the Commission or Member States may concern only aspects which may hinder trade or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators and not the fiscal or financial aspects of the measure.

2. The Commission and the Member States may make comments to the Member State which has forwarded a draft technical regulation; that Member State shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. Member States shall communicate the definitive text of a technical regulation to the Commission without delay.

4. Information supplied under this Article shall not be confidential except at the express request of the notifying Member State. Any such request shall be supported by reasons.

In cases of this kind, if necessary precautions are taken, the Committee referred to in Article 2 and the national authorities may seek expert advice from physical or legal persons in the private sector.

5. When draft technical regulations form part of measures which are required to be communicated to the Commission at the draft stage under another Union act, Member States may make a communication within the meaning of paragraph 1 under that other act, provided that they formally indicate that the said communication also constitutes a communication for the purposes of this Directive.

The absence of a reaction from the Commission under this Directive to a draft technical regulation shall not prejudice any decision which might be taken under other Union acts.

Article 6

1. Member States shall postpone the adoption of a draft technical regulation for three months from the date of receipt by the Commission of the communication referred to in Article 5(1).

2. Member States shall postpone:

— for four months the adoption of a draft technical regulation in the form of a voluntary agreement within the meaning of point (ii) of the second subparagraph of point (f) of Article 1(1),

— without prejudice to paragraphs 3, 4 and 5, for six months the adoption of any other draft technical regulation (except for draft rules on services),

from the date of receipt by the Commission of the communication referred to in Article 5(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of goods within the internal market,

— without prejudice to paragraphs 4 and 5, for four months the adoption of any draft rule on services, from the date of receipt by the Commission of the communication referred to in Article 5(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of services or to the freedom of establishment of service operators within the internal market.

With regard to draft rules on services, detailed opinions from the Commission or Member States may not affect any cultural policy measures, in particular in the audiovisual sphere, which Member States might adopt in accordance with the law of the Union, taking account of their linguistic diversity, their specific national and regional characteristics and their cultural heritage.

Tuesday 15 April 2014

The Member State concerned shall report to the Commission on the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction.

With respect to rules on services, the Member State concerned shall indicate, where appropriate, the reasons why the detailed opinions cannot be taken into account.

3. With the exclusion of draft rules relating to services, Member States shall postpone the adoption of a draft technical regulation for twelve months from the date of receipt by the Commission of the communication referred to in Article 5(1) if, within three months of that date, the Commission announces its intention of proposing or adopting a directive, regulation or decision on the matter in accordance with Article 288 of the TFEU.

4. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 5(1) if, within the three months following that date, the Commission announces its finding that the draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision presented to the European Parliament and the Council in accordance with Article 288 of the TFEU.

5. If the Council adopts a position at first reading during the standstill period referred to in paragraphs 3 and 4, that period shall, subject to paragraph 6, be extended to 18 months.

6. The obligations referred to in paragraphs 3, 4 and 5 shall lapse:

- (a) when the Commission informs the Member States that it no longer intends to propose or adopt a binding act;
- (b) when the Commission informs the Member States of the withdrawal of its draft or proposal;
- (c) when a binding act has been adopted by the Commission or by the European Parliament and the Council.

7. Paragraphs 1 to 5 shall not apply in cases where:

- (a) for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants, and for rules on services, also for public policy, notably the protection of minors, a Member State is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible; or
- (b) for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons, a Member State is obliged to enact and implement rules on financial services immediately.

In the communication referred to in Article 5, the Member State shall give reasons for the urgency of the measures taken. The Commission shall give its views on the communication as soon as possible. It shall take appropriate action in cases where improper use is made of this procedure. The European Parliament shall be kept informed by the Commission.

Article 7

1. Articles 5 and 6 shall not apply to those laws, regulations and administrative provisions of the Member States or voluntary agreements by means of which Member States:

- (a) comply with binding Union acts which result in the adoption of technical specifications or rules on services;
- (b) fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Union;
- (c) make use of safeguard clauses provided for in binding Union acts;
- (d) apply Article 12(1) of Directive 2001/95/EC of the European Parliament and of the Council⁽¹⁾;

⁽¹⁾ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

Tuesday 15 April 2014

- (e) restrict themselves to implementing a judgment of the Court of Justice of the European Union;
 - (f) restrict themselves to amending a technical regulation within the meaning of point (f) of Article 1(1), in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.
2. Article 6 shall not apply to the laws, regulations and administrative provisions of the Member States prohibiting manufacture insofar as they do not impede the free movement of products.
 3. Paragraphs 3 to 6 of Article 6 shall not apply to the voluntary agreements referred to in point (ii) of the second subparagraph of point (f) of Article 1(1).
 4. Article 6 shall not apply to the technical specifications or other requirements or the rules on services referred to in point (iii) of the second subparagraph of point (f) of Article 1(1).

Article 8

The Commission shall report every two years to the European Parliament, the Council and the European Economic and Social Committee on the results of the application of this Directive.

The Commission shall publish annual statistics on the notifications received in the *Official Journal of the European Union*.

Article 9

When Member States adopt a technical regulation, it shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of its official publication. The methods of making such reference shall be laid down by Member States.

Article 10

Directive 98/34/EC, as amended by the acts listed in Annex III, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law of the Directives set out in Annex III, Part B of the repealed Directive and in Annex III, Part B of this Directive.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IV.

Article 11

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 12

This Directive is addressed to the Member States.

Done at

For the European Parliament
The President

For the Council
The President

Tuesday 15 April 2014

ANNEX I**Indicative list of services not covered by the second subparagraph of point (b) of Article 1(1)****1. SERVICES NOT PROVIDED 'AT A DISTANCE'**

Services provided in the physical presence of the provider and the recipient, even if they involve the use of electronic devices:

- (a) medical examinations or treatment at a doctor's surgery using electronic equipment where the patient is physically present;
- (b) consultation of an electronic catalogue in a shop with the customer on site;
- (c) plane ticket reservation at a travel agency in the physical presence of the customer by means of a network of computers;
- (d) electronic games made available in a video-arcade where the customer is physically present.

2. SERVICES NOT PROVIDED 'BY ELECTRONIC MEANS'

— Services having material content even though provided via electronic devices:

- (a) automatic cash or ticket dispensing machines (banknotes, rail tickets);
- (b) access to road networks, car parks, etc., charging for use, even if there are electronic devices at the entrance/exit controlling access and/or ensuring correct payment is made,

— Off-line services: distribution of CD roms or software on diskettes,

— Services which are not provided via electronic processing/inventory systems:

- (a) voice telephony services;
- (b) telefax/telex services;
- (c) services provided via voice telephony or fax;
- (d) telephone/telefax consultation of a doctor;
- (e) telephone/telefax consultation of a lawyer;
- (f) telephone/telefax direct marketing.

3. SERVICES NOT SUPPLIED 'AT THE INDIVIDUAL REQUEST OF A RECIPIENT OF SERVICES'

Services provided by transmitting data without individual demand for simultaneous reception by an unlimited number of individual receivers (point to multipoint transmission):

- (a) television broadcasting services (including near-video on-demand services), covered by point (e) of Article 1(1) of Directive 2010/13/EU;
 - (b) radio broadcasting services;
 - (c) (televised) teletext.
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Tuesday 15 April 2014

ANNEX II

Indicative list of the financial services covered by Article 1(4)

- Investment services,
- Insurance and reinsurance operations,
- Banking services,
- Operations relating to pension funds,
- Services relating to dealings in futures or options.

Such services include in particular:

- (a) investment services referred to in the Annex to Directive 2004/39/EC; services of collective investment undertakings;
- (b) services covered by the activities subject to mutual recognition referred to in Annex I to Directive 2013/36/EU of the European Parliament and of the Council ⁽¹⁾;
- (c) operations covered by the insurance and reinsurance activities referred to in Directive 2009/138/EC of the European Parliament and of the Council ⁽²⁾.

—

⁽¹⁾ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

⁽²⁾ Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1).

Tuesday 15 April 2014

ANNEX III**Part A****Repealed Directive with list of the successive amendments thereto**

(referred to in Article 10)

Directive 98/34/EC of the European Parliament and of the Council

(OJ L 204, 21.7.1998, p. 37)

Directive 98/48/EC of the European Parliament and of the Council

(OJ L 217, 5.8.1998, p. 18)

Part 1, Title H of Annex II to Act of Accession 2004

(OJ L 236, 23.9.2003, p. 68)

Only as regards the reference to point 2 of Directive 98/34/EC

Council Directive 2006/96/EC

(OJ L 363, 20.12.2006, p. 81)

Only as regards the reference to Article 1 of Directive 98/34/EC

Regulation (EU) No 1025/2012 of the European Parliament and of the Council

(OJ L 316, 14.11.2012, p. 12)

Only Article 26(2)

Part B**List of time-limits for transposition into national law**

(referred to in Article 10)

Directive	Time-limit for transposition
98/34/EC	—
98/48/EC	5 August 1999
2006/96/EC	1 January 2007

Tuesday 15 April 2014

ANNEX IV

CORRELATION TABLE

Directive 98/34/EC	This Directive
Article 1, first subparagraph, introductory wording	Article 1(1), introductory wording
Article 1, first subparagraph, point (1)	Article 1(1), point (a)
Article 1, first subparagraph, point (2), first subparagraph	Article 1(1), point (b), first subparagraph
Article 1, first subparagraph, point (2), second subparagraph, first indent	Article 1(1), point (b), second subparagraph, point (i)
Article 1, first subparagraph, point (2), second subparagraph, second indent	Article 1(1), point (b), second subparagraph, point (ii)
Article 1, first subparagraph, point (2), second subparagraph, third indent	Article 1(1), point (b), second subparagraph, point (iii)
Article 1, first subparagraph, point (2), third subparagraph	Article 1(1), point (b), third subparagraph
Article 1, first subparagraph, point (2), fourth subparagraph, introductory wording	Article 1(2), introductory wording
Article 1, first subparagraph, point (2), fourth subparagraph, first indent	Article 1(2), point (a)
Article 1, first subparagraph, point (2), fourth subparagraph, second indent	Article 1(2), point (b)
Article 1, first subparagraph, point (3)	Article 1(1), point (c)
Article 1, first subparagraph, point (4)	Article 1(1), point (d)
Article 1, first subparagraph, point (5), first subparagraph	Article 1(1), point (e), first subparagraph
Article 1, first subparagraph, point (5), second subparagraph	Article 1(3)
Article 1, first subparagraph, point (5), third subparagraph	Article 1(4)
Article 1, first subparagraph, point (5), fourth subparagraph	Article 1(5)
Article 1, first subparagraph, point (5), fifth subparagraph, introductory sentence	Article 1(1), point (e), second subparagraph, introductory sentence
Article 1, first subparagraph, point (5), fifth subparagraph, first indent	Article 1(1), point (e), second subparagraph, point (i)
Article 1, first subparagraph, point (5), fifth subparagraph, second indent	Article 1(1), point (e), second subparagraph, point (ii)
Article 1, first subparagraph, point (11), first subparagraph	Article 1(1), point (f), first subparagraph
Article 1, first subparagraph, point (11), second subparagraph, introductory sentence	Article 1(1), point (f), second subparagraph, introductory sentence
Article 1, first subparagraph, point (11) second subparagraph, first indent	Article 1(1), point (f), second subparagraph, point (i)
Article 1, first subparagraph, point (11), second subparagraph, second indent	Article 1(1), point (f), second subparagraph, point (ii)
Article 1, first subparagraph, point (11), second subparagraph, third indent	Article 1(1), point (f), second subparagraph, point (iii)

Tuesday 15 April 2014

Directive 98/34/EC	This Directive
Article 1, first subparagraph, point (11), third subparagraph	Article 1(1), point (f), third subparagraph
Article 1, first subparagraph, point (11), fourth subparagraph	Article 1(1), point (f), fourth subparagraph
Article 1, first subparagraph, point (12)	Article 1(1), point (g)
Article 1, second subparagraph	Article 1(6)
Article 5	Article 2
Article 6(1) and (2)	Article 3(1) and (2)
Article 6(3), introductory wording	Article 3(3), introductory wording
Article 6(3), second indent	Article 3(3), point (a)
Article 6(3), third indent	Article 3(3), point (b)
Article 6(3), fourth indent	Article 3(3), point (c)
Article 6(4), introductory wording	Article 3(4), introductory wording
Article 6(4), point (c)	Article 3(4), point (a)
Article 6(4), point (d)	Article 3(4), point (b)
Article 6(5) to (8)	Article 3(5) to (8)
Article 7	Article 4
Article 8	Article 5
Article 9(1) to (5)	Article 6(1) to (5)
Article 9(6), introductory wording	Article 6(6), introductory wording
Article 9(6), first indent	Article 6(6), point (a)
Article 9(6), second indent	Article 6(6), point (b)
Article 9(6), third indent	Article 6(6), point (c)
Article 9(7), first subparagraph, introductory wording	Article 6(7), first subparagraph, introductory wording
Article 9(7), first subparagraph, first indent	Article 6(7), first subparagraph, point (a)
Article 9(7), first subparagraph, second indent	Article 6(7), first subparagraph, point (b)
Article 9(7), second subparagraph	Article 6(7), second subparagraph
Article 10(1), introductory wording	Article 7(1), introductory wording
Article 10(1), first indent	Article 7(1), point (a)
Article 10(1), second indent	Article 7(1), point (b)
Article 10(1), third indent	Article 7(1), point (c)
Article 10(1), fourth indent	Article 7(1), point (d)
Article 10(1), fifth indent	Article 7(1), point (e)
Article 10(1), sixth indent	Article 7(1), point (f)
Article 10(2), (3) and (4)	Article 7(2), (3) and (4)
Article 11, first sentence	Article 8, first subparagraph

Tuesday 15 April 2014

Directive 98/34/EC	This Directive
Article 11, second sentence	Article 8, second subparagraph
Article 12	Article 9
Article 13	—
—	Article 10
Article 14	Article 11
Article 15	Article 12
Annexe III	—
Annexe IV	—
Annexe V	Annexe I
Annexe VI	Annexe II
—	Annexe III
—	Annexe IV

Tuesday 15 April 2014

P7_TA(2014)0346

Accession of Croatia to the 1990 Convention on the elimination of double taxation *

European Parliament legislative resolution of 15 April 2014 on the recommendation for a Council decision concerning the accession of Croatia to the Convention of 23 July 1990 on the elimination of double taxation in connection with the adjustment of profits of associated enterprises (COM(2013)0586 — C7-0381/2013 — 2013/0308(CNS))

(Special legislative procedure — consultation)

(2017/C 443/28)

The European Parliament,

- having regard to the Commission recommendation to the Council (COM(2013)0586),
 - having regard to Article 3(4) and (5) of the Act of Accession of Croatia, pursuant to which the Council consulted Parliament (C7-0381/2013),
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs (A7-0214/2014),
1. Approves the Commission recommendation as amended;
 2. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 3. Calls on the Council, when deciding on the date of application of the Convention of 23 July 1990 on the elimination of double taxation in connection with the adjustment of profits of associated enterprises, to take into account Parliament's concerns regarding the need to minimise the tax burden on tax payers;
 4. Asks the Council to consult Parliament again if it intends to amend the Commission recommendation substantially;
 5. Instructs its President to forward its position to the Council, the Commission and the governments and national parliaments of Croatia and of the other Member States.

Amendment 1**Proposal for a decision****Article 3**

Text proposed by the Commission

The Arbitration Convention, as amended by the Protocol of 25 May 1999, the Conventions of 21 December 1995 and of 8 December 2004, Decision 2008/492/EC, as well as this Decision, enters into force on **XXX [date]** between Croatia and each of the other Member States of the European Union.

Amendment

The Arbitration Convention, as amended by the Protocol of 25 May 1999, the Conventions of 21 December 1995 and of 8 December 2004, Decision 2008/492/EC, as well as this Decision, enters into force on ... (*) between Croatia and each of the other Member States of the European Union.

(*) **Day following that of publication of this Decision in the Official Journal of the European Union.**

Tuesday 15 April 2014

P7_TA(2014)0347

Shift2Rail Joint Undertaking *

European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation establishing the Shift2Rail Joint Undertaking (COM(2013)0922 — C7-0034/2014 — 2013/0445(NLE))

(Consultation)

(2017/C 443/29)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2013)0922,
 - having regard to Articles 187 and the first paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0034/2014),
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy (A7-0259/2014),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, in accordance with Article 293(2) of the Treaty on the Functioning of the European Union;
 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 4. Asks the Council to consult Parliament again if it intends to substantially amend the Commission proposal;
 5. Instructs its President to forward its position to the Council and the Commission.

Tuesday 15 April 2014

Amendment 1
Proposal for a regulation
Recital 3

Text proposed by the Commission

- (3) Regulation (EU) No .../2013 of the European Parliament and of the Council **of ... 2013 establishing Horizon 2020 — the Framework Programme for Research and Innovation for the period 2014-2020** ('Horizon 2020 Framework Programme')⁽¹²⁾ aims to achieve a greater impact **of** research and innovation **efforts** by combining EU and private-sector funds in public-private partnerships (**PPPs**) in areas where research and innovation can contribute to the Union's wider competitiveness goals and help tackle societal challenges. **The** Union involvement in these partnerships can take the form of financial contributions to joint undertakings established on the basis of Article 187 of the Treaty.

⁽¹²⁾ OJ ... [H2020 FP]

Amendment

- (3) Regulation (EU) No **1291**/2013 of the European Parliament and of the Council⁽¹²⁾ ('the Horizon 2020 Framework Programme') aims to achieve a greater impact **on** research and innovation by combining **Horizon 2020 Framework Programme** and private-sector funds in public-private partnerships in **key** areas where research and innovation can contribute to the Union's wider competitiveness goals, **leverage private investment**, and help tackle societal challenges. **Those partnerships should be based on a long-term commitment, including a balanced contribution from all partners, be accountable for the achievement of their targets and be aligned with the Union's strategic goals relating to research, development and innovation. The governance and functioning of those partnerships should be open, transparent, effective and efficient and give the opportunity to a wide range of stakeholders active in their specific areas to participate based on a long-term commitment.** Union involvement in these partnerships can take the form of financial contributions to joint undertakings established on the basis of Article 187 of the Treaty **under Decision No 1982/2006/EC of the European Parliament and of the Council**^(12a) ('the Seventh Framework Programme').

⁽¹²⁾ Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020) and repealing Decision 1982/2006/EC (OJ L 347, 20.12.2013, p. 104).

^(12a) Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).

Tuesday 15 April 2014

Amendment 2
Proposal for a regulation
Recital 4

Text proposed by the Commission

- (4) In accordance with Decision (EU) No .../2013 of the Council of ... 2013 establishing the Specific Programme implementing Horizon 2020 (2014-2020) ⁽¹³⁾ support may be provided to joint undertakings established in the Horizon 2020 Framework Programme under the conditions specified in that Decision.

⁽¹³⁾ OJ ... [H2020 SP]

Amendment

- (4) In accordance with **Regulation (EU) No 1291/2013 and Council Decision 2013/743/EU** ⁽¹³⁾ support may be provided to joint undertakings established in the Horizon 2020 Framework Programme under the conditions specified in that Decision.

⁽¹³⁾ **Council Decision 2013/743/EU of 3 December 2013 establishing the Specific Programme implementing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC** (O) L 347, 20.12.2013, p. 965)

Amendment 3
Proposal for a regulation
Recital 7

Text proposed by the Commission

- (7) The Shift2Rail Joint Undertaking (hereinafter 'S2R Joint Undertaking') should be a PPP aimed at stimulating and better coordinating Union research and innovation investments in the rail sector with a view to accelerating and facilitating the transition towards a more integrated, efficient, sustainable and attractive EU railway market, in line with the business needs of the rail sector and with the general objective of achieving a Single European Railway Area. In particular, the S2R Joint Undertaking should contribute to specific objectives defined in the 2011 White Paper and in the Fourth Railway Package, including the improved efficiency of the rail sector for the benefit of the public purse; a considerable expansion or upgrading of the capacity of the rail network, so as to enable rail to compete effectively and take a significantly greater proportion of passenger and freight transport; an improvement in the quality of rail services by responding to the needs of rail passengers and freight forwarders; the removal of technical obstacles holding back the sector in terms of interoperability; and the reduction of negative externalities linked to railway transport. The progress of the S2R Joint Undertaking towards meeting these objectives should be measured against key performance indicators.

Amendment

- (7) The Shift2Rail Joint Undertaking (hereinafter 'S2R Joint Undertaking') should be a PPP aimed at stimulating and better coordinating Union research and innovation investments in the rail sector **while creating new employment opportunities**, with a view to accelerating and facilitating the transition towards a more integrated, **user-friendly**, efficient, sustainable and attractive EU railway market, in line with the business needs of the rail sector and with the general objective of achieving a Single European Railway Area. In particular, the S2R Joint Undertaking should contribute to specific objectives defined in the 2011 White Paper and in the Fourth Railway Package, including the improved efficiency of the rail sector for the benefit of the public purse; a considerable expansion or upgrading of the capacity of the rail network, so as to enable rail to compete effectively and take a significantly greater proportion of passenger and freight transport; an improvement in the quality of rail services by responding to the needs of rail passengers and freight forwarders; the removal of technical obstacles holding back the sector in terms of interoperability; and the reduction of negative externalities linked to railway transport. The progress of the S2R Joint Undertaking towards meeting these objectives should be measured against key performance indicators.

Tuesday 15 April 2014

Amendment 4
Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission

Amendment

- (7a) *The S2R Joint Undertaking should operate in an open and transparent way providing all relevant information in a timely manner to its appropriate bodies as well as promoting its activities, including information and dissemination activities to the wider public. The rules of procedure of the bodies of the S2R Joint Undertaking should be made publicly available.*

Amendment 5
Proposal for a regulation
Recital 11 a (new)

Text proposed by the Commission

Amendment

- (11a) *The Horizon 2020 Framework Programme should contribute to the closing of the research and innovation divide within the Union by promoting synergies with the European Structural and Investment Funds (ESIF). Therefore the S2R Joint Undertaking should seek to develop close interactions with the ESIF, which can specifically help to strengthen local, regional and national research and innovation capabilities in the area of the S2R Joint Undertaking and underpin smart specialisation efforts.*

Amendment 6
Proposal for a regulation
Recital 12

Text proposed by the Commission

Amendment

- (12) In order to achieve its objectives, the S2R Joint Undertaking should provide **financial support**, mainly in the form of grants to members **and through the most appropriate measures**, such as procurement or the award of grants following calls for proposals.

- (12) In order to achieve its objectives, **to guarantee a fair participation of other enterprises in particular small and medium-sized enterprises (SMEs) and other investors and to support the modernization of an integrated European rail sector**, the S2R Joint Undertaking should provide **the Union contribution to the actions through open and transparent procedures** mainly in the form of grants to members, such as procurement or the award of grants following **open and transparent** calls for proposals.

Tuesday 15 April 2014

Amendment 7
Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission

Amendment

- (12a) ***With a view to the overall aim of the Horizon 2020 Framework Programme of achieving greater simplification and harmonisation of the European research and innovation funding landscape, Joint Undertakings should establish simple governance models and avoid sets of rules that are different from those of the Horizon 2020 Framework Programme.***

Amendment 8
Proposal for a regulation
Recital 13

Text proposed by the Commission

Amendment

- (13) The S2R Joint Undertaking should operate in ***a*** transparent way providing all relevant available information to its appropriate bodies as well as promoting its activities accordingly.

- (13) The S2R Joint Undertaking should operate in ***an open and*** transparent way ***and put in place a mechanism of consultation with all interested actors that make use of rail sector goods and services,*** providing all relevant available information to its appropriate bodies as well as promoting its activities accordingly.

Amendment 9
Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

Amendment

- (13a) ***The S2R Joint Undertaking should also use electronic means managed by the Commission to ensure openness, transparency and facilitate participation. Therefore, the calls for proposals launched by the S2R Joint Undertaking should also be published on the single portal for participants as well as through other Horizon 2020 electronic means of dissemination managed by the Commission. Moreover, relevant data on inter alia proposals, applicants, grants and participants should be made available by S2R Joint Undertaking for inclusion in the Horizon 2020 reporting and dissemination electronic systems managed by the Commission, in an appropriate format and with the periodicity corresponding to the Commission's reporting obligations.***

Tuesday 15 April 2014

Amendment 10
Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission

Amendment

- (14a) *Without prejudice to the interim evaluation referred to in Article 11 and in accordance with Article 32 of Regulation (EU) No 1291/2013 and as part of the interim evaluation of the Horizon 2020 Framework Programme, Joint Undertakings as a particular funding instrument of the Horizon 2020 Framework Programme should be subject to an in-depth assessment which shall include, inter alia, an analysis of openness, transparency and efficiency of public-private partnerships based on Article 187 TFEU.*

Amendment 11
Proposal for a regulation
Recital 16

Text proposed by the Commission

Amendment

- (16) Participation in indirect actions funded by the S2R Joint Undertaking should comply with Regulation (EU) No .../2013 of the European Parliament and of the Council **of ... 2013 laying down the rules for participation and dissemination in 'Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020)'**⁽¹⁶⁾

- (16) Participation in indirect actions funded by the S2R Joint Undertaking should comply with Regulation (EU) No **1290/2013** of the European Parliament and of the Council ⁽¹⁶⁾. **The S2R Joint Undertaking should, moreover, ensure consistent application of those rules based on relevant measures adopted by the Commission.**

⁽¹⁶⁾ O] ... [H2020 RfP]

⁽¹⁶⁾ Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for the participation and dissemination in 'Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020)' and repealing Regulation (EC) No 1906/2006 (O) L 347, 20.12.2013, p. 81.

Amendment 12
Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission

Amendment

- (16a) **The S2R Joint Undertaking should take into account the OECD definitions regarding Technological Readiness Level (TRL) in the classification of technological research, product development and demonstration activities.**

Tuesday 15 April 2014

Amendment 13
Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission

Amendment

- (20a) *With a view to the overall aim of the Horizon 2020 Framework Programme to achieve greater simplification and coherence, all calls for proposals under the S2R Joint Undertaking should take into account the duration of the Horizon 2020 Framework Programme.*

Amendment 14
Proposal for a regulation
Recital 21

Text proposed by the Commission

Amendment

- (21) *In accordance with Article 287(1) of the Treaty, the constituent instrument of bodies, offices or agencies set up by the Union may preclude the examination of the accounts of all revenue and expenditure of those bodies, offices or agencies by the Court of Auditors. In accordance with Article 60(5) of Regulation (EU, Euratom) No 966/2012, the accounts of the bodies under Article 209 of Regulation (EU, Euratom) No 966/2012 are to be examined by an independent audit body which is to give an opinion inter alia on the reliability of the accounts and the legality and regularity of the underlying transactions. Avoidance of duplication of the examination of the accounts justifies that the accounts of the S2R Joint Undertaking should not be subject to examination by the Court of Auditors.*

- (21) *In view of the specific nature and the current status of the Joint Undertakings, and in order to ensure continuity with the Seventh Framework Programme, the Joint Undertakings should continue to be subject to a separate discharge. By way of derogation from Articles 60(7) and 209 of Regulation (EU, Euratom) No 966/2012, discharge for the implementation of the budget of the S2R Joint Undertaking should therefore be given by the European Parliament on the recommendation of the Council. Hence, the reporting requirements set out in Article 60(5) of Regulation (EU, Euratom) No 966/2012 should not apply to the contribution of the Union to the S2R Joint Undertaking but they should be aligned to the extent possible to the ones envisaged for bodies under Article 208 of that Regulation. The auditing of accounts and of the legality and regularity of the underlying transactions should be undertaken by the Court of Auditors.*

Amendment 15
Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission

Amendment

- (23a) *Given the importance of continuous innovation for the competitiveness of the Union's transport sector and the number of Joint Undertakings in this field, there should be an analysis in due time, notably in view of the interim evaluation of the Horizon 2020 Framework Programme, regarding the appropriateness of efforts in collaborative research in the field of transport.*

Tuesday 15 April 2014

Amendment 16**Proposal for a regulation****Article 1 — paragraph 1***Text proposed by the Commission*

1. In order to coordinate and manage Union research and innovation investments in the European rail sector, a joint undertaking within the meaning of Article 187 of the Treaty (the 'Shift2Rail Joint Undertaking' or 'S2R Joint Undertaking') is hereby established until 31 December 2024.

Amendment

1. In order to coordinate and manage Union research and innovation investments in the European rail sector, a joint undertaking within the meaning of Article 187 of the Treaty (the 'Shift2Rail Joint Undertaking' or 'S2R Joint Undertaking') is hereby established until 31 December 2024. **In order to take into account the duration of the Horizon 2020 Framework Programme, calls for proposals under S2R Joint Undertaking shall be launched at the latest by 31 December 2020. In duly justified cases calls for proposals may be launched until 31 December 2021.**

Amendment 17**Proposal for a regulation****Article 2 — paragraph 1 — point b***Text proposed by the Commission*

(b) to contribute to the achievement of the Single European Railway Area, to a faster and cheaper transition to a more attractive, competitive, efficient and sustainable European rail system, **and** to a modal shift from road and air to rail, through a comprehensive and co-ordinated approach addressing the research and innovation needs of the rail system and its users. This approach shall cover rolling stock, infrastructure and traffic management for the market segments of freight and of long-distance, regional, local and urban passenger traffic, as well as intermodal links between rail and other modes, providing users with an integrated end-to-end solution for their rail travel and transport needs — from transaction support to en-route assistance.

Amendment

(b) to contribute to the achievement of the Single European Railway Area, to a faster and cheaper transition to a more attractive, **user-friendly (including for persons with reduced mobility)**, competitive, efficient and sustainable European rail system, to a modal shift from road and air to rail, **and to the development of a strong and competitive European rail industry sector**, through a comprehensive and co-ordinated approach addressing the research and innovation needs of the rail system and its users. This approach shall cover rolling stock, infrastructure and traffic management for the market segments of freight and of long-distance, regional, local and urban passenger traffic, as well as intermodal links between rail and other modes, providing users with an integrated end-to-end solution for their rail travel and transport needs — from transaction support to en-route assistance.

Tuesday 15 April 2014

Amendment 18**Proposal for a regulation****Article 2 — paragraph 1 — point d***Text proposed by the Commission*

(d) to **act as** a central **reference point on** rail-related research and innovation actions funded at Union level, ensuring coordination among projects and providing all stakeholders with relevant information.

Amendment

(d) to **play** a central **role in** rail-related research and innovation actions funded at Union level, ensuring coordination among projects and providing all stakeholders with relevant information.

Amendment 19**Proposal for a regulation****Article 2 — paragraph 1 — point e***Text proposed by the Commission*

(e) to actively promote the participation and close involvement of all relevant stakeholders from the full rail value chain and from outside the traditional rail industry, in particular: manufacturers of railway equipment (both rolling stock and train control systems) and their supply chain, infrastructure managers, railway operators (both passenger and freight), rail vehicle leasing companies, certifying agencies, professional staff associations, user associations (both passenger and freight), as well as the relevant scientific institutions or the relevant scientific community. The involvement of small and medium sized enterprises (SMEs), as defined in Commission Recommendation 2003/361/EC ⁽²⁰⁾, shall be encouraged.

⁽²⁰⁾ Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36)

Amendment

(e) to actively promote the participation and close involvement of all relevant stakeholders from the full rail value chain and from outside the traditional rail industry, in particular: manufacturers of railway equipment (both rolling stock and train control **and traffic management** systems) and their supply chain, infrastructure managers, railway operators (both passenger and freight), rail vehicle leasing companies, certifying agencies, professional staff associations, user associations (both passenger and freight), as well as the relevant scientific institutions or the relevant scientific community. The involvement of small and medium sized enterprises (SMEs), as defined in Commission Recommendation 2003/361/EC ⁽²⁰⁾, shall be encouraged.

⁽²⁰⁾ Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36)

Amendment 20**Proposal for a regulation****Article 2 — paragraph 1 — point e a (new)***Text proposed by the Commission**Amendment*

(**ea**) **to implement measures that promote the participation of SMEs, universities and Research Centres. In this context, barriers preventing the participation of new comers in the S2R Joint Undertaking shall be identified and addressed.**

Tuesday 15 April 2014

Amendment 21**Proposal for a regulation****Article 2 — paragraph 1 — point e b (new)***Text proposed by the Commission**Amendment*

(eb) to seek complementarity and close synergies with the European Structural and Investment Funds ('ESIF') in order to help close the research and innovation divide in Europe. Where possible, to promote interoperability between the Horizon 2020 Framework Programme and those Funds and to encourage cumulative or combined funding. In this context, measures will aim at fully exploiting the potential of Europe's talent pool and thereby optimising the economic and social impact of research and innovation and will be distinct yet complementary with regard to policies and actions of the ESIF.

Amendment 22**Proposal for a regulation****Article 3 — paragraph 1 — introductory part***Text proposed by the Commission**Amendment*

1. The maximum Union financial contribution to the Shift2Rail initiative shall be EUR 450 million, including **EFTA** contributions, paid from the appropriations in the general budget of the Union allocated to the Horizon 2020 Specific Programme implementing the Horizon 2020 Framework Programme, in accordance with the relevant provisions of Article 58(1)(c)(iv) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012 for bodies referred to in Article 209 of that Regulation. This amount includes:

1. The maximum Union financial contribution to the Shift2Rail initiative shall be EUR 450 million, including **the** contributions **from the Member States of the European Free Trade Association (EFTA)**, paid from the appropriations in the general budget of the Union allocated to the Horizon 2020 Specific Programme implementing the Horizon 2020 Framework Programme, in accordance with the relevant provisions of Article 58(1)(c)(iv) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012 for bodies referred to in Article 209 of that Regulation. This amount includes:

Amendment 23**Proposal for a regulation****Article 3 — paragraph 2***Text proposed by the Commission**Amendment*

2. Additional funds complementing the contribution referred to in paragraph 1 may be allocated from other Union instruments to support actions for the deployment of mature outcomes of the S2R Joint Undertaking.

2. Additional funds complementing the contribution referred to in paragraph 1 may be allocated from other Union instruments to support actions for the deployment of mature **innovative** outcomes of the S2R Joint Undertaking.

Tuesday 15 April 2014

Amendment 24

Proposal for a regulation

Article 3 — paragraph 4 — point d and d a (new)

Text proposed by the Commission

(d) the arrangements regarding the provision of data necessary to ensure that the Commission is able to **draft its research and innovation policy and to meet its dissemination and reporting obligations;**

Amendment

(d) the arrangements regarding the provision of data necessary to ensure that the Commission is able to **meet its dissemination and reporting obligations; including on the single portal for participants as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.**

(da) provisions for the publication of calls for proposals of the S2R Joint Undertaking also on the single portal for participants as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.

Amendment 25

Proposal for a regulation

Article 4 — paragraph 4

Text proposed by the Commission

4. For the purpose of valuing the **in kind** contributions referred to in point (b) of paragraph 2 and clause 15(3)(b) of the Statutes set out in Annex I, the costs shall be determined according to the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where each entity is established, and to the applicable International Accounting Standards/ International Financial Reporting Standards. The costs shall be certified by an independent external auditor appointed by the entity concerned. The valuation **of the contributions shall** be verified by the S2R Joint Undertaking. **In case of remaining uncertainties, the valuation may** be audited by the **S2R Joint Undertaking, as referred to in clause 20 of the Statutes.**

Amendment

4. For the purpose of valuing the contributions referred to in point (b) of paragraph 2 and clause 15(3)(b) of the Statutes set out in Annex I, the costs shall be determined according to the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where each entity is established, and to the applicable International Accounting Standards/ International Financial Reporting Standards. The costs shall be certified by an independent external auditor appointed by the entity concerned. The valuation **method may** be verified by the S2R Joint Undertaking **should there be any uncertainty arising from the certification. For the purposes of this Regulation, the costs incurred in additional activities shall not** be audited by the **S2R Joint Undertaking or any Union body.**

Tuesday 15 April 2014

Amendment 26**Proposal for a regulation****Article 4 — paragraph 6***Text proposed by the Commission*

6. Further to paragraph 5, the Commission may terminate, proportionally reduce or suspend the Union financial contribution to the S2R Joint Undertaking or trigger the winding up procedure referred to in clause 23(2) of the Statutes set out in Annex I if those members or their affiliated entities do not contribute, contribute only partially or contribute late with regard to the contributions referred to in paragraph 2.

Amendment

6. Further to paragraph 5, the Commission may terminate, proportionally reduce or suspend the Union financial contribution to the S2R Joint Undertaking or trigger the winding up procedure referred to in clause 23(2) of the Statutes set out in Annex I if those members or their affiliated entities do not contribute, contribute only partially or contribute late with regard to the contributions referred to in paragraph 2. **The Commission decision shall not hinder the reimbursement of eligible costs already incurred or committed by the Members or the S2R Joint Undertaking by the time of the notification of the aforesaid decision to the S2R Joint Undertaking.**

Amendment 27**Proposal for a regulation****Article 5 — paragraph 1***Text proposed by the Commission*

The S2R Joint Undertaking shall adopt its specific financial rules in accordance with Article 209 of Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No ... [Delegated Regulation on the Model Financial Regulation for **bodies referred to in Article 209 of the Financial Regulation**].

Amendment

Without prejudice to Article 12, the S2R Joint Undertaking shall adopt its specific financial rules in accordance with Article 209 of Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No ... [Delegated Regulation on the Model Financial Regulation for **PPPs**].

Amendment 28**Proposal for a regulation****Article 6 — paragraph 2 — subparagraph 2***Text proposed by the Commission*

The Governing Board shall adopt, in accordance with Article 110 of the Staff Regulations, a decision based on Article 2 **paragraph 1** of the Staff Regulations and **on** Article 6 of the Conditions of Employment of Other Servants delegating the relevant appointing authority powers to the Executive Director and defining the conditions under which this delegation of powers can be suspended. The Executive Director **is** authorised to sub-delegate those powers.

Amendment

The Governing Board shall adopt, in accordance with Article 110 of the Staff Regulations, a decision based on Article 2(**I**) of the Staff Regulations and Article 6 of the Conditions of Employment of Other Servants delegating the relevant appointing authority powers to the Executive Director and defining the conditions under which this delegation of powers can be suspended. The Executive Director **shall report back to the Governing Board on the delegated powers and shall be** authorised to sub-delegate those powers.

Tuesday 15 April 2014

Amendment 29

Proposal for a regulation

Article 9 — paragraph 2

Text proposed by the Commission

2. In the case of non-contractual liability, the S2R Joint Undertaking shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its staff in the performance of their duties.

Amendment

2. In the case of non-contractual liability, the S2R Joint Undertaking shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its staff **or members of the Governing Board** in the performance of their duties.

Amendment 30

Proposal for a regulation

Article 11 — paragraph 1

Text proposed by the Commission

1. By **31 December** 2017, the Commission shall **conduct** an interim evaluation of the S2R Joint Undertaking. The Commission shall **send the** conclusions of the evaluation, **and its observations**, to the European Parliament and to the Council by **30 June 2018**.

Amendment

1. By **30 June** 2017 the Commission shall **carry out, with the assistance of independent experts**, an interim evaluation of the S2R Joint Undertaking, **including an assessment of the involvement and openness to small and medium enterprises, as well as the administrative functioning of the S2R Joint Undertaking with a special focus on addressing any administrative challenges or burdens**. The Commission shall **prepare a report on that evaluation which includes** conclusions of the evaluation **and observations by the Commission**. **The Commission shall send that report** to the European Parliament and to the Council by **31 December 2017**. **The results of the interim evaluation of S2R shall be taken into account in the in-depth assessment and in the interim evaluation referred to in Article 32 of Regulation (EU) No 1291/2013.**

Amendment 31

Proposal for a regulation

Article 12 — paragraph 1

Text proposed by the Commission

1. **The discharge of the budget implementation with regard to the Union contribution to the S2R Joint Undertaking shall be part of the discharge** given by the European Parliament, upon recommendation of the Council, **to the Commission** in accordance with the procedure provided for in **Article 319** of the **Treaty**.

Amendment

1. **By way of derogation from Articles 60(7) and 209 of Regulation (EU, Euratom) No 966/2012, the discharge for the implementation of the budget of the S2R Joint Undertaking shall be given by the European Parliament, upon recommendation of the Council in accordance with the procedure provided for in the financial rules of the S2R Joint Undertaking.**

Tuesday 15 April 2014

Amendment 32**Proposal for a regulation****Article 12 — paragraph 2***Text proposed by the Commission*

2. ***The S2R Joint Undertaking shall fully cooperate with the institutions involved in the discharge procedure and provide, as appropriate, any necessary additional information. In this context, it may be requested to be represented in meetings with the relevant institutions or bodies and assist the Commission authorising officer by delegation.***

*Amendment**deleted***Amendment 33****Proposal for a regulation****Article 14 — paragraph 1***Text proposed by the Commission*

1. ***Without prejudice to clause 19(4) of the Statutes set out in Annex I, the S2R Joint Undertaking shall grant Commission staff and other persons authorised by the S2R Joint Undertaking or the Commission, as well as the Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, needed in order to conduct their audits.***

Amendment

1. The S2R Joint Undertaking shall grant Commission staff and other persons authorised by the S2R Joint Undertaking or the Commission, as well as the Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, needed in order to conduct their audits.

Amendment 34**Proposal for a regulation****Article 14 — paragraph 5 a (new)***Text proposed by the Commission**Amendment*

5a. The staff of the Joint Undertaking, the Executive Director and the members of the Governing Board shall without delay notify OLAF of any instances of fraud which have come to their attention in the fulfilment of their duties or remit, without in any way being made accountable for them as a result.

Tuesday 15 April 2014

Amendment 35**Proposal for a regulation****Article 17 — paragraph 1 a (new)**

Text proposed by the Commission

Amendment

With a view to the overall aim of the Horizon 2020 Framework Programme of achieving greater simplification and harmonisation of the European research and innovation funding landscape, Joint Undertakings shall avoid sets of rules that are different from those of the Horizon 2020 Framework Programme.

Amendment 36**Proposal for a regulation****Annex I — clause 1 — paragraph 1**

Text proposed by the Commission

Amendment

1. 'Associated Member' means a legal entity or a grouping or consortium of legal entities, established in a Member State or in a country associated to the Horizon 2020 Framework Programme, that has been selected according to the procedure set out in clause 4(2), that fulfils the conditions set out in clauses 4(3) and 4(4), and that has accepted the present Statutes by signing a letter of endorsement;

1. 'Associated Member' means a legal entity or a grouping or consortium of legal entities, established in a Member State or in a country associated to the Horizon 2020 Framework Programme, that has been selected according to the procedure set out in clause 4(2), that fulfils the conditions set out in clauses 4(3) and 4(4), and that has accepted the present Statutes by signing a letter of endorsement ***following a decision by the body responsible for its governance;***

Amendment 37**Proposal for a regulation****Annex I — clause 1 — paragraph 2**

Text proposed by the Commission

Amendment

2. 'Founding Member other than the Union' refers to ***the contributors listed in Annex II***, having individually committed to an own contribution of at least EUR 30 million for the duration of the S2R Joint Undertaking and accepted the present Statutes by signing a letter of endorsement;

2. 'Founding Member other than the Union' refers to ***single legal entities***, having individually committed to an own contribution of at least EUR 30 million for the duration of the S2R Joint Undertaking, ***based on a shared vision***, and accepted the present Statutes by signing a letter of endorsement ***following a decision by the body responsible for their governance. The Founding Members are listed in Annex II;***

Tuesday 15 April 2014

Amendment 38**Proposal for a regulation****Annex I — clause 1 — paragraph 3 — introductory part***Text proposed by the Commission*

3. 'Innovation Programmes' or 'IPs' refer to the thematic areas around which the S2R Master Plan, referred to in paragraph 4, shall be structured. The IPs shall be selected for their capacity to best deliver performance benefits to one or more operating environments and reflect a railway system approach. Notwithstanding a decision of the Governing Board to modify this structure, the S2R Master Plan should foresee the creation of at least the five following IPs:

Amendment

3. 'Innovation Programmes' or 'IPs' refer to the thematic areas around which the S2R Master Plan, referred to in paragraph 4, shall be structured. The IPs shall be selected for their capacity to best deliver performance benefits to one or more operating environments and reflect a railway system **and customer-oriented** approach. **Their definition shall also allow for pioneering innovative ideas to be developed and tested.** Notwithstanding a decision of the Governing Board to modify this structure, the S2R Master Plan should foresee the creation of at least the five following IPs:

Amendment 39**Proposal for a regulation****Annex I — clause 1 — paragraph 3 — point a***Text proposed by the Commission*

(a) Cost-efficient and Reliable High Capacity Trains;

Amendment

(a) Cost-efficient and Reliable **Trains, including** High Capacity Trains **and High Speed Trains**

Amendment 40**Proposal for a regulation****Annex I — clause 1 — paragraph 3 — point c***Text proposed by the Commission*

(c) Cost-efficient and Reliable High Capacity Infrastructure;

Amendment

(c) Cost-efficient, **sustainable** and Reliable High Capacity Infrastructure;

Tuesday 15 April 2014

Amendment 41

Proposal for a regulation

Annex I — clause 2 — point h

Text proposed by the Commission

(h) pool user requirements and define interoperability standards to guide investment in research and innovation towards operational and marketable solutions;

Amendment

(h) pool user requirements and define interoperability **specifications and technical** standards to guide investment in research and innovation towards operational and marketable solutions;

Amendment 42

Proposal for a regulation

Annex I — clause 2 — point j

Text proposed by the Commission

(j) establish and develop close and long-term cooperation between the Union, the rail manufacturing industry and other stakeholders required to develop pioneering innovations and ensure a strong market uptake of innovative solutions, including the rail operating community and other rail stakeholders, as well as actors outside the traditional rail sector;

Amendment

(j) establish and develop close and long-term cooperation between the Union, the rail manufacturing industry and other stakeholders required to develop pioneering innovations and ensure a strong market uptake of innovative solutions, including **organisations representing customers**, the rail operating community and other rail **private and public** stakeholders, **including at regional level**, as well as actors outside the traditional rail sector;

Amendment 44

Proposal for a regulation

Annex I — clause 2 — point k a (new)

Text proposed by the Commission

Amendment

(ka) **liaising with a broad range of stakeholders including research organisations and universities;**

Tuesday 15 April 2014

Amendment 45

Proposal for a regulation

Annex I — clause 3 — paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Should any member of S2R Joint Undertaking be in default of its commitments concerning its agreed financial contribution, the Executive Director shall put this in writing and set a reasonable period within which such default shall be remedied. If the situation is not remedied within that period, the Executive Director shall convene a meeting of the Governing Board to decide whether the defaulting member's membership is to be revoked or if any other measures are to be taken until its obligations have been met. The Governing Board may initially suspend the voting rights of all members in breach of their obligations, once they have been heard and given the opportunity of regularising matters.

Amendment 46

Proposal for a regulation

Annex I — clause 4 — paragraph 2

Text proposed by the Commission

Amendment

2. The Associated Members of the S2R Joint Undertaking shall be selected through an open, non-discriminatory and competitive call. **The first call for Associated Members shall be launched within three months at the latest following the establishment of the S2R Joint Undertaking. Any additional calls shall be driven by the need for key capabilities to implement the S2R Master Plan. All calls shall be published on the S2R website and communicated through the States Representatives Group and other channels in order to ensure the widest possible participation in the interest of the achievement of the objectives of the S2R Master Plan. The S2R Joint Undertaking shall encourage the participation of SMEs, and of actors from the entire rail value chain, as well as from outside the traditional rail sector.**

2. The Associated Members of the S2R Joint Undertaking shall be selected through an open, non-discriminatory and competitive call **launched by the Commission and subject to a transparent evaluation by the Governing Board. This evaluation and selection shall take into account, inter alia, the relevance and the potential added value of the applicant for the achievement of the objectives of the S2R Joint Undertaking, the financial soundness of the applicant, and any potential conflicts of interest regarding the objectives of the S2R Joint Undertaking.**

Tuesday 15 April 2014

Amendment 47

Proposal for a regulation

Annex I — clause 4 — paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Taking into account the results of the evaluation, the Commission shall make the final decision on the selection of associated members with a view to ensuring geographical balance, as well as balanced participation of SMEs, of the research community and of actors from the entire rail value chain, including from outside the traditional rail sector.

Amendment 48

Proposal for a regulation

Annex I — clause 4 — paragraph 5

Text proposed by the Commission

Amendment

5. Any member may terminate its membership to the S2R Joint Undertaking. The termination shall become effective and irrevocable six months after notification to the other members. As of then, the former member shall be discharged from any obligations other than those approved or incurred by the S2R Joint Undertaking prior to terminating the membership.

5. Any member may terminate its membership to the S2R Joint Undertaking. The termination shall become effective and irrevocable six months after notification to the other members. As of then, the former member shall be discharged from any obligations other than those approved or incurred by the S2R Joint Undertaking prior to terminating the membership. **In such cases, an account shall be opened for settlement of financial obligations between the departing member and the S2R Joint Undertaking.**

Amendment 49

Proposal for a regulation

Annex I — clause 4 — paragraph 6

Text proposed by the Commission

Amendment

6. Membership of the S2R Joint Undertaking may not be transferred to a third party without the prior and unanimous agreement of the Governing Board.

6. Membership of the S2R Joint Undertaking may not be transferred to a third party without the prior and unanimous agreement of the Governing Board. **The Commission shall be notified of such agreement and shall have the right to object.**

Tuesday 15 April 2014

Amendment 50**Proposal for a regulation****Annex I — clause 6 — point c***Text proposed by the Commission*

(c) at least one representative of Associated Members per Innovation Programme, referred to in clause 1(3). **These** representatives **will** be designated by the Governing Board of the S2R Joint Undertaking, with a view to ensuring balanced representation of actors **from** the entire rail value chain, as well as from outside the traditional rail sector.

Amendment

(c) at least one representative of Associated Members per Innovation Programme, referred to in clause 1(3). **Associated Member fulfilling, as a single legal entity, the criteria listed in clause 1(2), [meaning an own contribution of at least 30 million] and that contributes to meeting the objectives in points (a), (b) and (c) of Article 2(2), shall be represented in the Governing Board. The other** representatives **shall** be designated by the Governing Board of the S2R Joint Undertaking, with a view to ensuring balanced representation of actors, **in terms of territorial representation and guaranteeing the representation of** the entire rail value chain, as well as from outside the traditional rail sector. **At least two of these should be representatives of railway undertakings.**

Amendment 51**Proposal for a regulation****Annex I — clause 7 — paragraph 5 — subparagraph 5***Text proposed by the Commission*

A representative of the European Railway Agency **and the chairperson or the vice-chair person of the States Representatives Group** shall participate in the meetings of the Governing Board as observers.

Amendment

A representative of the European Railway Agency shall participate in the meetings of the Governing Board as observers.

Amendment 52**Proposal for a regulation****Annex I — clause 7 — paragraph 5 — subparagraph 5 a (new)***Text proposed by the Commission**Amendment*

The chairperson or the vice-chair person of the States Representatives Group shall have the right to attend meetings of the Governing Board as an observer and take part in its deliberations, but shall have no voting rights.

Tuesday 15 April 2014

Amendment 53

Proposal for a regulation

Annex I — clause 7 — paragraph 5 — subparagraph 5 b (new)

Text proposed by the Commission

Amendment

The chairperson of the Scientific Committee shall have the right, whenever issues falling within that Committee's tasks are discussed, to attend meetings of the Governing Board as an observer and take part in its deliberations, but shall have no voting rights.

Amendment 54

Proposal for a regulation

Annex I — clause 8 — paragraph - 1 (new)

Text proposed by the Commission

Amendment

The Commission, within its role in the Governing Board, shall seek to ensure coordination between the activities of the S2R Joint Undertaking and the relevant activities of the Horizon 2020 Framework Programme with a view to promoting synergies when identifying priorities covered by collaborative research.

Amendment 55

Proposal for a regulation

Annex I — clause 8 — paragraph 1 — point c a (new)

Text proposed by the Commission

Amendment

(ca) decide on the final composition of the Governing Board, in particular by selecting the representatives of Associated Members, other than those fulfilling the criteria in clause 1(2). The final selection should ensure a balanced participation of SMEs and of actors from the entire rail value chain, including from outside the traditional rail sector;

Tuesday 15 April 2014

Amendment 56

Proposal for a regulation

Annex I — clause 8 — paragraph 1 — point n a (new)

Text proposed by the Commission

Amendment

(na) ensure the transparency of the choice of any subcontracting agreements that may be established within the framework of this Regulation

Amendment 57

Proposal for a regulation

Annex I — clause 9 — paragraph 1

Text proposed by the Commission

Amendment

1. The Executive Director shall be appointed by the Governing Board, from a list of candidates proposed by the Commission, **following** an open and transparent **selection procedure**.

1. The Executive Director shall be appointed by the Governing Board **on the grounds of merit and documented administrative and managerial skills, as well as relevant competence and experience**, from a list of candidates proposed by the Commission, **after** an open and transparent **competition, following the publication of a call for expressions of interest in the Official Journal of the European Union and elsewhere. The European Parliament shall be entitled to object.**

Before being appointed, the candidate selected by the Governing Board shall answer the questions by the members of the Committee on Industry, Research and Energy and the Committee on Budgetary Control of the European Parliament.

Amendment 58

Proposal for a regulation

Annex I — clause 10 — paragraph 4 — point g a (new)

Text proposed by the Commission

Amendment

(ga) **inform the States Representatives Group and the Scientific Committee regularly of all matters relevant to their advisory role;**

Tuesday 15 April 2014

Amendment 59

Proposal for a regulation

Annex I — clause 11 — introductory part

Text proposed by the Commission

The European Railway Agency shall **have observer status on the Governing Board and** contribute to the definition and implementation of the S2R Master Plan, in particular by performing the following advisory tasks:

Amendment

The European Railway Agency shall contribute to the definition and implementation of the S2R Master Plan, in particular by performing the following advisory tasks:

Amendment 60

Proposal for a regulation

Annex I — clause 11 — point a

Text proposed by the Commission

(a) proposing possible amendments to the S2R Master Plan and to the annual work plans, in particular to ensure that research needs relating to the realisation of the Single European Railway Area are covered;

Amendment

(a) proposing possible amendments to the S2R Master Plan and to the annual work plans, in particular to ensure that research needs relating to the realisation of the Single European Railway Area are covered **and ascertaining their relevance to the objectives identified in Article 2(2)**;

Amendment 61

Proposal for a regulation

Annex I — clause 11 — point b

Text proposed by the Commission

(b) proposing, after consultation with the stakeholders referred to in Article 2(1)(e) of this Regulation, **technical standards** for research, development **and validation** activities with a view to guaranteeing the interoperability and safety of results;

Amendment

(b) proposing, after consultation with the stakeholders referred to in Article 2(1)(e) of this Regulation, **guidelines** for research **and** development activities **leading to technical standards** with a view to guaranteeing the interoperability and safety of results;

Tuesday 15 April 2014

Amendment 62**Proposal for a regulation****Annex I — clause 13 — paragraph 5 — point a***Text proposed by the Commission*

(a) the status of relevant national or regional research and innovation programmes and identification of potential areas of cooperation, including deployment of relevant technologies;

Amendment

(a) the status of relevant national or regional research and innovation programmes and identification of potential areas of cooperation, including deployment of relevant technologies **in order to benefit from synergies**;

Amendment 63**Proposal for a regulation****Annex I — clause 13 — paragraph 5 a (new)***Text proposed by the Commission**Amendment*

5a. The States Representatives Group shall receive information on a regular basis, among others on the participation in actions funded by the S2R Joint Undertaking, on the outcome of each call and project implementation, on synergies with other relevant Union programmes, on the execution of the S2R budget.

Amendment 64**Proposal for a regulation****Annex I — clause 13 — paragraph 6***Text proposed by the Commission*

6. The States Representatives Group may issue, on its own initiative, recommendations to the **S2R Joint Undertaking** on technical, managerial and financial matters, in particular when those matters affect national or regional interests. The **S2R Joint Undertaking** shall inform the States Representatives Group of the follow up it has given to such recommendations.

Amendment

6. The States Representatives Group may issue, on its own initiative, recommendations to the **Governing Board** on technical, managerial and financial matters, in particular when those matters affect national or regional interests. The **Governing Board** shall inform the States Representatives Group of the follow up it has given to such recommendations.

Tuesday 15 April 2014

Amendment 65

Proposal for a regulation

Annex I — clause 14 — paragraph 1

Text proposed by the Commission

1. In order to carry out the tasks provided for in clause 2, the Governing Board of the S2R Joint Undertaking can set up a limited number of working groups to carry out activities which are delegated to it by the Governing Board. These groups shall be composed of professionals and shall work in a transparent manner.

Amendment

1. In order to carry out the tasks provided for in clause 2, the Governing Board of the S2R Joint Undertaking can set up a limited number of working groups to carry out activities which are delegated to it by the Governing Board. These groups shall be composed of professionals **with relevant expertise including from research organisations, SMEs and railway operators** and shall work in a transparent manner.

Amendment 66

Proposal for a regulation

Annex I — clause 15 — paragraph 3 — point b

Text proposed by the Commission

- (b) in-kind contributions by the members other than the Union and their affiliated entities, consisting of the costs incurred by them in implementing indirect actions less the contribution of the Joint Undertaking and any other Union contribution to those costs.

Amendment

- (b) in-kind **or in-cash** contributions by the members other than the Union and their affiliated entities, consisting of the costs incurred by them in implementing indirect actions less the contribution of the Joint Undertaking and any other Union contribution to those costs.

Amendment 67

Proposal for a regulation

Annex 1 — clause 19

Text proposed by the Commission

1. The Executive Director shall report annually to the Governing Board on the performance of his duties in accordance with the financial rules of the S2R Joint Undertaking.
2. **By 15 February each year** the Executive Director shall submit to the Governing Board for approval an annual activity report on the progress made by the S2R Joint Undertaking in the previous calendar year, in particular in relation to the annual work plan for that year. That report shall include, inter alia, information on the following matters:
- (a) research, innovation and other actions carried out and the corresponding expenditure;

Amendment

1. The Executive Director shall report annually to the Governing Board on the performance of his duties in accordance with the financial rules of the S2R Joint Undertaking.
2. **Within two months of the closure of each financial year**, the Executive Director shall submit to the Governing Board for approval an annual activity report on the progress made by the S2R Joint Undertaking in the previous calendar year, in particular in relation to the annual work plan for that year. That report shall include, inter alia, information on the following matters:
- (a) research, innovation and other actions carried out and the corresponding expenditure;

Tuesday 15 April 2014

Text proposed by the Commission

- (b) the actions submitted, including a breakdown by participant type, including SMEs, and by country;
- (c) the actions selected for funding, including a breakdown by participant type, including SMEs, and by country and indicating the contribution of the S2R Joint Undertaking to the individual participants and actions.

Once approved by the Governing Board, the annual activity report shall be transmitted to the States Representatives Group and made publicly available.

3. The S2R Joint Undertaking shall report annually to the Commission in accordance with Article 60(5) of Regulation (EU, Euratom) No 966/2012.

4. The accounts of the S2R Joint Undertaking shall be examined by an independent audit body as laid down in Article 60(5) of Regulation (EU, Euratom) No 966/2012.

The accounts of the S2R Joint Undertaking shall not be subject to examination by the Court of Auditors.

Amendment

- (b) the actions submitted, including a breakdown by participant type, including SMEs, and by country;
- (c) the actions selected for funding, including a breakdown by participant type, including SMEs, and by country and indicating the contribution of the S2R Joint Undertaking to the individual participants and actions.

Once approved by the Governing Board, the annual activity report shall be transmitted to the States Representatives Group and made publicly available.

3. By 1 March of the following financial year, the accounting officer of the S2R Joint Undertaking shall send the provisional accounts to the Commission's accounting officer and the Court of Auditors.

By 31 March of the following financial year, the S2R Joint Undertaking shall send the report on the budgetary and financial management to the European Parliament, the Council and the Court of Auditors.

On receipt of the Court of Auditors' observations on the S2R Joint Undertaking's provisional accounts pursuant to Article 148 of the Regulation (EU, Euratom) No 966/2012, the accounting officer shall draw up the S2R Joint Undertaking's final accounts and the Executive Director shall submit them to the Governing Board for an opinion.

The Governing Board shall deliver an opinion on the S2R Joint Undertaking's final accounts.

The Executive Director shall, by 1 July following each financial year, send the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Governing Board's opinion.

The final accounts shall be published in the Official Journal of the European Union by 15 November of the following year.

The Executive Director shall send the Court of Auditors a reply to its observations made in its annual report by 30 September. The Executive Director shall also send this reply to the Governing Board.

The Executive Director shall submit to the European Parliament, at the latter's request any information required for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 165(3) of the Regulation (EU, Euratom) No 966/2012.

Tuesday 15 April 2014

P7_TA(2014)0349

Mobilisation of the European Globalisation Adjustment Fund — application EGF/2012/007 IT/VDC Technologies

European Parliament resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the mobilisation of the European Globalisation Adjustment Fund, in accordance with point 13 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management (application EGF/2012/007 IT/VDC Technologies from Italy) (COM(2014)0119 — C7-0089/2014 — 2014/2025(BUD))

(2017/C 443/30)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2014)0119 — C7-0089/2014),
 - having regard to Regulation (EC) No 1927/2006 of the European Parliament and of the Council of 20 December 2006 on establishing the European Globalisation Adjustment Fund ⁽¹⁾, (EGF Regulation),
 - having regard to Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 ⁽²⁾, and in particular Article 12 thereof,
 - having regard to the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management ⁽³⁾ (IIA of 2 December 2013), and in particular point 13 thereof,
 - having regard to trilogue procedure provided for in point 13 of the IIA of 2 December 2013,
 - having regard to the letter of the Committee on Employment and Social Affairs,
 - having regard to the report of the Committee on Budgets (A7-0261/2014),
- A. whereas the European Union has set up legislative and budgetary instruments to provide additional support to workers who are suffering from the consequences of major structural changes in world trade patterns and to assist their reintegration into the labour market,
- B. whereas the Union's financial assistance to workers made redundant should be dynamic and made available as quickly and efficiently as possible, in accordance with the Joint Declaration of the European Parliament, the Council and the Commission adopted during the conciliation meeting on 17 July 2008, and having due regard for the IIA of 2 December 2013 in respect of the adoption of decisions to mobilise the EGF,
- C. whereas Italy submitted application EGF/2012/007 IT/VDC Technologies for a financial contribution from the EGF, following 1 164 redundancies in VDC Technologies SpA and one supplier with 1 146 workers targeted for EGF co-funded measures, during the reference period from 26 February 2012 to 25 June 2012,
- D. whereas the application fulfils the eligibility criteria set up by the EGF Regulation,
1. Agrees with the Commission that the conditions set out in Article 2(a) of the EGF Regulation are met and that, therefore, Italy is entitled to a financial contribution under that Regulation;

⁽¹⁾ OJ L 406, 30.12.2006, p. 1.

⁽²⁾ OJ L 347, 20.12.2013, p. 884.

⁽³⁾ OJ C 373, 20.12.2013, p. 1.

Tuesday 15 April 2014

2. Notes that the Italian authorities submitted the application for EGF financial contribution on 31 August 2012 and regrets that its assessment was made available by the European Commission only on 5 March 2014; deplores the lengthy evaluation period of 19 months and believes that this delay contradicts the aim of the European Globalisation Adjustment Fund to provide a quick aid to workers made redundant;
3. Considers that the redundancies in VDC Technologies SpA and one supplier (manufacture of television sets, television monitors and displays as well as air-conditioning units) are linked to major structural changes in world trade patterns due to globalisation, referring to serious economic disruption for the sector of manufacture of electrical equipment due to intensified competition from third countries, particularly China;
4. Recognises the need to draw lessons from numerous EGF applications based on globalisation criterion in a given sector in view of reforming the Union trade policy, both in terms of liberalisation and trade defence instruments;
5. Notes that the 1 164 redundancies in question along with the 54 redundancies due to the same cause before and after the four-month reference period have a strong negative impact on the labour market and economic situation in the affected area located in the NUTS 3 level region ITI45 Frosinone and in the NUTS 2 level region ITI4 Lazio;
6. Welcomes the fact that, in order to provide workers with speedy assistance, the Italian authorities decided to initiate the implementation of the personalised services to the affected workers on 30 November 2012, nine months before the EGF application submission and well ahead of the final decision on granting the EGF support for the proposed coordinated package;
7. Notes that the coordinated package of personalised services to be co-funded includes measures for the reintegration of 1 146 redundant workers into employment such as occupational guidance/ skills assessment, training, service to individuals, support to entrepreneurship, recruitment bonus, participation allowance;
8. Notes that almost 40 % of dismissed workers are older than 55 years; regrets that the package does not contain any specific measures targeting older workers;
9. Points out that the package contains various types of financial allowances: allowance for workers living with persons who need care, mobility allowance, and participation allowance; points out to relatively high level of recruitment incentive (EUR 6 000 per worker) but welcomes the fact that this measure is conditioned upon offering a permanent contract or a fixed-term contract of 24 months to workers;
10. Welcomes the fact that the coordinated package of personalised services was consulted with the social partners (trade unions CGIL, USB, CISAL, CISL, UIL, UGL) and that a local support network was activated with the involvement of various local partners, and that a policy of equality of women and men as well as the principle non-discrimination will be applied during the various stages of the implementation of and in access to the EGF;
11. Recalls the importance of improving the employability of all workers by means of adapted training and the recognition of skills and competences gained throughout a worker's professional career; expects the training on offer in the coordinated package to be adapted not only to the needs of the dismissed workers but also to the actual business environment;
12. Welcomes the fact training is foreseen for every worker targeted by the EGF package; regrets however that the Commission proposal does not describe the areas and sectors in which the training will be offered;
13. Notes that the information provided on the coordinated package of personalised services to be funded from the EGF includes information on complementarity with actions funded by the Structural Funds; stresses that the Italian authorities confirm that the eligible actions do not receive assistance from other Union financial instruments; reiterates its call to the Commission to present a comparative evaluation of those data in its annual reports in order to ensure full respect of the existing regulations and that no duplication of Union-funded services can occur;

Tuesday 15 April 2014

14. Stresses that, in accordance with Article 6 of the EGF Regulation, it shall be ensured that the EGF supports the reintegration of individual redundant workers into stable employment; stresses, furthermore, that EGF assistance can co-finance only active labour market measures which lead to durable, long-term employment; reiterates that assistance from the EGF must not replace actions which are the responsibility of companies by virtue of national law or collective agreements nor measures restructuring companies or sectors;

15. Welcomes the agreement reached between the European Parliament and the Council regarding the new EGF Regulation, for the period 2014-2020, to reintroduce the crisis mobilisation criterion, to increase Union financial contribution to 60 % of the total estimated cost of proposed measures, to increase efficiency for the treatment of EGF applications in the Commission and by the European Parliament and the Council by shortening time for assessment and approval, to widen eligible actions and beneficiaries by introducing self-employed persons and young people and to finance incentives for setting up own businesses;

16. Approves the decision annexed to this resolution;

17. Instructs its President to sign the decision with the President of the Council and arrange for its publication in the *Official Journal of the European Union*;

18. Instructs its President to forward this resolution, including its annex, to the Council and the Commission.

Tuesday 15 April 2014

ANNEX

DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the mobilisation of the European Globalisation Adjustment Fund, in accordance with Point 13 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management (application EGF/2012/007 IT/VDC Technologies from Italy)

(The text of this annex is not reproduced here since it corresponds to the final act, Decision 2014/254/EU.)

Tuesday 15 April 2014

P7_TA(2014)0350

Mobilisation of the European Globalisation Adjustment Fund — application EGF/2012/004 ES/Grupo Santana

European Parliament resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the mobilisation of the European Globalisation Adjustment Fund, in accordance with point 13 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management (application EGF/2012/004 ES/Grupo Santana from Spain) (COM(2014)0116 — C7-0101/2014 — 2014/2027(BUD))

(2017/C 443/31)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2014)0116 — C7-0101/2014),
 - having regard to Regulation (EC) No 1927/2006 of the European Parliament and of the Council of 20 December 2006 on establishing the European Globalisation Adjustment Fund ⁽¹⁾ (EGF Regulation),
 - having regard to Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 ⁽²⁾, and in particular Article 12 thereof,
 - having regard to the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management ⁽³⁾ (IIA of 2 December 2013), and in particular point 13 thereof,
 - having regard to trilogue procedure provided for in point 13 of the IIA of 2 December 2013,
 - having regard to the letter of the Committee on Employment and Social Affairs,
 - having regard to the report of the Committee on Budgets (A7-0260/2014),
- A. whereas the European Union has set up legislative and budgetary instruments to provide additional support to workers who are suffering from the consequences of major structural changes in world trade patterns and to assist their reintegration into the labour market,
- B. whereas the Union's financial assistance to workers made redundant should be dynamic and made available as quickly and efficiently as possible, in accordance with the Joint Declaration of the European Parliament, the Council and the Commission adopted during the conciliation meeting on 17 July 2008, and having due regard for the IIA of 2 December 2013 in respect of the adoption of decisions to mobilise the EGF,
- C. whereas Spain submitted application EGF/2012/004 ES/Grupo Santana ⁽⁴⁾ for a financial contribution from the EGF, following 330 redundancies in Grupo Santana and 15 suppliers and downstream producers with 285 workers targeted for EGF co-funded measures, during the reference period from 15 November 2011 to 15 March 2012,
- D. whereas the application fulfils the eligibility criteria set up by the EGF Regulation,

⁽¹⁾ OJ L 406, 30.12.2006, p. 1.

⁽²⁾ OJ L 347, 20.12.2013, p. 884.

⁽³⁾ OJ C 373, 20.12.2013, p. 1.

⁽⁴⁾ Santana Motor S.A.U.; Santana Motor Andalucía S.L.U. and Santana Militar S.L.U.

Tuesday 15 April 2014

1. Agrees with the Commission that the conditions set out in Article 2(c) of the EGF Regulation are met and that, therefore, Spain is entitled to a financial contribution under that Regulation;
2. Notes the explanations of the Commission that the 330 layoffs within the reference period and the additional 689 redundancies are related to the same collective dismissal procedure and that the dismissals combined with very fragile economic and social situation of the region fulfil the condition of exceptionality of the case in line with Article 2(c) of the EGF Regulation;
3. Notes that the Spanish authorities submitted the application for EGF financial contribution on 16 May 2012 and regrets that its assessment was made available by the European Commission only on 5 March 2014; deplores the lengthy period of evaluation of 22 months and believes that this delay contradicts the aim of the European Globalisation Adjustment Fund to provide a quick aid to workers made redundant;
4. Considers that the redundancies in Grupo Santana and 15 suppliers and downstream producers are linked to major structural changes in world trade patterns due to globalisation, referring to a reduction of the EU share in world motor vehicle production and the rapid growth in Asian markets which EU producers are less able to benefit from;
5. Notes that the 330 redundancies in question along with the 689 redundancies due to the same cause before and after the four-month reference period have a significantly negative impact on employment and the economy at local and NUTS III level, and aggravates already fragile economic situation of the affected territory;
6. Notes that this is yet another EGF application addressing dismissals in the automotive sector and that with 17 applications this sector has been subject to the most numerous EGF applications submitted both in relation to crisis and to globalisation criterion; points out that this is another case concerning the automotive industry which demonstrates the need for a Union industrial strategy and illustrates how the EGF assists workers in the restructuring process;
7. Welcomes the fact that the region of Andalucía, where the unemployment rate is much higher than the national and Union average, yet again avails itself of the EGF; points to the fact that EGF has already supported workers of Delphi located in Andalucía (EGF/2008/002 ES/Delphi);
8. Welcomes the fact that in order to provide workers with speedy assistance, the Spanish authorities decided to initiate the implementation of the personalised services to the affected workers on 1 August 2011, ten months before EGF application submission and well ahead of the final decision on granting the EGF support for the proposed coordinated package;
9. Notes that the coordinated package of personalised services to be co-funded includes measures for the reintegration of 285 redundant workers into employment such as vocational on-the-job training, counselling to business projects, active job search assistance and job matching;
10. Welcomes the fact that the training offered is of considerable length and that it will be complemented with on-the-job activities; welcomes the fact that the training will be matched to the skills and qualifications needs of the enterprises settling in the business park, which makes part of the measures provided in addition to the EGF funded package;
11. In this context, welcomes the fact that the city of Linares, heavily affected by the closure of Santana (and of its suppliers) which was the main employer in the municipality, took a global and comprehensive approach reflected in the strategy of rehabilitation of Grupo Santana business park to attract new investors; is of the view that the fact that the city of Linares decided to improve the environment for businesses will boost the effect of the EGF measures targeting workers;
12. Welcomes the fact that the city of Linares consulted the package with the social partners (trade unions MCA-UGT Andalucía and Federación de la industria de CCOO-Andalucía) and that the social partners are monitoring the implementation of the measures, and that a policy of equality of women and men as well as the principle of non-discrimination will be applied during the various stages of the implementation of and in access to the EGF;

Tuesday 15 April 2014

13. Recalls the importance of improving the employability of all workers by means of adapted training and the recognition of skills and competences gained throughout a worker's professional career; expects the training on offer in the coordinated package to be adapted not only to the needs of the dismissed workers but also to the actual business environment;

14. Points out the fact that the EGF will provide 'training wage' allowances amounting to 150 % of the Spanish minimum wage; welcomes however the confirmation of the Commission that those allowances do not substitute the unemployment benefits and will be provided in addition to the unemployment benefits paid out under the national legislation; stresses in this context that the new EGF regulation for 2014-2020 will limit the inclusion of financial allowances in the package to a maximum of 35 % of the cost of the measures and that accordingly the rate of allowances within the coordinated package for this demand will not repeat under this new regulation;

15. Welcomes the Spanish regional and Linares local authorities initiative to invest in the industrial facilities and promotion of the renewed industrial area in order to attract new companies and to diversify its industrial structure rather than focusing on the automotive sector; underlines that these efforts are not submitted for EGF co-financing and are financed by regional and local budgets under severe constraints after the loss of tax income due to the plant closure;

16. Notes that the information provided on the coordinated package of personalised services to be funded from the EGF includes information on complementarity with actions funded by the Structural Funds; stresses that the Spanish authorities confirm that the eligible actions do not receive assistance from other Union financial instruments; reiterates its call to the Commission to present a comparative evaluation of those data in its annual reports in order to ensure full respect of the existing regulations and that no duplication of Union-funded services can occur;

17. Stresses that, in accordance with Article 6 of the EGF Regulation, it shall be ensured that the EGF supports the reintegration of individual redundant workers into stable employment; stresses, furthermore, that EGF assistance can co-finance only active labour market measures which lead to durable, long-term employment; reiterates that assistance from the EGF must not replace actions which are the responsibility of companies by virtue of national law or collective agreements nor measures restructuring companies or sectors;

18. Welcomes the agreement reached between the European Parliament and the Council regarding the new EGF Regulation, for the period 2014-2020, to reintroduce the crisis mobilisation criterion, to increase Union financial contribution to 60 % of the total estimated cost of proposed measures, to increase efficiency for the treatment of EGF applications in the Commission and by the European Parliament and the Council by shortening time for assessment and approval, to widen eligible actions and beneficiaries by introducing self-employed persons and young people and to finance incentives for setting up own businesses;

19. Approves the decision annexed to this resolution;

20. Instructs its President to sign the decision with the President of the Council and arrange for its publication in the *Official Journal of the European Union*;

21. Instructs its President to forward this resolution, including its annex, to the Council and the Commission.

Tuesday 15 April 2014

ANNEX

DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the mobilisation of the European Globalisation Adjustment Fund, in accordance with Point 13 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management (application EGF/2012/004 ES/Grupo Santana from Spain)

(The text of this annex is not reproduced here since it corresponds to the final act, Decision 2014/253/EU.)

Tuesday 15 April 2014

P7_TA(2014)0351

Deposit Guarantee Schemes ***II

European Parliament legislative resolution of 15 April 2014 on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council Deposit Guarantee Schemes (recast) (05199/1/2014 — C7-0094/2014 — 2010/0207(COD))

(Ordinary legislative procedure: second reading)

(2017/C 443/32)

The European Parliament,

- having regard to the Council position at first reading (05199/1/2014 — C7-0094/2014),
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Danish Parliament, the German Bundestag, the German Bundesrat and the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Central Bank of 16 February 2011 ⁽¹⁾,
 - having regard to its position at first reading ⁽²⁾ on the Commission proposal to Parliament and the Council (COM(2010)0368),
 - having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 72 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on Economic and Monetary Affairs (A7-0216/2014),
1. Approves the Council position at first reading;
 2. Notes that the act is adopted in accordance with the Council position;
 3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;
 4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;
 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 99, 31.3.2011, p. 1.

⁽²⁾ OJ C 249 E, 30.8.2013, p. 81.

Tuesday 15 April 2014

P7_TA(2014)0352

Alternative fuels infrastructure *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on the deployment of alternative fuels infrastructure (COM(2013)0018 — C7-0022/2013 — 2013/0012(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/33)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0018),
 - having regard to Article 294(2) and Article 91 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0022/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 22 May 2013 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 4 July 2013 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 26 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism and the opinion of the Committee on Industry, Research and Energy (A7-0444/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0012

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the deployment of alternative fuels infrastructure

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/94/EU.)

⁽¹⁾ OJ C 271, 19.9.2013, p. 111.

⁽²⁾ OJ C 280, 27.9.2013, p. 66.

Tuesday 15 April 2014

P7_TA(2014)0353

Dimensions and weights of road vehicles circulating within the Community *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (COM(2013)0195 — C7-0102/2013 — 2013/0105(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/34)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0195),
 - having regard to Article 294(2) and Article 91 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0102/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 11 July 2013 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism (A7-0256/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0105

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Council Directive 96/53/EC laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 thereof,

⁽¹⁾ OJ C 327, 12.11.2013, p. 133.

Tuesday 15 April 2014

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

after consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) The White Paper 'Roadmap to a Single European Transport Area — Towards a competitive and resource efficient transport system' published in 2011 emphasised the need to reduce greenhouse gas emissions, particularly carbon dioxide (CO₂) emissions, by 60 % in comparison with 1990 levels by 2050, **as well as by 20 % by 2020**. [Am. 1]
- (1a) **As there are currently no policies in place to deal with the rising CO₂ emissions from trucks, the Commission should assess the introduction of fuel efficiency standards for trucks, further extending its legislative approach in respect of cars and vans.** [Am. 2]
- (2) In this context, the White Paper proposed to adapt Council Directive 96/53/EC ⁽³⁾ in the aim of reducing energy consumption and greenhouse gas emissions, so as to adapt the legislation to technological developments and changing market needs and to facilitate intermodal transport.
- (3) Technological developments include the possibility of attaching retractable or foldable aerodynamic devices to the rear of vehicles, mainly trailers or semi-trailers, but which then exceed the maximum lengths allowed under Directive 96/53/EC. This equipment may be installed as soon as this Directive enters into force, as the products are available on the market and already used in other continents. **The same applies to energy-absorbing aerodynamic cowls and underrun protective devices affixed in the area of the wheels on the sides and at the rear under the trailers, semi-trailers and vehicles. These can significantly improve the energy efficiency of the vehicle while also significantly reducing the risk of injury to other road users. This Directive should also encourage and facilitate innovation in vehicle and transport unit design.** [Am. 3]
- (3a) **The Commission should develop an approach aimed at reducing empty runs in road freight transport within the framework of measures concerning 'weights and dimensions', as well as minimum harmonisation rules for road cabotage, in order to avoid dumping practices. Furthermore, the review of Directive 1999/62/EC of the European Parliament and of the Council ⁽⁴⁾ ('the Eurovignette Directive') should also be used to reflect progress in estimating the external costs, and to mandate the internalisation of external costs, for heavy goods vehicles. The Commission should present, before 1 January 2015, a proposal to amend the Eurovignette Directive.** [Am. 4]

⁽¹⁾ OJ C 327, 12.11.2013, p. 133.

⁽²⁾ Position of the European Parliament of 15 April 2014.

⁽³⁾ Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorized dimensions in national and international traffic and the maximum authorized weights in international traffic (OJ L 235, 17.9.1996, p. 59).

⁽⁴⁾ **Directive 1999/62/EC of the European Parliament and of the Council of 17 June 1999 on the charging of heavy goods vehicles for the use of certain infrastructures (OJ L 187, 20.7.1999, p. 42).**

Tuesday 15 April 2014

- (4) **Heavy-goods vehicles are responsible for about 26 % of road transport CO₂ emissions in Europe while their fuel efficiency has hardly improved over the last 20 years.** The improved aerodynamics of the cabs of motor vehicles would also allow significant gains ~~on~~ in the energy performance of vehicles, in conjunction with the devices mentioned in recital 3 above, **and are urgently needed in order for the road freight sector to significantly reduce vehicle emissions.** However, this improvement is impossible under the current maximum lengths set by Directive 96/53/EC without reducing the vehicle load capacity and threatening the economic equilibrium of the sector. Therefore a derogation from this maximum length is required. **Any such derogation should not be used to increase the payload of the vehicle.** [Am. 5]
- (5) In its policy orientations on road safety 2011-2020, the Commission set out measures to make vehicles safer and better protect vulnerable road users. The importance of visibility for vehicle drivers was also underlined in the Commission's report to the European Parliament and the Council on the implementation of Directive 2007/38/EC of the European Parliament and of the Council ⁽¹⁾. A new cab profile will also contribute to improving road safety by reducing the blind spot in the drivers' vision, including under the windscreen **and to the side of the vehicle**, which should help save the lives of many vulnerable road users such as pedestrians or cyclists. **The new cab profile should therefore, after an appropriate transitional period, become mandatory.** This new profile ~~could~~ **should** also incorporate energy absorption structures in the event of a collision. The potential gain in the volume of the cab would also improve the driver's comfort and safety. [Am. 6]
- (6) Aerodynamic devices and their installation in vehicles must be tested, **in accordance with the test procedure for the measurement of aerodynamic performance which is being developed by the Commission**, before being put on the market. To this end, Member States are to issue certificates that will be recognised by other Member States. **The Commission should develop detailed technical guidelines on the application and requirements for certificates.** [Am. 7]
- (6a) **The 2011 White Paper on Transport provides that 30 % of road freight carried over distances of more than 300 km should shift to other modes, such as rail or waterborne transport, by 2030, and more than 50 % by 2050, facilitated by efficient and green freight corridors. In order to meet this goal, appropriate infrastructure will need to be developed. This goal was approved by the European Parliament in its resolution of 15 December 2011 on the Roadmap to a Single European Transport Area — Towards a competitive and resource efficient transport system ⁽²⁾.** [Am. 8]
- (6b) **In order to meet the objectives of the 2011 White Paper on Transport, the revision of Directive 96/53/EC will present an opportunity to improve the safety and comfort of drivers, taking into account the requirements laid down in Council Directive 89/391/EEC ⁽³⁾ ('the Occupational Health and Safety Framework Directive').** [Am. 9]
- (7) Longer vehicles may be used in cross-border transport if the two Member States concerned already allow it and if the conditions for derogation under Article 4(3), (4) or (5) of the Directive are met. The European Commission has already provided guidance on the application of Article 4 of the Directive. The transport operations referred to in Article 4(4) do not have a significant impact on international competition if the cross-border use remains limited to two Member States where the existing infrastructure and the road safety requirements allow it. This balances the Member States' right under the principle of subsidiarity to decide on transport solutions suited to their specific circumstances with the need to prevent such policies from distorting the internal market. The provisions of Article 4 (4) are clarified in this respect. [Am. 10]

⁽¹⁾ Directive 2007/38/EC of the European Parliament and of the Council of 11 July 2007 on the retrofitting of mirrors to heavy goods vehicles registered in the Community (OJ L 184, 14.7.2007, p. 25).

⁽²⁾ OJ C 168 E, 14.6.2013, p. 72.

⁽³⁾ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

Tuesday 15 April 2014

- (8) Using alternative engines that no longer rely only on fossil fuels and are therefore non-polluting or less polluting, such as electric or hybrid engines for heavy-duty vehicles or buses (mainly in urban or suburban environments) generates extra weight which should not be counted at the expense of the effective load of the vehicle so that the road transport sector is not penalised in economic terms. **Vehicles equipped with low-carbon technologies should be permitted to exceed the maximum weight by up to one tonne, depending on the weight required for the technology. However, the extra weight should not increase the load capacity of the vehicle. The principle of technological neutrality should be maintained.** [Am. 11]
- (9) The White Paper on Transport also stresses the need to monitor developments in intermodal transport, particularly in the area of containerisation, where 45-foot containers are increasingly used. They are transported by rail or inland waterways. But the road components of intermodal journeys can only be undertaken today if both the Member States and the transporters follow cumbersome administrative procedures or if these containers have patented chamfered corners, the cost of which is prohibitive. Increasing the length of the vehicles transporting them by 15 cm could eliminate these administrative procedures for transporters and facilitate intermodal transport, without risk or prejudice to the infrastructure or other road users. The small increase that this 15 cm represents in relation to the length of an articulated truck (16,50 m) does not constitute an additional risk to road safety. ~~In the policy orientation of the White Paper on Transport, this increase is however authorised only for intermodal transport, for which the road component does not exceed 300 km for operations involving a rail, river or sea component. This distance appeared sufficient to link an industrial or commercial site with a freight terminal or a river port. To link a seaport and support the development of motorways of the sea, a longer distance is possible for a short intra-European maritime transport operation.~~ [Am. 12]
- (10) To further promote intermodal transport and take into account the unladen weight of 45-foot containers, the provision authorising the circulation of 44-tonne combinations of vehicles with 5 or 6 axles transporting 40-foot containers in intermodal transport should be extended to those carrying 45-foot containers.
- (11) Since the adoption of Directive 96/53/EC, the average weight of bus passengers and their luggage has increased substantially, leading to a gradual reduction in the number of passengers carried, given the weight limits imposed by the Directive. The need to promote public transport over private transport in the interests of better energy efficiency means that the previous number of bus passengers must be re-established, taking into account this increase in their weight and that of their luggage. This can be done by increasing the authorised weight for buses with two axles, within limits that nonetheless ensure that the infrastructure is not damaged through faster erosion.
- (12) The authorities responsible for enforcing road transport-related requirements note a high number of infringements, sometimes serious, particularly in relation to the weight of transport vehicles. This situation stems from the insufficient number of checks conducted under Directive 96/53/EC, or from their inefficiency. Furthermore, the procedures and rules for checks differ between Member States, creating legal uncertainty for drivers of vehicles operating in several Member States of the Union. Furthermore, transporters that do not comply with the relevant rules enjoy a significant competitive advantage over competitors that do comply with the rules, and over other modes of transport. This situation constitutes an obstacle to the proper functioning of the internal market **and a risk to road safety**. It is therefore important that Member States increase the pace **and efficiency** of checks carried out, both the manual checks and the pre-selections for manual checks, **based on a risk-rating system**. [Am. 13]
- (13) Simple technological solutions, fixed or mobile, are now available that allow inspectors to preselect vehicles suspected of infringements without stopping the vehicles in question, which is less disadvantageous in terms of traffic flow, less onerous and allows optimal safety conditions. Some devices may be installed onboard heavy goods vehicles and give the driver a way of checking whether his or her vehicle is compliant with the law. These onboard devices may also use a microwave communication interface to communicate their data to officials or to roadside automatic inspection systems without stopping the vehicle. The pre-selection should have a minimum threshold of one weighing per 2 000 vehicle kilometres to ensure the effectiveness of the roadside checks on the territory of the Union, because this would allow every vehicle to be checked on a statistical average of every three days.

Tuesday 15 April 2014

- (14) The observation of a high number of infringements of the provisions of Directive 96/53/EC is to a large extent due to the non-deterrent level of penalties prescribed by Member States' legislation for violations of these rules, or even the absence of any such penalties. This weak point is further compounded by the wide variety in the levels of administrative penalties applicable in the different Member States. To remedy these weak points, the levels and categories of administrative penalties for infringements of Directive 96/53/EC should be approximated at Union level. These administrative penalties should be effective, proportionate, ~~and~~ **dissuasive and non-discriminatory.** [Am. 14]
- (15) The inspection authorities in the Member States must be able to exchange information to make checking the weight of vehicles or vehicle combinations more effective at international level, and to facilitate the smooth operation of these checks, in particular the identification of offenders, the description of offences and penalties applied, and the state of good repute of the undertaking concerned. The contact point designated in accordance with Article 18(1) of Regulation (EC) No 1071/2009 of the European Parliament and of the Council ⁽¹⁾ could serve as a relay for this exchange of information.
- (16) The European Parliament and the Council should be regularly informed of the checks on road traffic carried out by the Member States **through their respective contact points.** This information, provided by the Member States, will enable the Commission to ensure compliance with this Directive by hauliers and to define whether or not additional coercive measures should be developed. [Am. 15]
- (16a) The Commission should review Annex I to Directive 96/53/EC and report on its implementation, taking into account, inter alia, impacts on international competition, modal split, costs of infrastructure adaption and the environmental and safety objectives of the European Union as set in the 2011 White Paper on Transport.** [Am. 16]
- (17) The Commission should be empowered to adopt delegated acts, in accordance with Article 290 of the Treaty on the Functioning of the European Union, to define the requirements imposed on new aerodynamic **and underrun protective** devices placed **at the sides and** in the rear of the vehicle or the design of new motor vehicles, **with a view to reviewing European type-approval procedures as referred to in Directive 2007/46/EC of the European Parliament and of the Council** ⁽²⁾ **within the framework of UNECE regulations,** as well as the technical specifications to ensure full interoperability of onboard weighing devices, and guidelines on the procedures for checking the weight of vehicles in circulation. It is particularly important that the Commission carry out appropriate consultations during its preparatory work, including at expert level. **The consultations should include the interested parties such as manufacturers, drivers, road safety associations, traffic authorities, and training centres.** The Commission, ~~when preparing and drawing up delegated acts, shall ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council~~ **shall publish a report on the results of the consultation. The interested parties should be left sufficient time to comply with these requirements.** [Am. 17]
- (18) Since the objectives of this Directive cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of this Directive, be better achieved at Union level, the Union may take the necessary measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in the same Article, this Directive does not exceed what is necessary in order to achieve that objective.
- (19) Directive 96/53/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/53/EC is hereby amended as follows:

- (1) The references to Council Directive 70/156/EEC are replaced by a reference to Directive 2007/46/EC.
- (2) The following definitions are added to the first subparagraph of Article 2:

⁽¹⁾ Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator and repealing Council Directive 96/26/EC (OJ L 300, 14.11.2009, p. 51).

⁽²⁾ **Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (OJ L 263, 9.10.2007, p. 1.)**

Tuesday 15 April 2014

- ~~‘hybrid propulsion vehicle’~~ **‘low carbon technology’** means **technology which does not fully rely on fossil oil sources in the energy supply to transport and which significantly contribute to the decarbonisation of transport. The sources include:** a vehicle within the meaning of Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles ⁽¹⁾; equipped with one or more traction motor(s) operated by electric power and not permanently connected to the grid and one or more traction motor(s) operated by internal combustion;
- *electricity,*
 - *hydrogen,*
 - *synthetic fuels,*
 - *advanced Biofuels,*
 - *natural gas, including biomethane, in gaseous form (compressed natural gas — CNG) and liquefied form (liquefied natural gas — LNG), and*
 - *waste heat.* [Am. 18]
- ~~‘electric vehicle’~~ means a vehicle within the meaning of Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles ⁽²⁾; equipped with one or more traction motor(s) operated by electric power and not permanently connected to the grid; [Am. 19]
- ~~‘intermodal transport~~ **loading** unit’ means a unit belonging to one of the following categories: container, swap body, semi-trailer; [Am 20. This amendment applies throughout the text]
- (a) The word ‘national’ is deleted from points (a) and (b) of paragraph 1. [Am. 21]
- (b) The first phrase of the second subparagraph of Article 4(4) is replaced by the following phrase:
- ~~‘Transport operations shall be considered to not significantly affect international competition in the transport sector if they take place on the territory of a Member State or, for a cross-border operation, between only two neighbouring Member States who have both adopted measures taken in application of this paragraph, and if one of the conditions under (a) and (b) is fulfilled.’~~ [Am. 22]
- (3) Article 4(6) is deleted.
- (4) Article 5 is amended as follows:
- (a) The words ‘Without prejudice to Article 4 (6):’ are deleted.
 - (b) Point (b) is deleted.
- (5) Article 8 is replaced by the following:
- ‘Article 8
1. With the aim of improving the aerodynamic performance of vehicles or combinations of vehicles, vehicles or combinations of vehicles equipped with devices that meet the criteria set out below may exceed the maximum lengths provided for in point 1.1 of Annex I **by up to 500 mm**. The only purpose of these exceedances is to allow the addition to the rear of vehicles or vehicle combinations of devices increasing their aerodynamic characteristics. [Am. 23]

⁽¹⁾ OJ L 263, 9.10.2007, p. 1.

⁽²⁾ OJ L 263, 9.10.2007, p. 1.

Tuesday 15 April 2014

2. The performance and safety requirements to be met by the devices referred to in the first paragraph are as follows:

— significant improvement in the aerodynamic performance of the vehicles,

— in terms of road safety and safety of intermodal transport, in particular:

(i) secure attachment of the devices in such a way as to ~~reduce their~~ **ensure that there is no** risk of their detachment ~~over time~~, [Am. 24]

(ii) day and night markings **in accordance with type-approval rules on the installation of lighting and light-signalling devices**, effective even in poor weather conditions, that ~~allows~~ **allow** other road users to gauge the external bodywork of the vehicle, [Am. 25]

(iii) a design that limits the risks for other vehicles and their passengers in the event of collision,

(iv) the device does not significantly increase the risk of being overturned by crosswinds,

(iva) a design which does not reduce the driver's visibility of the rear of the vehicle, [Am. 26]

— integration into existing networks, in particular:

(i) the maintenance of the manoeuvrability of vehicles or combinations of vehicles on urban and inter-urban road infrastructures,

(ii) the inclusion of the trailers and semi-trailers concerned in the rail, river and sea units during intermodal transport operations,

(iii) these devices can be easily folded, retracted or removed ~~by the driver~~. [Am. 27]

The exceedances of maximum lengths do not increase the **load** capacity of vehicles or combinations of vehicles. [Am. 28]

3. Before being put on the market, the additional aerodynamic devices and their installation on vehicles shall be authorised by the Member States, ~~which~~ **within the framework of Directive 2007/46/EC** of the European Parliament and of the Council (*). **Member States** shall issue a certificate to this effect, attesting compliance with the requirements mentioned in paragraph 2 above and indicating that the device contributes significantly to improving aerodynamic performance. The certificates of authorisation issued in one Member State shall be recognised by the other Member States. [Am. 29]

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 16, to complement the requirements referred to in paragraph 2. These shall take the form of technical characteristics, minimum levels of performance, design constraints, and procedures for the establishment of the test certificate referred to in paragraph 3. **The delegated acts shall be, for the first time, adopted no later than 2 years after the publication of this Directive.** [Am. 30]

When exercising its power, the Commission shall ensure coherence with the Union's legal acts on type approval. [Am. 31]

~~5. Pending the adoption of the delegated acts, the vehicles or combinations of vehicles equipped with aerodynamic devices to the rear, which meet the requirements referred to in paragraph 2 and were tested in accordance with paragraph 3 may circulate if their length exceeds the length laid down in Annex I, point 1.1 by no more than two metres. This transitional measure shall apply from the date of entry into force of this Directive.~~ [Am. 32]

(*) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (OJ L 263, 9.10.2007, p. 1).'

(6) Article 8a is deleted.

Tuesday 15 April 2014

(7) Article 9 is replaced by the following:

‘Article 9

1. In the aim of improving the aerodynamic performance and road safety of vehicles or combinations of vehicles, vehicles or combinations of vehicles that meet the criteria set out in paragraph 2 below may exceed the maximum lengths provided for in point 1.1 of Annex I. The main purpose of these exceedances is to allow the construction of tractor cabs improving the aerodynamic characteristics of vehicles or combinations of vehicles, and improving road safety **for vulnerable road users and vehicles involved in rear-end collisions**. [Am. 33]

2. The performance and safety requirements to be met by the cabs referred to in the first paragraph are as follows:

— improved aerodynamic performance of the vehicles,

— enhanced road safety and security in intermodal transport, in particular to ensure that the front of the cab

(i) ~~makes~~ **improves direct vision to make** vulnerable road users more visible to the driver, in particular by reducing the blind ~~spot~~ **spots** under the front windscreen **and all around the cab, and, where necessary, by fitting additional equipment, such as mirrors and camera systems**, [Am. 34]

(ii) **reduces** the damage in the event of a collision **with other vehicles and improves the energy absorption performance by fitting of an energy absorbing crash management system**, [Am. 35]

(iii) **improves pedestrian protection by adjusting the frontal design to minimise the risk of overruns in case of collisions with vulnerable road users by encouraging the sideways diversion of vulnerable users**, [Am. 36]

— the manoeuvrability of vehicles or vehicle combinations in infrastructure and without imposing restrictions on the use of vehicles in intermodal terminals,

— the comfort and safety of the drivers **with a view to improving workplace conditions**. [Am. 37]

The exceedances of the maximum length shall not lead to the increase in the load capacity of vehicles or combinations of vehicles.

2a. **With the aim of improving the driver's safety and comfort, and ultimately to ensure the improvement of road safety of the vehicles in the scope of this Directive, the safety and comfort requirements referred to in Article 9(2) to be met by the driver's cabs are as follows:**

— **compliance with the requirements set out in Council Directive 89/391/EEC (*) ('the Occupational Health and Safety Framework Directive'), with its hierarchy of prevention measure for the elimination of sources of whole-body vibration and of musculoskeletal disorders;**

— **the provision of the driver's cab with safety features starting with a secure fire exit of the cab;**

— **the increase in size of the driver's cab to adapt to comfort and safety requirements for driver's seats and couchettes taking into account emergency situations**. [Am. 38]

3. Before they are put on the market, the aerodynamic **and safety** performance of new motor vehicle designs shall be tested **within the framework of Directive 2007/46/EC** by Member States, who will issue a certificate to this end. This will certify compliance with the requirements of paragraph 2 above. **The test of the aerodynamic performance of these vehicles shall be in line with the relevant rules for measurement of aerodynamic performance developed by the Commission**. The test certificates issued in one Member State shall be recognised by the other Member States. [Am. 39]

Tuesday 15 April 2014

3a. New N2 and N3 vehicles and combination of vehicles shall use cabs that comply with the safety requirements referred to in Article 9(2) from [seven years from the entry into force of this Directive]. [Am. 40]

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 16 **and in line with the existing UN ECE regulations**, to complement the requirements which the new tractor cabs must meet, and which are referred to in paragraph 2. These shall take the form of technical characteristics, minimum levels of **safety and aerodynamic** performance, design constraints, and procedures for the establishment of the test certificate referred to in paragraph 3. **The delegated acts shall be, for the first time, adopted no later than 2 years after the publication of this Directive.** [Am. 41]

(*) **Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).'**

(8) In Article 10, the words 'from the date in Article 11' are replaced by the words '17 September 1997'.

(9) Article 10a is replaced by the following:

'Article 10a

The maximum weights of vehicles ~~with hybrid propulsion or fully electric propulsion~~ **equipped with low carbon technologies** shall be those set out in Annex I, point ~~2.3.1~~**2.3.4.** [Am. 42]

The vehicles ~~with hybrid or electric propulsion~~ **equipped with low-carbon technologies** must however comply with the limits set out in Annex I point 3: maximum authorized axle weight.' [Am. 43]

(10) Article 11 is replaced by the following:

'Article 11

The maximum dimensions laid down in Annex I points 1.1 and 1.6 may be exceeded by 15 cm for vehicles or combinations of vehicles engaged in the transport of 45-foot containers or swap bodies, if the road transport of the container or swap body is part of ~~an intermodal~~ **a combined** transport operation. [Am. 44]

~~For the purposes of this Article, and of point 2.2.2(c) of Annex I, an intermodal transport operation shall include at least rail, river or sea transport at least. It shall also include a road section for its initial and/or terminal journey. Each of these road sections shall be less than 300 km in the territory of the European Union or just as far as the closest terminals between which there is a regular service. A transport operation shall also be regarded as intermodal transport if it uses intra-European short-sea shipping, regardless of the lengths of the initial and terminal road journeys. The initial road journey and the terminal road journey for an operation using intra-European short-sea shipping takes place from the point where the goods are loaded to the nearest appropriate seaport for the initial leg, and/or where appropriate between the nearest appropriate seaport and the point where the goods are unloaded for the final leg. By 2017, the Commission shall, if appropriate, make a legislative proposal to amend Council Directive 92/106/EEC (*) and, in particular, the existing definition of combined transport, in order to take into account the development of containerisation and in view of facilitating the development of efficient intermodal transport.~~ [Am. 45]

(*) **Council Directive 92/106/EEC of 7 December 1992 on the establishment of common rules for certain types of combined transport of goods between Member States (OJ L 368, 17.12.1992, p. 38).'**

(11) Article 12 is replaced by the following:

'Article 12

1. The Member States shall establish a system for pre-selecting, ~~and~~ targeting **and carrying out** checks on vehicles or combinations of vehicles in circulation, in order to ensure compliance with the requirements of this Directive. [Am. 46]

Tuesday 15 April 2014

Member States shall ensure that the information concerning the number and severity of any infringements of this Directive that an individual undertaking has committed is introduced into the risk rating system established under Article 9 of Directive 2006/22/EC of the European Parliament and of the Council (*). [Am. 47]

When identifying vehicles to be subject to checks, Member States may select as a priority vehicles operated by undertakings with a high-risk profile as referred to in Directive 2006/22/EC. Vehicles may also be selected randomly for checks. [Am. 48]

2. After the expiry of a period of two years from the date of entry into force of this Directive, Member States shall measure the weight of vehicles or combination of vehicles in circulation. The purpose of these pre-selection measures is to **increase the efficiency of the checks and** identify vehicles that are likely to have committed an offence and that should be checked manually. These measures may be taken with the aid of automatic systems set up on the infrastructure, or onboard systems installed in vehicles in line with paragraph 6 below. The automatic systems must enable the identification of the vehicles suspected of exceeding the maximum authorised weights. As these automatic systems are only to be used for pre-selection purposes, and not to define an offence, they do not have to be certified by the Member States. **The onboard systems may be integrated with digital tachographs installed in vehicles in line with Regulation (EU) No 165/2014 of the European Parliament and of the Council (**). [Am. 49]**

3. Member States shall take a number of preselection measures equivalent to at least one weighing per 2 000 vehicle kilometres per year on average.

4. Member States shall ensure that the competent authorities exchange the information necessary to make these checks more effective at EU level, and to facilitate their conduct, notably through the national contact point responsible for the exchange of information with the other Member States. This necessary information shall include in particular the identification of offenders, the description of the offences committed and penalties imposed, and the reputation of the company concerned. The contact point is designated in accordance with Article 18(1) of Regulation (EC) No 1071/2009 of the European Parliament and of the Council (**).

5. Vehicles suspected of being overweight following the pre-selection procedure conducted pursuant to paragraph 2 shall be subject to at least one of the following measures:

- (i) roadside inspection with approved measurement equipment after interception of the vehicle,
- (ii) sending the transport company notification of the suspected overloading of the vehicle,
- (iii) inspection of the transport company on its premises, particularly in the case of repeated infringements after the sending of the notification referred to in (ii).

6. In accordance with paragraph 1, ~~Member States shall encourage the equipment of new N2 and N3 vehicles and vehicle combinations~~ **shall be fitted** with onboard weighing ~~devices~~ **systems** (total weight and axle load) ~~to that~~ enable the weight data to be communicated at any time from a moving vehicle to an authority carrying out roadside inspections or responsible for regulating the transport of goods **from [five years from the entry into force of this Directive]**. This communication shall be through the interface defined by the CEN DSRC (****) standards EN 12253, EN 12795, EN 12834, EN 13372 and ISO 14906. **The information shall also be accessible for the driver. [Am. 50]**

7. The Commission shall be empowered to adopt delegated acts, in accordance with Article 16, concerning:

- the additional technical specifications to ensure full interoperability at Union level of the on-board weighing equipment mentioned in paragraph 6 above, so that the authorities of all Member States can communicate in the same way with vehicles or vehicle combinations registered in any Member State and, where appropriate, exchange information received with the authorities of other Member States.

Tuesday 15 April 2014

- the procedures for the pre-selection checks referred to in paragraph 2 of this Article, the technical specifications, precision requirements and instructions for use of the equipment used for these preselection checks. These procedures, specifications and instructions for use are intended to ensure that the checks are performed in the same way in all Member States, thereby ensuring equal treatment for all transporters throughout the territory of the Union.
- *the common procedures and specifications to achieve a sufficient level of reliability that allows the onboard systems to be used for the enforcement of the provisions of this Directive, in particular of Article 13.* [Am. 51]

7a. The Commission shall assess whether the onboard systems, when interconnected to the digital tachograph, can be useful to enforce other road transport legislation. The Commission shall, if appropriate, come forward with legislative proposals. [Am. 52]

- (*) *Directive 2006/22/EC of the European Parliament and of the Council of 15 March 2006 on minimum conditions for the implementation of Council Regulations (EEC) No 3820/85 and (EEC) No 3821/85 concerning social legislation relating to road transport activities and repealing Council Directive 88/599/EEC (OJ L 102, 11.4.2006, p. 35).*
- (**) *Regulation (EU) No 165/2014 of the European Parliament and of the Council of 4 February 2014 on tachographs in road transport, repealing Council Regulation (EEC) No 3821/85 on recording equipment in road transport and amending Regulation (EC) No 561/2006 of the European Parliament and of the Council on the harmonisation of certain social legislation relating to road transport (OJ L 60, 28.2.2014, p. 1).*
- (***) Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator and repealing Council Directive 96/26/EC (OJ L 300, 14.11.2009, p. 51).
- (****) DSRC: Dedicated Short-Range Communications.'

(12) Article 13 is replaced by the following:

'Article 13

1. Infringements of this Directive are divided into different categories according to their severity.
2. An overload of less than ~~52~~ % of the maximum authorised weight in points 2, 3, 4.1 and 4.3 of Annex 1 shall give rise to a written warning to the transport company, which could give rise to a penalty, if the national legislation provides for this type of penalty; [Am. 53]
3. An overload of between ~~52~~ % and ~~10~~15 % of the maximum authorised weight in points 2, 3, 4.1 and 4.3 of Annex 1 shall be considered as a minor offence within the meaning of this Directive, and shall give rise to a ~~financial~~ penalty. The inspection authorities may also immobilise the vehicle for unloading until it reaches the maximum authorised weight; [Am. 54]
4. An overload of between 10 and ~~20~~ 15 % of the maximum authorised weight in points 2, 3, 4.1 and 4.3 of Annex 1 shall be considered a serious infringement within the meaning of this Directive. It shall give rise to a ~~financial~~ penalty and the immediate immobilisation of the vehicle for unloading until it reaches the maximum authorised weight, [Am. 55]
5. An overload of more than ~~20~~ 15 % of the maximum authorised weight in points 2, 3, 4.1 and 4.3 of Annex 1 shall be considered a very serious infringement within the meaning of this Directive, because of the increased risks incurred by other road users. This shall give rise to an immediate immobilisation of the vehicle for unloading until it reaches the maximum authorised weight, and to a ~~financial~~ penalty. ~~The procedure leading to the loss of good repute of the transport company shall be implemented in accordance with Article 6 of Regulation (EC) No 1071/2009~~ ⁽¹⁾, [Am. 56]
6. An excess length or ~~excess~~, **height or** width of less than ~~2~~ 1 % of the maximum dimensions indicated in point 1 of Annex 1 shall give rise to a written warning to the transport company, which could give rise to a penalty, if the national legislation provides for such a penalty. [Am. 57]

(1) ~~OJ L 300, 14.11.2009, p. 51.~~

Tuesday 15 April 2014

7. An excess length ~~or excess~~, **height or** width of between ~~21~~ and ~~20%~~ **10 %** of the maximum dimensions indicated in point 1 of Annex 1, either of the load on board or of the vehicle itself, shall give rise a ~~financial~~ **financial** penalty **for the haulier**. The inspection authorities shall immobilise the vehicle until its unloading if the excess length or excess width comes from the load or until the transport company obtains a special permit in accordance with Article 4(3); [Am. 58]

8. An excess length ~~or excess~~, **height or** width of the load or of the vehicle of more than ~~20%~~ **10 %** of the maximum dimensions indicated in point 1 of Annex 1 shall be considered as a very serious infringement within the meaning of this Directive, because of the increased risks incurred by other road users. It shall give rise to a ~~financial~~ **financial** penalty **for the haulier** and to the immediate immobilisation of the vehicle by the inspection authorities, until its unloading or until the transport company obtains a special permit in accordance with Article 4(3), if the excess length or excess width comes from the load. ~~The procedure leading to the loss of good repute of the transport company shall be implemented in accordance with Article 6 of Regulation (EC) No 1071/2009.~~ [Am. 59]

9. The ~~financial~~ penalties referred to in paragraphs 3, 4, 5, 7, and 8 shall be effective, proportionate and dissuasive.'

(13) The following Article is added:

'Article 14

For the transport of containers, the shipper shall give the road haulier to whom it entrusts the transport of a container, **in advance of loading**, a **written** statement indicating the **gross** weight of the container moved. ~~If this~~ **That statement can also be submitted by electronic means. Irrespective of its form, the document declaring the gross weight of the container shall be signed by a person duly authorised by the shipper. If the information on the gross weight of the container** information is missing or incorrect, the shipper shall incur liability in the same way as the haulier if the vehicle is overloaded. [Am. 60]

In intermodal transport operations, the information on the gross weight of a packed container shall be provided to the next party taking custody of the container.' [Am. 61]

(14) The following Article is added:

'Article 15

Every two years in the first quarter of the calendar year, the Member States shall send the Commission a report on the checks carried out in the previous two calendar years, the results of these checks and the penalties imposed on the offenders. The Commission shall produce an analysis of these reports and send it to the European Parliament and the Council in the second quarter of the calendar year.'

(15) The following Article is added:

'Article 16

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 8(4), Article 9(5) and Article 12(7) shall be conferred on the Commission for ~~an indeterminate~~ **a** period of ~~five~~ **five years** from the [date of entry into force of this Directive]. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.** [Am. 62]

3. The delegation of power referred to in Articles 8(4), 9(5) and 12(7) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Tuesday 15 April 2014

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 8(4), Article 9(5) and Article 12(7) shall enter into force only if the European Parliament or the Council did not express an objection within a period of two months of notification of that act to these two institutions, or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission of their intention not to raise objections. That period can be extended by two months at the initiative of the European Parliament or the Council.'

(15a) *The following Article is added:*

'Article 16a

By 2016, the Commission shall review Annex I to Directive 96/53/EC and submit a report on its implementation to the European Parliament and the Council. On the basis of this report, the Commission, shall, if appropriate, make a legislative proposal duly accompanied by an impact assessment. The report shall be made available at least 6 months prior to any legislative proposal.' [Am. 63]

(15b) *The following Article is added:*

'Article 16b

By 1 January 2016 the Commission shall complete a review of this Directive and, if appropriate, on the basis of such a review and its impact assessment, shall submit a proposal to the European Parliament and to the Council by 1 January 2017, to mandate the safety requirements laid down in Article 9(2) for all new M2 and M3 vehicles.' [Am. 64]

(16) Annex I is amended as follows:

(-a) *The following indent shall be added to point 1.1:*

'— loaded vehicle transporters: 20,75m' [Am. 65]

(a) Point 1.2(b) is replaced by the following:

'(b) superstructures of conditioned vehicles or vehicles transporting conditioned intermodal transport loading units: 2,60 m'

(aa) *Point 1.4 is replaced by the following:*

'1.4 Removable superstructures and standardized freight items such as containers are included in the dimensions specified in points 1.1, 1.2, 1.3, 1.6, 1.7, 1.8 and 4.4. Due to the indivisible nature of finished vehicles such as new cars loaded upon specialised transporters, such loaded transporters may exceed the dimensions in point 1.1 to the extent that national regulations and infrastructure conditions allow it and as long as these vehicle transporters when empty comply in full with the abovementioned points.' [Am. 66]

(b) Point 2.2.2 (c) is replaced by the following:

'(c) two- or three-axle motor vehicle with two or three-axle semi-trailer carrying, in intermodal transport, one or more intermodal transport loading units, for a total maximum length of 40 or 45 feet: 44 tonnes.' [Am. 70]

(c) Point 2.3.1 is replaced by the following:

'(a) two-axle motor vehicles other than buses: 18 tonnes'

~~"two-axle motor vehicles other than buses, and with hybrid or electric propulsion: 19 tonnes"~~ [Am. 67]

Tuesday 15 April 2014

(b) two-axle buses: ~~19~~ 19,5 tonnes' [Am. 68]

(ca) *The following point shall be inserted:*

'2.3.4 Vehicles equipped with low carbon technology:

The maximum weight is that mentioned in point 2.3.1, 2.3.2, 2.3.3 or 2.4 increased by the additional weight required for the low carbon technology, with a maximum of 1 tonne. That additional weight shall be indicated in the official registration documents of the motor vehicle issued by the Member State where the vehicle is registered. In cases where this information is missing, the values mentioned in points 2.3.1., 2.3.2, 2.3.3 or 2.4 shall apply.' [Am. 69]

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to conform to this Directive not later than 18 months from the date of its publication in the *Official Journal of the European Union*. They shall immediately communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at ...,

For the European Parliament
The President

For the Council
The President

Tuesday 15 April 2014

P7_TA(2014)0354

Framework for the recovery and resolution of credit institutions and investment firms *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directives 77/91/EEC and 82/891/EEC, Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC and 2011/35/EU and Regulation (EU) No 1093/2010 (COM(2012)0280 — C7-0136/2012 — 2012/0150(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/35)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0280),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0136/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Central Bank of 29 November 2012 ⁽¹⁾,
 - having regard to the opinion of the European Economic and Social Committee of 12 December 2012 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 20 December 2013 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Budgets and the Committee on Legal Affairs (A7-0196/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0150

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/59/EU.)

⁽¹⁾ OJ C 39, 12.2.2013, p. 1.

⁽²⁾ OJ C 44, 15.2.2013, p. 68.

Tuesday 15 April 2014

P7_TA(2014)0355

Undertakings for collective investment in transferable securities (UCITS V) *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Directive 2009/65/EC on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) as regards depositary functions, remuneration policies and sanctions (COM(2012)0350 — C7-0178/2012 — 2012/0168(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/36)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0350),
 - having regard to Article 294(2) and Article 53(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0178/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Central Bank of 11 January 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 19 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs (A7-0125/2013),
1. Adopts its position at first reading hereinafter set out ⁽²⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0168

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Directive 2009/65/EC on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) as regards depositary functions, remuneration policies and sanctions

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/91/EU.)

⁽¹⁾ OJ C 96, 4.4.2013, p. 18.

⁽²⁾ This position replaces the amendments adopted on 3 July 2013 (Texts adopted P7_TA(2013)0309).

Tuesday 15 April 2014

P7_TA(2014)0356

Payment accounts ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features (COM(2013)0266 — C7-0125/2013 — 2013/0139(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/37)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0266),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0125/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Central Bank of 19 November 2013 ⁽¹⁾,
 - having regard to the opinion of the European Economic and Social Committee of 18 September 2013 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 4 April 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Legal Affairs (A7-0398/2013),
1. Adopts its position at first reading hereinafter set out ⁽³⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0139

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/92/EU.)

⁽¹⁾ OJ C 51, 22.2.2014, p. 3.

⁽²⁾ OJ C 341, 22.11.2013, p. 40.

⁽³⁾ This position replaces the amendments adopted on 12 December 2013 (Texts adopted P7_TA(2013)0587).

Tuesday 15 April 2014

P7_TA(2014)0357

Key information documents for investment products *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on key information documents for investment products (COM(2012)0352 — C7-0179/2012 — 2012/0169(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/38)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0352),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0179/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Central Bank of 11 December 2012 ⁽¹⁾,
 - having regard to the opinion of the European Economic and Social Committee of 14 November 2012 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 4 April 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs (A7-0368/2013),
1. Adopts as its position at first reading hereinafter set out ⁽³⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0169**Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on key information documents for packaged retail and insurance based investment products (PRIIPs)***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1286/2014.)*

⁽¹⁾ OJ C 70, 9.3.2013, p. 2.⁽²⁾ OJ C 11, 15.1.2013, p. 59.⁽³⁾ This position replaces the amendment adopted on 20 November 2013 (P7_TA(2013)0489).

Tuesday 15 April 2014

P7_TA(2014)0358

Court of Justice of the European Union: number of judges at the General Court *I**

European Parliament legislative resolution of 15 April 2014 on the draft regulation of the European Parliament and of the Council amending the Protocol on the Statute of the Court of Justice of the European Union by increasing the number of Judges at the General Court (02074/2011 — C7-0126/2012 — 2011/0901B(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/39)

The European Parliament,

- having regard to the request by the Court of Justice submitted to Parliament and the Council (02074/2011),
 - having regard to the first paragraph of Article 254 and the second paragraph of Article 281 of the Treaty on the Functioning of the European Union, pursuant to which the draft act was submitted to Parliament (C7-0126/2012),
 - having regard to Article 294(3) and (15) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the Commission (COM(2011)0596),
 - having regard to the letter of the Court of Justice of 8 May 2012,
 - having regard to the letter of the Commission of 30 May 2012,
 - having regard to paragraphs 2 and 3 of its legislative resolution of 5 July 2012 on the draft regulation of the European Parliament and of the Council amending the Protocol on the Statute of the Court of Justice of the European Union and Annex I thereto ⁽¹⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Legal Affairs (A7-0252/2013),
1. Adopts as its position at first reading the text adopted on 12 December 2013 ⁽²⁾;
 2. Instructs its President to forward its position to the Council, the Court of Justice, the Commission and the national parliaments.

P7_TC1-COD(2011)0901B

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending the Protocol on the Statute of the Court of Justice of the European Union by increasing the number of Judges at the General Court [Amendment No 1]

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular the second subparagraph of Article 19(2) thereof,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first paragraph of Article 254 and the second paragraph of Article 281 thereof,

⁽¹⁾ OJ C 349 E, 29.11.2013, p. 555.

⁽²⁾ Texts adopted, P7_TA(2013)0581.

Tuesday 15 April 2014

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a(1) thereof,

Having regard to the request of the Court of Justice,

Having regard to the opinion of the Commission,

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

-
- (5) As a consequence of the progressive expansion of its jurisdiction since its creation, the number of cases before the General Court is now constantly increasing.
 - (6) The number of cases brought before the General Court **has been steadily increasing over the years**, resulting **over time** in **an** increase in the number of cases pending before that court and an increase in the duration of proceedings.
 - (7) That increase in the duration of proceedings does not appear to be acceptable from the point of view of litigants, particularly in the light of the requirements set out in Article 47 of the Charter of Fundamental Rights of the European Union and in Article 6 of the European Convention for the Protection of Human Rights and Fundamental Freedoms.
 - (8) The situation in which the General Court finds itself has structural causes relating to the increase in the number and variety of legislative and regulatory acts of the institutions, bodies, offices and agencies of the European Union, as well as to the volume and complexity of the cases brought before the General Court, particularly in the areas of competition and State aid.
 - (9) Consequently, the necessary measures should be taken to address this situation, and the possibility, provided for by the Treaties, of increasing the number of Judges of the General Court is such as to enable both the volume of pending cases and the excessive duration of proceedings before the General Court to be reduced within a short time.
 - (9a) **Those measures should also provide a permanent solution to the question of judges' Member States of origin, since the current arrangement, under which judges are appointed per Member State, cannot apply where there are more judges than Member States.**
 - (9b) **Pursuant to Article 19(2) of the Treaty on European Union, the General Court includes at least one judge per Member State. As that already ensures an appropriate geographical balance and representation of national legal systems, additional judges should be appointed exclusively on the basis of their professional and personal suitability, taking into account their knowledge of the legal systems of the European Union and of the Member States. However, there should be no more than two Judges for any Member State,**

■

HAVE ADOPTED THIS REGULATION:

Article 1

Protocol No 3 on the Statute of the Court of Justice of the European Union **is** amended as follows:

■

(6a) In Article 47, the first paragraph is replaced by the following:

'Article 9a, Articles 14 and 15, the first, second, fourth and fifth paragraphs of Article 17 and Article 18 shall apply to the General Court and its members.'

(7) ■ Article 48 **is** replaced by the **following:**

'In the General Court, there shall be one Judge per Member State and 12 additional Judges. There shall be no more than two Judges for any Member State.'

⁽¹⁾ Position of the European Parliament of 15 April 2014.

Tuesday 15 April 2014

All Judges shall have the same status and the same rights and obligations.

When, every three years, the Judges are partially replaced, one half of them shall be replaced, alternately, if there is an even number of Judges; and, on an alternating basis, if there is an uneven number of Judges, an even number of Judges and an uneven number of Judges, i.e. that number minus one, shall be replaced.’;

(7a) *The following Article is inserted:*

‘Article 48a

In respect of the Judges to be appointed per Member State, the right of nomination shall lie with the government of the Member State in question.’;

(7b) *The following Article is inserted:*

‘Article 48b

1. The additional Judges shall be appointed regardless of nominees’ Member States of origin.

2. During a procedure to appoint one or more of the 12 additional Judges, all Member State governments may submit nominations. Furthermore, Judges retiring from the General Court may nominate themselves in a written submission to the chair of the panel referred to in Article 255 of the Treaty on the Functioning of the European Union.

3. During a procedure to appoint one or more of the 12 additional Judges, the panel referred to in Article 255 of the Treaty on the Functioning of the European Union shall give an opinion on nominees’ suitability to perform the duties of Judge of the General Court. The panel shall append to its opinion on candidates’ suitability a list of candidates having the most suitable high-level experience, by order of merit. That list shall contain the names of at least twice as many nominees as there are Judges to be appointed by common accord of the governments of the Member States, provided that there is a sufficient number of suitable nominees.’.

Article 3

1. This Regulation shall enter into force on the first day of the month following that of its publication in the Official Journal of the European Union.

2. The 12 additional Judges appointed on the basis, and following the entry into force, of this Regulation shall take up their duties immediately once they have taken the oath.

The term of office of six of them, chosen by lot, shall end six years after the first partial replacement of the General Court following the entry into force of this Regulation. The term of the other six judges shall end six years after the second partial replacement of the General Court following the entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

For the Council

The President

The President

Tuesday 15 April 2014

P7_TA(2014)0359

Deployment of the interoperable EU-wide eCall *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the deployment of the interoperable EU-wide eCall (COM(2013)0315 — C7-0173/2013 — 2013/0166(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/40)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0315),
 - having regard to Article 294(2) and Article 91 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0173/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 19 September 2013 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 19 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0482/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0166**Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the deployment of the interoperable EU-wide eCall service**

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 585/2014/EU.)

⁽¹⁾ OJ C 341, 21.11.2013, p. 47.

Tuesday 15 April 2014

P7_TA(2014)0360

Measures to reduce the cost of deploying high-speed electronic communications networks *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on measures to reduce the cost of deploying high-speed electronic communications networks (COM(2013)0147 — C7-0082/2013 — 2013/0080(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/41)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0147),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0082/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Netherlands House of Representatives, the Romanian Chamber of Deputies, the Swedish Parliament and the United Kingdom House of Commons, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 10 July 2013 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 3 July 2013 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 28 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy (A7-0455/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0080

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on measures to reduce the cost of deploying high-speed electronic communications networks

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/61/EU.)

⁽¹⁾ OJ C 327, 12.11.2013, p. 102.

⁽²⁾ OJ C 280, 27.9.2013, p. 50.

Tuesday 15 April 2014

P7_TA(2014)0361

Inland waterway transport *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 718/1999 on a Community-fleet capacity policy to promote inland waterway transport (COM(2013)0621 — C7-0265/2013 — 2013/0303(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/42)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0621),
 - having regard to Article 294(2) and Article 91(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0265/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 21 January 2014 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 31 January 2014 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 7 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism and the opinion of the Committee on Employment and Social Affairs (A7-0142/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0303

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 718/1999 on a Community-fleet capacity policy to promote inland waterway transport

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 546/2014.)

⁽¹⁾ Not yet published in the Official Journal.

⁽²⁾ Not yet published in the Official Journal.

Tuesday 15 April 2014

P7_TA(2014)0362

Agricultural products on the internal market and in third countries *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on information provision and promotion measures for agricultural products on the internal market and in third countries (COM(2013)0812 — C7-0416/2013 — 2013/0398(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/43)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0812),
 - having regard to Article 294(2) and Articles 42 and 43(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0416/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - after consulting the European Economic and Social Committee,
 - having regard to the undertaking given by the Council representative by letter of 2 April 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Agriculture and Rural Development (A7-0217/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0398

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on information provision and promotion measures concerning agricultural products implemented in the internal market and in third countries and repealing Council Regulation (EC) No 3/2008

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1144/2014.)

Tuesday 15 April 2014

P7_TA(2014)0363

Active and Assisted Living Research and Development Programme *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in the Active and Assisted Living Research and Development Programme jointly undertaken by several Member States (COM(2013)0500 — C7-0219/2013 — 2013/0233(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/44)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0500),
 - having regard to Article 294(2), Article 185 and the second paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0219/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 10 December 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 26 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy and the opinion of the Committee on Women's Rights and Gender Equality (A7-0076/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0233

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the Union in the Active and Assisted Living Research and Development Programme jointly undertaken by several Member States

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 554/2014/EU.)

⁽¹⁾ Not yet published in the *Official Journal*.

Tuesday 15 April 2014

P7_TA(2014)0364

Research and Development Programme for research performing SMEs *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in a Research and Development Programme jointly undertaken by several Member States aimed at supporting research performing small and medium-sized enterprises (COM(2013)0493 — C7-0220/2013 — 2013/0232(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/45)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0493),
 - having regard to Article 294(2), Article 185 and the second paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0220/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 10 December 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 26 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy (A7-0077/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0232

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the Union in a Research and Development Programme jointly undertaken by several Member States aimed at supporting research and development performing small and medium-sized enterprises

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 553/2014/EU.)

⁽¹⁾ Not yet published in the *Official Journal*.

Tuesday 15 April 2014

P7_TA(2014)0365

European Metrology Programme for Innovation and Research *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in a European Metrology Programme for Innovation and Research jointly undertaken by several Member States (COM(2013)0497 — C7-0221/2013 — 2013/0242(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/46)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0497),
 - having regard to Article 294(2) and Article 185 and the second paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0221/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 10 December 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 26 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy (A7-0063/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0242

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the Union in a European Metrology Programme for Innovation and Research (EMPIR) jointly undertaken by several Member States

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 555/2014/EU.)

⁽¹⁾ Not yet published in the Official Journal.

Tuesday 15 April 2014

P7_TA(2014)0366

European and Developing Countries Clinical Trials Partnership Programme *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States (COM(2013)0498 — C7-0222/2013 — 2013/0243(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/47)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0498),
 - having regard to Article 294(2) and Article 185 and the second paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0222/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 10 December 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 26 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy and the opinion of the Committee on Development (A7-0064/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0243

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 556/2014/EU.)

⁽¹⁾ Not yet published in the Official Journal.

Tuesday 15 April 2014

P7_TA(2014)0367

European Account Preservation Order *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council creating a European Account Preservation Order to facilitate cross-border debt recovery in civil and commercial matters (COM(2011)0445 — C7-0211/2011 — 2011/0204(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/48)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0445),
 - having regard to Article 294(2) and points (a), (e) and (f) of Article 81(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0211/2011),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 26 April 2012 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 6 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Legal Affairs and the opinion of the Committee on Economic and Monetary Affairs (A7-0227/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2011)0204**Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council establishing a European Account Preservation Order procedure to facilitate cross-border debt recovery in civil and commercial matters***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 655/2014.)*

⁽¹⁾ OJ C 191, 29.6.2012, p. 57.

Tuesday 15 April 2014

P7_TA(2014)0368

Disclosure of non-financial and diversity information by certain large companies and groups *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Council Directives 78/660/EEC and 83/349/EEC as regards disclosure of non-financial and diversity information by certain large companies and groups (COM(2013)0207 — C7-0103/2013 — 2013/0110(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/49)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0207),
 - having regard to Article 294(2) and Article 50(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0103/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Estonian Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 11 July 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 26 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Legal Affairs and the opinions of the Committee on Foreign Affairs, the Committee on Development, the Committee on Economic and Monetary Affairs, the Committee on Employment and Social Affairs, the Committee on Industry, Research and Energy, the Committee on the Internal Market and Consumer Protection and the Committee on Women's Rights and Gender Equality (A7-0006/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0110

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/95/EU.)

⁽¹⁾ OJ C 327, 12.11.2013, p. 47.

Tuesday 15 April 2014

P7_TA(2014)0369

Conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer (COM(2010)0378 — C7-0179/2010 — 2010/0209(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/50)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2010)0378),
 - having regard to Article 294(2) and points (a) and (b) of Article 79(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0179/2010),
 - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 4 May 2011 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 31 March 2011 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 27 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 55 and 37 of its Rules of Procedure,
 - having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs and the opinion of the Committee on Employment and Social Affairs (A7-0170/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Approves the joint statement by Parliament, the Council and the Commission annexed to this resolution;
 3. Takes note of the Commission statements annexed to this resolution;
 4. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 218, 23.7.2011, p. 101.

⁽²⁾ OJ C 166, 7.6.2011, p. 59.

Tuesday 15 April 2014

P7_TC1-COD(2010)0209

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/66/EU.)

Tuesday 15 April 2014

ANNEX TO THE LEGISLATIVE RESOLUTION**JOINT STATEMENT BY PARLIAMENT, THE COUNCIL AND THE COMMISSION**

This Directive establishes an autonomous mobility scheme providing for specific rules, adopted on the basis of points (a) and (b) of Article 79(2) TFEU, regarding the conditions of entry, stay and freedom of movement of a third-country national for the purpose of work as an intra-corporate transferee in Member States other than the one that issued the intra-corporate transferee permit, which are to be considered as a *lex specialis* with respect to the Schengen *acquis*.

Parliament and the Council take note of the Commission's intention to examine whether any action needs to be taken in order to enhance legal certainty as regards the interaction between the two legal regimes, and in particular to examine the need for updating the Schengen Handbook.

COMMISSION STATEMENTS

1) Statement on the definition of specialist:

The Commission considers that the definition of 'specialist' in point (f) of Article 3 of this Directive is in line with the equivalent definition ('person possessing uncommon knowledge') used in the EU's schedule of specific commitments of the WTO's General Agreement on Trade in Services (GATS). The use of the word 'specialised' instead of 'uncommon' does not entail any change or extension of the GATS definition and is only adapted to the language now in use.

2) Statement on the bilateral agreements referred to in points (c) and (d) of Article 18(2):

The Commission will monitor the implementation of points (c) and (d) of Article 18(2) of this Directive in order to assess the possible impact of the bilateral agreements referred to in that Article on the treatment of intra-corporate transferees and on the application of Regulation (EU) No 1231/2010 and take, where necessary, any appropriate measure.

Tuesday 15 April 2014

P7_TA(2014)0370

Clean Sky 2 Joint Undertaking *

European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the Clean Sky 2 Joint Undertaking (COM(2013)0505 — C7-0255/2013 — 2013/0244(NLE))

(Consultation)

(2017/C 443/51)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2013)0505),
 - having regard to Article 187 and the first paragraph of 188 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0255/2013),
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy (A7-0083/2014),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, in accordance with Article 293(2) of the Treaty on the Functioning of the European Union;
 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 4. Asks the Council to consult Parliament again if it intends to substantially amend the Commission proposal;
 5. Instructs its President to forward its position to the Council and the Commission.

P7_TC1-NLE(2013)0244

Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council regulation (EU) No .../2014 establishing the Clean Sky 2 Joint Undertaking

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Council Regulation (EU) No 558/2014)

Tuesday 15 April 2014

P7_TA(2014)0371

Bio-Based Industries Joint Undertaking ***European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the Bio-Based Industries Joint Undertaking (COM(2013)0496 — C7-0257/2013 — 2013/0241(NLE))****(Consultation)**

(2017/C 443/52)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2013)0496),
 - having regard to Article 187 and the first paragraph of 188 of the Treaty on European Union, pursuant to which the Council consulted Parliament (C7-0257/2013),
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy and the opinion of the Committee on Regional Development (A7-0092/2014),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, in accordance with Article 293(2) of the Treaty on the Functioning of the European Union;
 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 4. Asks the Council to consult Parliament again if it intends to substantially amend the Commission proposal;
 5. Instructs its President to forward its position to the Council and the Commission.

P7_TC1-NLE(2013)0241**Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council regulation (EU) No .../2014 establishing the Bio-based Industries Joint Undertaking**

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Council Regulation (EU) No 560/2014)

Tuesday 15 April 2014

P7_TA(2014)0372

SESAR Joint Undertaking *

European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation amending Regulation (EC) No 219/2007 on establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR) as regards the extension of the Joint Undertaking until 2024 (COM(2013)0503 — C7-0254/2013 — 2013/0237(NLE))

(Consultation)

(2017/C 443/53)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2013)0503),
 - having regard to Articles 187 and 188 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0254/2013),
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy and the opinion of the Committee on Transport and Tourism (A7-0062/2014),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, in accordance with Article 293(2) of the Treaty on the Functioning of the European Union;
 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 4. Asks the Council to consult Parliament again if it intends to substantially amend the Commission proposal;
 5. Instructs its President to forward its position to the Council and the Commission.

P7_TC1-NLE(2013)0237

Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council regulation (EU) No .../2014 amending Regulation (EC) No 219/2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR) as regards the extension of the Joint Undertaking until 2024

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Council Regulation (EU) No 721/2014)

Tuesday 15 April 2014

P7_TA(2014)0373

Innovative Medicines Initiative 2 Joint Undertaking ***European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the Innovative Medicines Initiative 2 Joint Undertaking (COM(2013)0495 — C7-0259/2013 — 2013/0240(NLE))****(Consultation)**

(2017/C 443/54)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2013)0495),
 - having regard to Article 187 and the first paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0259/2013),
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy (A7-0105/2014),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, in accordance with Article 293(2) of the Treaty on the Functioning of the European Union;
 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 4. Asks the Council to consult Parliament again if it intends to substantially amend the Commission proposal;
 5. Instructs its President to forward its position to the Council and the Commission.

P7_TC1-NLE(2013)0240**Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council regulation (EU) No .../2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Council Regulation (EU) No 557/2014)*

Tuesday 15 April 2014

P7_TA(2014)0374

ECSEL Joint Undertaking *

European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the ECSEL Joint Undertaking (COM(2013)0501 — C7-0258/2013 — 2013/0234(NLE))

(Consultation)

(2017/C 443/55)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2013)0501),
 - having regard to Article 187 and the first paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0258/2013),
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy and the opinion of the Committee on Budgetary Control (A7-0074/2014),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, in accordance with Article 293(2) of the Treaty on the Functioning of the European Union;
 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 4. Asks the Council to consult Parliament again if it intends to substantially amend the Commission proposal;
 5. Instructs its President to forward its position to the Council and the Commission.

P7_TC1-NLE(2013)0234

Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council Regulation (EU) No .../2014 establishing the ECSEL Joint Undertaking

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Council Regulation (EU) No 561/2014)

Tuesday 15 April 2014

P7_TA(2014)0375

Fuel Cells and Hydrogen 2 Joint Undertaking ***European Parliament legislative resolution of 15 April 2014 on the proposal for a Council regulation on the Fuel Cells and Hydrogen 2 Joint Undertaking (COM(2013)0506 — C7-0256/2013 — 2013/0245(NLE))****(Consultation)**

(2017/C 443/56)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2013)0506),
 - having regard to Article 187 and the first paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0256/2013),
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Industry, Research and Energy (A7-0094/2014),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, in accordance with Article 293(2) of the Treaty on the Functioning of the European Union;
 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 4. Asks the Council to consult Parliament again if it intends to substantially amend the Commission proposal;
 5. Instructs its President to forward its position to the Council and the Commission.

P7_TC1-NLE(2013)0245**Position of the European Parliament adopted on 15 April 2014 with a view to the adoption of Council Regulation (EU) No .../2014 establishing the Fuel Cells and Hydrogen 2 Joint Undertaking***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Council Regulation (EU) No 559/2014)*

Tuesday 15 April 2014

P7_TA(2014)0376

Interinstitutional agreement on the transparency register

European Parliament decision of 15 April 2014 on the modification of the interinstitutional agreement on the Transparency Register (2014/2010(ACI))

(2017/C 443/57)

The European Parliament,

- having regard to the meeting of its Bureau of 13 January 2014, at which the latter approved the recommendations adopted on 12 December 2013 by the High-level Interinstitutional Working Group for the revision of the Transparency Register,
 - having regard to the draft interinstitutional agreement between the European Parliament and the European Commission on the Transparency Register for organisations and self-employed individuals engaged in EU policy-making and policy implementation (hereinafter referred to as ‘the modified agreement’),
 - having regard to Article 11(1) and (2) of the Treaty on European Union (TEU),
 - having regard to Article 295 of the Treaty on the Functioning of the European Union (TFEU),
 - having regard to its decision of 11 May 2011 on conclusion of an interinstitutional agreement between the European Parliament and the Commission on a common Transparency Register ⁽¹⁾,
 - having regard to the interinstitutional agreement of 23 June 2011 between the European Parliament and the European Commission on the establishment of a transparency register for organisations and self-employed individuals engaged in EU policy-making and policy implementation (hereinafter referred to as ‘the Agreement of 23 June 2011’) ⁽²⁾,
 - having regard to Rule 127(1) of its Rules of Procedure,
 - having regard to the report of the Committee on Constitutional Affairs (A7-0258/2014),
- A. whereas Article 11(2) TEU states: ‘The institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society’;
- B. whereas the transparency of that dialogue requires the good functioning of a common register of the organisations and persons trying to influence EU policy-making and policy implementation processes;
- C. whereas its resolution of 8 May 2008 on the development of the framework for the activities of interest representatives (lobbyists) in the European institutions ⁽³⁾ laid down the principles on the basis of which the European Parliament entered into negotiations with the Commission concerning a common transparency register;
- D. whereas its abovementioned decision of 11 May 2011 endorsed the rules and the framework of the Transparency Register for organisations and self-employed individuals engaged in EU policy-making and policy implementation;
- E. Whereas unregulated and non-transparent lobbying poses a significant threat to policy-making and to the public interest;

⁽¹⁾ OJ C 377 E, 7.12.2012, p. 176.

⁽²⁾ OJ L 191, 22.7.2011, p. 29.

⁽³⁾ OJ C 271 E, 12.11.2009, p. 48.

Tuesday 15 April 2014

1. Regrets that the proposal for a modification of the Agreement of 23 June 2011 will not lead to the establishment of a mandatory transparency register; reiterates therefore its call for mandatory registration in relation to the conduct of lobbying activities at the EU institutions, as already stated in its abovementioned resolution of 8 May 2008 and its abovementioned decision of 11 May 2011;
2. Considers the proposed modification of the Agreement of 23 June 2011 to be a partial step forward at the present stage;
3. Calls on the Commission to submit, by the end of 2016, a legislative proposal for the establishment of a mandatory register on the basis of Article 352 TFEU;
4. Asks the Commission to include, in the context of any forthcoming proposals for a comprehensive reform of the Treaties, a proposal either for an amendment of Article 298 TFEU or for an appropriate specific legal basis allowing a mandatory register to be set up in accordance with the ordinary legislative procedure;
5. Considers that future reviews of the Transparency Register should be as transparent and inclusive as possible and should fully involve its competent committee and allow for strong civil society participation;
6. Insists that the next review of the Transparency Register is accompanied by a public consultation;
7. Considers that in any event, a further evaluation of the Transparency Register should be completed before the end of 2017 at the latest;
8. Recognises the role played by the Council since the establishment of the Transparency Register, and welcomes the fact that the Council has become involved, as an observer, in the process of keeping the Agreement of 23 June 2011 under review; however, in order to ensure transparency at all stages in the law-making process at Union level, reiterates its call to the Council to join the Transparency Register as soon as possible;
9. Welcomes the improved specification of the information to be provided pursuant to the modified agreement, which should be implemented by insisting on disclosure of the identity of all clients represented by organisations and self-employed individuals engaged in EU policy-making and policy implementation processes, and by clearly linking all activities covered by the Register to the clients concerned;
10. Considers that, when interpreting 'inappropriate behaviour' within the meaning of point (b) of the Code of Conduct annexed to the modified agreement, in addition to the generally accepted principles as outlined in the Code, in particular in its points (c), (f) or (g), this expression includes:
 - interference in the private sphere or personal life of decision-makers, e.g. by sending gifts to a decision-maker's home address or approaching decision-makers at their home address or via their relatives or friends;
 - performance, or any active promotion, of activities in the field of communication with the EU institutions and their Members or staff which are liable to impair the functionality of the EU institutions' communication systems, particularly in cases where such activities are performed anonymously;
 - failing to declare the interests or clients being represented when contacting a Member of the European Parliament or officials or other staff of the European Parliament with regard to the legislative process;
 - employing 'front groups', i.e. organisations which hide the interests and parties they serve, the latter not being registered in the Transparency Register; and employing the representatives of third countries when engaged in direct and indirect lobbying activities;
 - offer or grant support, whether financial or in terms of staff or material to Members of the European Parliament or their assistants;
11. Believes that the Code of Conduct attached to the Agreement of 23 June 2011 and the Code of Conduct for Members of the European Parliament with respect to financial interests and conflicts of interest should be amended in order to ensure that Members do not enter into any kind of agreement or contractual relationship with an external body to either fund or directly employ individuals within a Member's staff;

Tuesday 15 April 2014

12. Welcomes the clearer definitions describing exceptions to the scope of coverage of activities of law firms;
13. Expects that such clearer definitions will help to encourage further registrations and bring about a better understanding of the meaning of covered activities of law firms, in order that they may benefit from the incentives offered by the Transparency Register and participate in a transparent manner in the decision-making process;
14. Insists that registered law firms should declare in the Transparency Register all the clients on whose behalf they perform covered activities;
15. Encourages the Commission to be equally ambitious, when it comes to introducing incentive measures for registrants in order to enhance participation in the Transparency Register; considers that such incentives could include:
 - (a) granting patronage only to registered organisations, for any events organised by an organisation falling within the scope of the Transparency Register,
 - (b) reducing the number of meetings with non-registered organisations or interest representatives,
 - (c) considering limitations on the participation of non-registered organisations in Commission advisory bodies and expert groups,
 - (d) encouraging Commissioners and Commission officials and other staff to refuse invitations to events organised by non-registered organisations,
 - (e) restricting to registered organisations the possibility of hosting or co-hosting events on Commission premises;
16. Welcomes the recent decisions taken by the Brussels and Paris Bars recognising the differences between court-related activities of lawyers and other activities falling within the scope of the Transparency Register; moreover, invites the Council of Bars and Law Societies of Europe to encourage its members to adopt similar measures;
17. Notes that, in some Member States, statutory provisions exist on the rules governing the exercise of professions, which in particular objectively prevent lawyers' firms from having themselves entered in the Transparency Register and in the process revealing the information about their clients which the Register requires; also, however, perceives a substantial risk in that such statutory provisions can also be abused to avoid publishing information required for a correct entry in the Register; welcomes, in this connection, the perceptible readiness of professional organisations to work in partnership to ensure that, in the interests of their profession, such withholding of information is confined exclusively to what the legislation objectively permits; calls on the Commission and the President of the European Parliament to secure a practical outcome from this readiness and to enshrine a result in the modified agreement as soon as possible;
18. Welcomes the intention of its Bureau to introduce a significant number of incentive measures in order to enhance participation in the Transparency Register;
19. With a view to full implementation of those measures, invites its Bureau to consider the following concrete proposals for inclusion in the relevant Bureau decisions:
 - (a) encourage European Parliament officials or other staff, when approached by a representative of an organisation or individuals undertaking an activity falling within the scope of the Transparency Register, to check whether the organisation in question is registered, and, if it is not, to encourage it to register before meeting its representative;
 - (b) restrict access to European Parliament premises for non-registered organisations or individuals;
 - (c) allow events to be co-organised and/or co-hosted with organisations or individuals falling within the scope of the Transparency Register only if those organisations or individuals are registered;

Tuesday 15 April 2014

- (d) allow representatives of organisations or individuals falling within the scope of the Transparency Register to participate as speakers on the panel at committee hearings only if they are registered;
- (e) withhold European Parliament's patronage of any event organised by an organisation falling within the scope of the Transparency Register to cases where such an organisation is registered;
- (f) increase its vigilance against granting Parliamentary privileges to front organisations of third countries which do not respect European Union values;
20. Requests the Bureau to develop a standardised form for rapporteurs to publish on a voluntary basis a 'legislative footprint', which is a form annexed to reports drafted by Members detailing all the lobbyists with whom rapporteurs in charge of a particular file have met in the process of drawing up the report, where this has led to a substantial impact on the report.
21. Asks former Members of the European Parliament to comply with the relevant provisions⁽¹⁾ when carrying on activities falling within the scope of the Transparency Register; believes that in carrying on such activities, former Members should not use their Members' badge to access the premises of the European Parliament; requests the Bureau to present to the Conference of Presidents a proposal for appropriate measures to prevent misuse of privileges to which former Members are entitled;
22. Requests the Joint Transparency Register Secretariat to provide, at regular intervals, a report on the functioning of the incentives system, with a view, ultimately, to the establishment of a mandatory register;
23. Underlines that non-registered organisations or individuals, which are eligible for registration and expected to register, even if their non-registration is only temporary, will not have access to the new incentives and advantages linked to registration;
24. Welcomes and encourages the role played by non-institutional watchdogs in monitoring the transparency of the EU Institutions;
25. Considers that the structure and the staff of the Joint Transparency Register Secretariat need to be reinforced in order to implement the new provisions in the modified agreement, to deal with the procedures for alerts and for the investigation and treatment of complaints, and to improve the procedures for verifying the reliability of information provided by registrants;
26. Expects that the annual report on the operation of the Joint Transparency Register will include an analysis of the progress made in terms of coverage and quality of entries;
27. Encourages the Commission, in performing its function of coordinating the Transparency Register, to closely monitor the proper implementation of the modified agreement;
28. Approves the modified agreement as set out below and decides to annex it to its Rules of Procedure;
29. Instructs its President to sign the modified agreement together with the President of the European Commission and to arrange for its publication in the Official Journal of the European Union;
30. Instructs its President to forward this decision, including its annex, to the Council, the Commission and the parliaments of the Member States.

⁽¹⁾ As laid down by the Quaestors at their ordinary meeting held on 19 April 2012, PV QUAEST.

Tuesday 15 April 2014

ANNEX

AGREEMENT BETWEEN THE EUROPEAN PARLIAMENT AND THE EUROPEAN COMMISSION ON THE TRANSPARENCY REGISTER FOR ORGANISATIONS AND SELF-EMPLOYED INDIVIDUALS ENGAGED IN EU POLICY-MAKING AND POLICY IMPLEMENTATION

The European Parliament and the European Commission ('the parties hereto'),

Having regard to the Treaty on European Union, in particular Article 11(1) and (2) thereof, the Treaty on the Functioning of the European Union, in particular Article 295 thereof, and the Treaty establishing the European Atomic Energy Community (hereinafter together referred to as 'the Treaties'),

Whereas European policy-makers do not operate in isolation from civil society, but maintain an open, transparent and regular dialogue with representative associations and civil society;

Whereas the parties hereto have reviewed the Transparency Register (hereinafter 'the register') established by the agreement between the European Parliament and the European Commission of 23 June 2011 on the establishment of a transparency register for organisations and self-employed individuals engaged in EU policy-making and policy implementation⁽¹⁾ pursuant to paragraph 30 of that agreement,

AGREE AS FOLLOWS:

I. Principles of the register

1. The establishment and operation of the register shall not affect or prejudice the objectives of the European Parliament as expressed in its resolution of 8 May 2008 on the development of the framework for the activities of interest representatives (lobbyists) in the European institutions⁽²⁾ and in its decision of 11 May 2011 on conclusion of an interinstitutional agreement between the European Parliament and the Commission on a common Transparency Register⁽³⁾.
2. The operation of the register shall respect the general principles of Union law, including the principles of proportionality and non-discrimination.
3. The operation of the register shall respect the rights of Members of the European Parliament to exercise their parliamentary mandate without restriction.
4. The operation of the register shall not impinge on the competences or prerogatives of the parties hereto or affect their respective organisational powers.
5. The parties hereto shall strive to treat all operators engaged in similar activities in a similar manner, and to allow for a level playing-field for the registration of organisations and self-employed individuals engaged in EU policy-making and policy implementation.

II. Structure of the register

6. The structure of the register shall be as follows:
 - (a) provisions on the scope of the register, activities covered by the register, definitions, incentives and exemptions;
 - (b) sections for registration (Annex 1);

⁽¹⁾ OJ L 191, 22.7.2011, p. 29.

⁽²⁾ OJ C 271 E, 12.11.2009, p. 48.

⁽³⁾ OJ C 377 E, 7.12.2012, p. 176.

Tuesday 15 April 2014

- (c) information required from registrants, including financial disclosure requirements (Annex 2);
- (d) code of conduct (Annex 3);
- (e) alert and complaint mechanisms and measures to be applied in the event of non-compliance with the code of conduct, including the procedures for alerts and for the investigation and treatment of complaints (Annex 4);
- (f) implementation guidelines with practical information for registrants.

III. *Scope of the register*

Activities covered

7. The scope of the register covers all activities, other than those referred to in paragraphs 10 to 12, carried out with the objective of directly or indirectly influencing the formulation or implementation of policy and the decision-making processes of the EU institutions, irrespective of where they are undertaken and of the channel or medium of communication used, for example via outsourcing, media, contracts with professional intermediaries, think tanks, platforms, forums, campaigns and grassroots initiatives.

For the purpose of this agreement, 'directly influencing' means influencing by way of a direct contact or communication with the EU institutions or other action following up on such activities and 'indirectly influencing' means influencing through the use of intermediate vectors such as media, public opinion, conferences or social events, targeting the EU institutions .

In particular, those activities include:

- contacting Members and their assistants, officials or other staff of the EU institutions;
 - preparing, circulating and communicating letters, information material or discussion papers and position papers;
 - organising events, meetings, promotional activities, conferences or social events, invitations to which have been sent to Members and their assistants, officials or other staff of the EU institutions; and
 - voluntary contributions and participation in formal consultations or hearings on envisaged EU legislative or other legal acts and other open consultations.
8. All organisations and self-employed individuals, irrespective of their legal status, engaged in activities, whether on-going or under preparation, covered by the register are expected to register.

Any activity covered by the register and which is developed under contract by an intermediary providing legal and other professional advice, shall entail eligibility for registration both for the intermediary and for its client. Such intermediaries shall declare all clients under such contracts as well as the revenue per client for representation activities as set out in Annex 2 at point II.C.2.B. This requirement does not exempt clients from registering and including in their own cost estimates the cost of any activities subcontracted to an intermediary.

Activities not covered

9. An organisation shall only be eligible to register if it carries out activities, covered by the register, which have resulted in direct or indirect communication with EU institutions. An organisation deemed non-eligible may be removed from the register.

10. Activities concerning the provision of legal and other professional advice are not covered by the register in so far as:

- they consist of advisory work and contacts with public bodies in order to better inform clients about a general legal situation or about their specific legal position, or to advise them whether a particular legal or administrative step is appropriate or admissible under the existing legal and regulatory environment;

Tuesday 15 April 2014

- they consist of advice given to clients to help them ensure that their activities comply with the relevant law;
- they consist of analyses and studies prepared for clients on the potential impact of any legislative or regulatory changes with regard to their legal position or field of activity;
- they consist of representation in the context of a conciliation or mediation procedure aimed at preventing a dispute from being brought before a judicial or administrative body; or
- they relate to the exercise of the fundamental right of a client to a fair trial, including the right of defence in administrative proceedings, such as activities carried out by lawyers or by any other professionals involved therein.

If a company and its advisers are involved as a party in a specific legal or administrative case or procedure, any activity relating directly thereto which does not seek as such to change the existing legal framework is not covered by the register. This subparagraph applies to all business sectors in the European Union.

However, the following activities concerning the provision of legal and other professional advice are covered by the register where they are intended to influence the EU institutions, their Members and their assistants or their officials or other staff:

- the provision of support, via representation or mediation, or of advocacy material, including argumentation and drafting; and
- the provision of tactical or strategic advice, including the raising of issues the scope of which and the timing of communication of which are intended to influence the EU institutions, their Members and their assistants or their officials or other staff.

11. Activities of the social partners as participants in the social dialogue (trade unions, employers' associations, etc.) are not covered by the register where those social partners perform the role assigned to them in the Treaties. This paragraph applies *mutatis mutandis* to any entity specifically designated in the Treaties to play an institutional role;

12. Activities in response to direct and individual requests from EU institutions or Members of the European Parliament, such as ad hoc or regular requests for factual information, data or expertise, are not covered by the register.

Specific provisions

13. The register does not apply to churches and religious communities. However, the representative offices or legal entities, offices and networks created to represent churches and religious communities in their dealings with the EU institutions, as well as their associations, are expected to register.

14. The register does not apply to political parties. However, any organisations created or supported by them which are engaged in activities covered by the register are expected to register.

15. The register does not apply to Member States' government services, third countries' governments, international intergovernmental organisations and their diplomatic missions.

16. Regional public authorities and their representative offices are not expected to register, but can register if they wish to do so. Any association or network created to represent regions collectively is expected to register.

17. All sub-national public authorities other than those referred to in paragraph 16, such as local and municipal authorities or cities, or their representation offices, associations or networks, are expected to register.

Tuesday 15 April 2014

18. Networks, platforms or other forms of collective activity, which have no legal status or legal personality but which constitute de facto a source of organised influence and which are engaged in activities covered by the register, are expected to register. Members of such forms of collective activity shall designate a representative to act as their contact person responsible for liaising with the 'Joint Transparency Register Secretariat' (JTRS).

19. The activities to be taken into account for assessing eligibility to register are those aimed (directly or indirectly) at all EU institutions, agencies and bodies, and their Members and their assistants, officials and other staff. Such activities do not include activities directed at Member States, in particular those directed at their permanent representations to the European Union.

20. European networks, federations, associations or platforms are encouraged to produce common, transparent guidelines for their members identifying the activities covered by the register. They are expected to make those guidelines public.

IV. Rules applicable to registrants

21. By registering, the organisations and individuals concerned:

- agree that the information which they provide for inclusion in the register shall be in the public domain;
- agree to act in compliance with the code of conduct set out in Annex 3 and, where relevant, to provide the text of any professional code of conduct by which they are bound ⁽¹⁾;
- guarantee that the information provided for inclusion in the register is correct and agree to co-operate with administrative requests for complementary information and updates;
- accept that any alert or complaint concerning them will be handled on the basis of the rules in the code of conduct set out in Annex 3;
- agree to be subject to any measures to be applied in the event of non-compliance with the code of conduct set out in Annex 3 and acknowledge that the measures provided for in Annex 4 may be applied to them in the event of non-compliance with the code;
- note that the parties hereto may, upon request and subject to the provisions of Regulation (EC) No 1049/2001 of the European Parliament and of the Council ⁽²⁾, have to disclose correspondence and other documents concerning the activities of registrants.

V. Implementation

22. The Secretaries-General of the European Parliament and the European Commission shall be responsible for supervision of the system and for all key operational aspects, and shall by common accord take the measures necessary to implement this agreement.

23. Although the system is operated jointly, the parties hereto remain free to use the register independently for their own specific purposes.

24. In order to implement the system, the services of the European Parliament and the European Commission maintain a joint operational structure, designated as the JTRS. The JTRS is made up of a group of officials from the European Parliament and the European Commission pursuant to an arrangement agreed by the competent services. The JTRS operates under the coordination of a Head of Unit in the Secretariat-General of the European Commission. The tasks of the JTRS include producing implementation guidelines, within the limits of this agreement, to facilitate a consistent interpretation of the rules by registrants, and monitoring the quality of the content of the register. The JTRS shall use the administrative resources available to perform quality checks of the content of the register, on the understanding, however, that registrants are ultimately responsible for the information they have provided.

⁽¹⁾ The professional code of conduct by which a registrant is bound may impose obligations which are more stringent than the requirements of the code of conduct set out in Annex 3.

⁽²⁾ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Tuesday 15 April 2014

25. The parties hereto shall organise appropriate training and internal communication projects to raise awareness of the register and of the alert and complaints procedures among their Members and staff.

26. The parties hereto shall take appropriate measures externally to raise awareness of the register and promote its use.

27. A series of basic statistics, extracted from the database of the register, shall be published regularly on the *Europa* Transparency Register website and shall be accessible via a user-friendly search engine. The public content of that database shall be available in electronic, machine-readable formats.

28. An annual report on the operation of the register shall be submitted by the Secretaries-General of the European Parliament and the European Commission respectively to the relevant Vice-President of the European Parliament and to the relevant Vice-President of the European Commission. The annual report shall provide factual information about the register, its content and its evolution, and shall be published each year for the preceding calendar year.

VI. *Measures applicable for compliant registrants*

29. Access passes to the European Parliament's premises will only be issued to individuals representing, or working for, organisations falling within the scope of the register where those organisations or individuals have registered. However, registration shall not confer an automatic entitlement to such an access pass. The issue and control of passes affording long-term access to the European Parliament's premises shall remain an internal procedure of the Parliament under its own responsibility.

30. The parties hereto shall offer incentives, in the framework of their administrative authority, in order to encourage registration within the framework created by this agreement.

Incentives offered by the European Parliament to registrants may include:

- further facilitation of access to its premises, its Members and their assistants, its officials and other staff;
- authorisation to organise or co-host events on its premises;
- facilitated transmission of information, including specific mailing lists;
- participation as speakers in committee hearings;
- patronage by the European Parliament.

Incentives offered by the European Commission to registrants may include:

- measures with regard to the transmission of information to registrants when launching public consultations;
- measures with regard to expert groups and other advisory bodies;
- specific mailing lists;
- patronage by the European Commission.

Specific incentives available to registrants shall be communicated to them by the parties hereto.

VII. *Measures in the event of non-compliance with the code of conduct*

31. Any person may lodge alerts and complaints, using the standard contact form, available on the website of the register, concerning possible non-compliance with the code of conduct set out in Annex 3. Alerts and complaints shall be handled in accordance with the procedures laid down in Annex 4.

32. An alert mechanism is a tool to complement the quality checks performed by the JTRS in accordance with paragraph 24. Any person may lodge an alert with regard to factual mistakes concerning the information provided by the registrants. Alerts may also be lodged with regard to non-eligible registrations.

Tuesday 15 April 2014

33. Any person may lodge a formal complaint where non-compliance by a registrant with the code of conduct, other than factual mistakes, is suspected. Complaints shall be substantiated by material facts with regard to the suspected non-compliance with the code.

The JTRS shall investigate the suspected non-compliance with due regard for the principles of proportionality and good administration. Intentional non-compliance with the code of conduct by registrants or by their representatives shall lead to the application of the measures laid down in Annex 4.

34. Where repeated non-co-operation, repeated inappropriate behaviour, or serious non-compliance with the code of conduct, has been identified by the JTRS under the procedures referred to in paragraphs 31 to 33, the registrant concerned shall be removed from the register for a time period of either one year or two years and the measure will be publicly mentioned in the register, as laid down in Annex 4.

VIII. *Involvement of other institutions and bodies*

35. The European Council and the Council are invited to join the register. Other EU institutions, bodies and agencies are encouraged to use the framework created by this agreement themselves as a reference instrument for their own interaction with organisations and self-employed individuals engaged in EU policy-making and policy implementation.

IX. *Final provisions*

36. This agreement shall replace the agreement between the European Parliament and the European Commission of 23 June 2011 whose effects shall cease to apply on the date of application of this agreement.

37. The register shall be subject to a review in 2017.

38. This agreement shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. It shall apply from (*) or from 1 January 2015 whichever date is the earliest.

Entities already registered at the date of application of this agreement shall amend their registration to satisfy the new requirements resulting from this agreement within a period of three months following that date.

Done at ...,

For the European Parliament
The President

For the European Commission
The President

(*) OJ: please insert the date: 3 months after the date of entry into force of this agreement.

Tuesday 15 April 2014

Annex 1

'Transparency Register'

Organisations and self-employed individuals engaged in EU policy-making and policy implementation

Sections		Characteristics/remarks
I - Professional consultancies/law firms/self-employed consultants		
Subsection	Professional consultancies	Firms carrying on, on behalf of clients, activities involving advocacy, lobbying, promotion, public affairs and relations with public authorities.
Subsection	Law firms	Law firms carrying on, on behalf of clients, activities involving advocacy, lobbying, promotion, public affairs and relations with public authorities.
Subsection	Self-employed consultants	Self-employed consultants or lawyers carrying on, on behalf of clients, activities involving advocacy, lobbying, promotion, public affairs and relations with public authorities. This subsection is for registration of entities involving only one person.
II - In-house lobbyists and trade/business/professional associations		
Subsection	Companies and groups	Companies or groups of companies (with or without legal status) carrying on in-house, for their own account, activities involving advocacy, lobbying, promotion, public affairs and relations with public authorities.
Subsection	Trade and business associations	Organisations (either profit or non-profit making themselves) representing profit-making companies or mixed groups and platforms.
Subsection	Trade unions and professional associations	Interest representation of workers, employees, trades or professions.

Tuesday 15 April 2014

Sections		Characteristics/remarks
Subsection	Other organisations including: <ul style="list-style-type: none"> — event-organising entities (profit or non-profit making); — interest-related media or research oriented entities linked to private profit making interests; — ad-hoc coalitions and temporary structures (with profit-making membership). 	
III - Non-governmental organisations		
Subsection	Non-governmental organisations, platforms, networks, ad-hoc coalitions, temporary structures and other similar organisations.	Not-for-profit organisations (with or without legal status), which are independent from public authorities or commercial organisations. Includes foundations, charities, etc. Any such entity including profit-making elements among its membership must register in Section II.
IV - Think tanks, research and academic institutions		
Subsection	Think tanks and research institutions	Specialised think tanks and research institutions dealing with the activities and policies of the European Union.
Subsection	Academic institutions	Institutions whose primary purpose is education but that deal with the activities and policies of the European Union.
V - Organisations representing churches and religious communities		
Subsection	Organisations representing churches and religious communities	Legal entities, offices, networks or associations set up for representation activities.
VI - Organisations representing local, regional and municipal authorities, other public or mixed entities, etc.		
Subsection	Regional structures	Regions themselves and their representative offices are not expected to register but can register if they wish to do so. Associations or networks created to represent regions collectively are expected to register.

Tuesday 15 April 2014

Sections		Characteristics/remarks
Subsection	Other sub-national public authorities	All other sub-national public authorities, such as cities, local and municipal authorities, or their representation offices, and national associations or networks, are expected to register.
Subsection	Transnational associations and networks of public regional or other sub-national authorities	
Subsection	Other public or mixed entities, created by law whose purpose is to act in the public interest	Includes other organisations with public or mixed (public/private) status.

Tuesday 15 April 2014

Annex 2**Information to be provided by registrants****I. GENERAL AND BASIC INFORMATION**

- a) organisation name(s), address of head office and Brussels, Luxembourg or Strasbourg address where relevant, phone number, e-mail address, website;
- b) names of the person legally responsible for the organisation and of the organisation's director or managing partner or, if applicable, principal contact point in respect of activities covered by the register (i.e. head of EU affairs); names of the persons with authorisation for access to the European Parliament's premises ⁽¹⁾;
- c) number of persons (members, staff, etc) involved in activities covered by the register and of persons benefiting from an access pass to the European Parliament's premises and the amount of time spent by each person on such activities according to the following percentages of a full-time activity: 25 %, 50 %, 75 % or 100 %;
- d) goals/remit — fields of interest — activities — countries in which operations are carried out — affiliations to networks — general information falling within the scope of the register;
- e) membership and, if applicable, number of members (individuals and organisations).

II. SPECIFIC INFORMATION**A. ACTIVITIES COVERED BY THE REGISTER**

Specific details shall be provided on the main legislative proposals or policies targeted by activities of the registrant, and which are covered by the register. Reference to other specific activities, such as events or publications, may be made.

B. LINKS WITH EU INSTITUTIONS

- a) Membership of high-level groups, consultative committees, expert groups, other EU supported structures and platforms, etc.
- b) Membership of, or participation in, European Parliament intergroups or industry forums, etc.

C. FINANCIAL INFORMATION RELATED TO THE ACTIVITIES COVERED BY THE REGISTER**1. All registrants shall provide:**

- a) An estimate of the annual costs related to activities covered by the register. Financial figures shall cover a full year of operations and refer to the most recent financial year closed, as of the date of registration or of the annual update of the registration details.
- b) The amount and source of funding, received from EU institutions in the most recent financial year closed, as of the date of registration or of the annual update of the registration details. That information shall correspond to the information provided by the European Financial Transparency System ⁽²⁾.

⁽¹⁾ Registrants can request authorisation for access to the European Parliament's premises at the end of the registration process. The names of individuals who receive access passes to the European Parliament's premises shall be inserted in the register. Registration shall not confer an automatic entitlement to such an access pass.

⁽²⁾ http://ec.europa.eu/budget/fts/index_en.htm

Tuesday 15 April 2014

2. Professional consultancies/law firms/self-employed consultants (Section I of Annex 1) shall additionally provide:

a) The turnover attributable to the activities covered by the register according to the following grid:

Annual turnover for representation activities in euros
0 — 99 999
100 000– 499 999
500 000 — 1 000 000
> 1 000 000

b) A list of all clients, on behalf of whom activities covered by the register are carried out. Revenue from clients for representation activities shall be listed according to the following grid:

Bracket size of representation activities per client per annum in euros
0 — 9 999
10 000 — 24 999
25 000 — 49 999
50 000 — 99 999
100 000 — 199 999
200 000 — 299 999
300 000 — 399 999
400 000 — 499 999
500 000 — 599 999
600 000 — 699 999
700 000 — 799 999
800 000 — 899 999
900 000 — 1 000 000
> 1 000 000

c) Clients are also expected to register. The financial declaration made by professional consultancies/law firms/self-employed consultants concerning their clients (list and grid) does not exempt those clients from their obligation to include subcontracted activities in their own declarations, so as to avoid an underestimation of their declared financial outlay.

3. In-house lobbyists and trade/business/professional associations (Section II of Annex I) shall additionally provide:

the turnover attributable to the activities covered by the register, including for amounts less than EUR 10 000.

Tuesday 15 April 2014

4. Non-governmental organisations — Think tanks, research and academic institutions — organisations representing churches and religious communities — organisations representing local, regional and municipal authorities, other public or mixed entities, etc. (Sections III to VI of Annex 1) shall additionally provide:

- a) the total budget of the organisation
 - b) a breakdown of the main amounts and sources of funding.
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Tuesday 15 April 2014

Annex 3

Code of conduct

The parties hereto consider that all interest representatives interacting with them, whether on a single occasion or more frequently, registered or not, should behave in conformity with this code of conduct.

In their relations with EU institutions and their Members, officials and other staff, interest representatives shall:

- (a) always identify themselves by name and, by registration number, if applicable, and by the entity or entities they work for or represent; declare the interests, objectives or aims they promote and, where applicable, specify the clients or members whom they represent;
- (b) not obtain or try to obtain information or decisions dishonestly or by use of undue pressure or inappropriate behaviour;
- (c) not claim any formal relationship with the European Union or any of its institutions in their dealings with third parties, or misrepresent the effect of registration in such a way as to mislead third parties or officials or other staff of the European Union, or use the logos of EU institutions without express authorisation;
- (d) ensure that, to the best of their knowledge, information, which they provide upon registration, and subsequently in the framework of their activities covered by the register, is complete, up-to-date and not misleading; accept that all information provided is subject to review and agree to co-operate with administrative requests for complementary information and updates;
- (e) not sell to third parties copies of documents obtained from EU institutions;
- (f) in general, respect, and avoid any obstruction to the implementation and application of, all rules, codes and good governance practices established by EU institutions;
- (g) not induce Members of the institutions of the European Union, officials or other staff of the European Union, or assistants or trainees of those Members, to contravene the rules and standards of behaviour applicable to them;
- (h) if employing former officials or other staff of the European Union, or assistants or trainees of Members of EU institutions, respect the obligation of such employees to abide by the rules and confidentiality requirements which apply to them;
- (i) obtain the prior consent of the Member or Members of the European Parliament concerned as regards any contractual relationship with, or employment of, any individual within a Member's designated entourage;
- (j) observe any rules laid down on the rights and responsibilities of former Members of the European Parliament and the European Commission;
- (k) inform whomever they represent of their obligations towards the EU institutions.

Individuals who have registered with the European Parliament with a view to being issued with a personal, non-transferable pass affording access to the European Parliament's premises shall:

- (l) ensure that they wear the access pass visibly at all times in European Parliament premises;
 - (m) comply strictly with the relevant European Parliament Rules of Procedure;
 - (n) accept that any decision on a request for access to the European Parliament's premises is the sole prerogative of the Parliament and that registration shall not confer an automatic entitlement to an access pass.
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Tuesday 15 April 2014

Annex 4**Procedures for alerts and for the investigation and treatment of complaints****I. ALERTS**

Any person may lodge an alert to the JTRS by completing the standard contact form, available on the website of the register, with regard to information contained in the register and non-eligible registrations.

Where alerts are made about information contained in the register, they will be treated as allegations of non-compliance with point (d) of the code of conduct set out in Annex 3⁽¹⁾. The registrant concerned will be asked to update the information or explain to the JTRS why the information does not need to be updated. Where the registrant concerned does not co-operate, measures as outlined in the table of measures below (rows 2 to 4), may be applied.

II. COMPLAINTS**Stage 1: Submitting a complaint**

1. Any person may submit a complaint to the JTRS by completing a standard form available on the website of the register. That form shall contain the following information:

- (a) the registrant that is the subject of the complaint;
- (b) the name and contact details of the complainant;
- (c) details of the alleged non-compliance with the code of conduct, including possible documents or other materials supporting the complaint, an indication of whether any harm was caused to the complainant and grounds for suspecting intentional non-compliance.

Anonymous complaints shall not be considered.

2. The complaint shall specify the clauses of the code of conduct which the complainant alleges have not been complied with. Any complaint, where the non-compliance is, from the outset, deemed to be clearly unintentional by the JTRS, may be re-qualified by the JTRS as an 'alert'.

3. The code of conduct shall apply exclusively to relations between interest representatives and the EU institutions and may not be used to regulate relations between third parties or between registrants.

Stage 2: Admissibility

4. On reception of the complaint the JTRS shall:

- (a) acknowledge receipt of the complaint to the complainant within five working days;
- (b) determine whether the complaint falls within the scope of the register, as outlined in the code of conduct set out in Annex 3 and stage 1 above;

⁽¹⁾ Point (d) requires interest representatives, in their relations with the EU institutions and their Members, officials and other staff, to 'ensure that, to the best of their knowledge, information which they provide upon registration and subsequently in the framework of their activities covered by the register is complete, up-to-date and not misleading' and to 'accept that all information provided is subject to review and agree to co-operate with administrative requests for complementary information and updates'.

Tuesday 15 April 2014

- (c) verify any evidence adduced to support the complaint, whether this takes the form of documents, other materials or personal statements; in principle any material evidence shall be sourced from the registrant concerned, from a document issued by a third party or from publicly available sources. Mere value judgments presented by the complainant shall not be considered to be evidence;
 - (d) on the basis of the analyses referred to in points (b) and (c), decide on the admissibility of the complaint.
5. If the complaint is deemed inadmissible, the JTRS shall inform the complainant in writing, stating the reasons for the decision.
6. If the complaint is deemed admissible, both the complainant and the registrant concerned shall be informed by the JTRS of the decision and of the procedure to be followed, as set out below.

Stage 3: Handling of an admissible complaint — examination and provisional measures

7. The registrant concerned shall be notified by the JTRS of the content of the complaint and of the clause(s) allegedly not complied with and shall be invited at the same time to submit a position in response to that complaint within 20 working days. In support of that position, and within the same timeframe, a memorandum produced by a representative professional organisation may also be submitted by the registrant, in particular for regulated professions or organisations subject to a professional code of conduct.
8. Non-compliance with the deadline indicated in paragraph 7 shall lead to a temporary suspension of the registrant concerned from the register until co-operation is resumed.
9. All information collected during the investigation shall be examined by the JTRS which may decide to hear the registrant concerned, or the complainant, or both.
10. If examination of the material provided shows the complaint to be unfounded, the JTRS shall inform both the registrant concerned and the complainant of the decision to that effect, stating the reasons for the decision.
11. If the complaint is upheld, the registrant concerned shall be temporarily suspended from the register pending the taking of steps to address the issue (see Stage 4 below) and may be subject to a number of additional measures including removal from the register and withdrawal, where applicable, of any authorisation for access to the European Parliament's premises in accordance with the internal procedures of that institution (see Stage 5 and rows 2-4 in the table of measures below), notably in cases of non co-operation.

Stage 4: Handling of an admissible complaint — resolution

12. Where a complaint is upheld and problematic issues are identified, the JTRS will take all necessary steps in cooperation with the registrant concerned to address and resolve the issue.
13. If the registrant concerned co-operates, a reasonable period of time shall be allocated by the JTRS, on a case-by-case basis, to achieve resolution.
14. Where a possible resolution of the issue has been identified, and the registrant concerned co-operates to give effect to that resolution, the registration pertaining to that registrant shall be reactivated, and the complaint closed. The JTRS shall inform both the registrant concerned and the complainant of the decision to that effect, stating the reasons for the decision.
15. Where a possible resolution of the issue has been identified, and the registrant concerned does not co-operate to give effect to that resolution, the registration pertaining to that registrant shall be deleted (see rows 2 and 3 of the table of measures below). The JTRS shall inform both the registrant concerned and the complainant of the decision to that effect, stating the reasons for the decision.
16. Where a possible resolution of the issue requires a decision from a third party, including an authority in a Member State, the final decision by the JTRS shall be suspended until such time as that decision has been taken.
17. If the registrant does not co-operate within 40 working days of the notification of the complaint under paragraph 7, measures for non-compliance shall be applied (see paragraphs 19 to 22 of Stage 5 and rows 2 to 4 of the table of measures below).

Tuesday 15 April 2014

Stage 5: Handling of an admissible complaint — measures to be applied in the event of non-compliance with the code of conduct

18. Where immediate corrections are made by the registrant concerned, both the complainant and the registrant concerned will receive from the JTRS written acknowledgement of the facts and their corrections (see row 1 of the table of measures below).

19. Failure to react by the registrant concerned within the deadline of 40 days set out in paragraph 17 shall result in removal from the register (see row 2 of the table of measures below) and loss of access to any incentives linked to registration.

20. Where inappropriate behaviour has been identified, the registrant concerned shall be removed from the register (see row 3 of the table of measures below) and shall lose any incentives linked to registration.

21. In cases referred to in paragraphs 19 and 20, the registrant concerned may re-register, if the grounds leading to removal have been remedied.

22. Where either non-co-operation or inappropriate behaviour are deemed to be repeated and deliberate, or where serious non-compliance has been identified (see row 4 of the table of measures below), a decision to prohibit re-registration for a time period of either one year or two years (depending on the gravity of the case) shall be adopted by the JTRS.

23. Any measure adopted under paragraphs 18 to 22 or rows 1 to 4 in the table of measures below shall be notified by the JTRS to the registrant concerned and to the complainant.

24. In cases where a measure adopted by the JTRS results in a long-term removal from the register (see row 4 in the table of measures below), the registrant concerned may — within 20 working days of the notification of the measure — submit a reasoned request for re-examination of that measure to the Secretaries-General of the European Parliament and of the European Commission.

25. Upon expiry of the 20 days deadline or after the Secretaries-General have taken a final decision, the relevant Vice-President of the European Parliament and the relevant Vice-President of the European Commission shall be informed and the measure shall be mentioned publicly in the register.

26. Where a decision on prohibiting re-registration for a certain time period entails a withdrawal of the possibility of requesting authorisation to access the European Parliament's premises as an interest representative, a proposal by the Secretary-General of the European Parliament shall be submitted to the College of Quaestors, who shall be invited to authorise the withdrawal of the related access authorisation held by the individual or individuals concerned for that time period.

27. In its decisions on applicable measures under this Annex, the JTRS shall have due regard to the principles of proportionality and good administration. The JTRS shall operate under the coordination of a Head of Unit in the Secretariat-General of the European Commission, and under the authority of the Secretaries-General of the European Parliament and the European Commission, who shall be kept duly informed.

Table of measures available in the event of non-compliance with the code of conduct

	Type of non-compliance (numbers refer to the paragraphs above)	Measure	Publication of measure in the register	Formal decision to withdraw access to European Parliament premises
1	Non-compliance, immediately corrected (18)	Written notification acknowledging the facts and their correction.	No	No
2	Non-co-operation with JTRS (19 and 21)	Removal from the register, de-activation of the authorisation for access to European Parliament premises and loss of other incentives	No	No

Tuesday 15 April 2014

	Type of non-compliance (numbers refer to the paragraphs above)	Measure	Publication of measure in the register	Formal decision to withdraw access to European Parliament premises
3	Inappropriate behaviour (20 and 21)	Removal from the register, de-activation of the authorisation for access to European Parliament premises and loss of other incentives.	No	No
4	Repeated and deliberate non-co-operation or repeated inappropriate behaviour (22) and/or serious non-compliance.	<p>a) Removal from the register for one year, and formal withdrawal of the authorisation for access to European Parliament premises (as an accredited interest group representative);</p> <p>b) Removal from the register for two years and formal withdrawal of the authorisation for access to European Parliament premises (as an accredited interest group representative).</p>	Yes, by decision of the Secretaries-General of the European Parliament and of the European Commission.	Yes, by decision of College of Quaestors

Tuesday 15 April 2014

P7_TA(2014)0379

Enhancing worker mobility by improving the acquisition and preservation of supplementary pension rights *II**

European Parliament legislative resolution of 15 April 2014 on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on minimum requirements for enhancing worker mobility between Member States by improving the acquisition and preservation of supplementary pension rights (17612/1/2013 — C7-0059/2014 — 2005/0214(COD))

(Ordinary legislative procedure: second reading)

(2017/C 443/58)

The European Parliament,

- having regard to the Council position at first reading (17612/1/2013 — C7-0059/2014),
 - having regard to its position at first reading⁽¹⁾ on the Commission proposal to Parliament and the Council (COM(2005)0507),
 - having regard to the amended Commission proposal (COM(2007)0603),
 - having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 72 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on Employment and Social Affairs (A7-0188/2014),
1. Approves the Council position at first reading;
 2. Notes that the act is adopted in accordance with the Council position;
 3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;
 4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;
 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 146 E, 12.6.2008, p. 216.

Tuesday 15 April 2014

P7_TA(2014)0380

Food and feed law, rules on animal health and welfare, plant health, plant reproductive material and plant protection products *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [...] /2013 and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official Controls Regulation) (COM(2013)0265 — C7-0123/2013 — 2013/0140(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/59)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0265),
 - having regard to Article 294(2) and Articles 43(2), 114 and 168(4)(b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0123/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Luxembourg Chamber of Deputies, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 16 October 2013 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 29 November 2013 ⁽²⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A7-0162/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 67, 6.3.2014, p. 166.

⁽²⁾ OJ C 114, 15.4.2014, p. 96.

Tuesday 15 April 2014

P7_TC1-COD(2013)0140

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, ~~plant reproductive material~~, plant protection products and amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 1/2005, (EC) No 396/2005, (EC) No 834/2007, (EC) No 1099/2009, (EC) No 1069/2009, (EC) No 1107/2009, Regulations (EU) No 1151/2012, (EU) No .../2013 (*), and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation) [Am. 1]

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114 and point (b) of Article 168(4) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) The Treaty on the Functioning of the European Union ("Treaty") requires a high level of human health protection to be ensured in the definition and implementation of all Union policies and activities. The achievement of that objective should, inter alia, be pursued via measures in the veterinary and phytosanitary fields which have as their direct objective the protection of human health.
- (2) The Treaty also provides that the Union is to contribute to the attainment of a high level of consumer protection by the measures it adopts in the context of the completion of the internal market.
- (3) Union legislation provides for a set of harmonised rules to ensure that food and feed are safe and wholesome and that activities which might have an impact on the safety of the food chain or on the protection of consumers interests in relation to food and food information are carried out in accordance with specific requirements. Union rules exist also to ensure a high level of human, **and** animal ~~and plant~~ health and animal welfare along the food chain and in all those areas of activity where a key objective is the fight against the possible spread of animal diseases, in some cases transmissible to humans, or of pests injurious to plants or plant products, and to ensure the protection of the environment from risks that might arise from genetically modified organisms (GMOs) and plant protection products. ~~Union rules also guarantee the identity and quality of plant reproductive material.~~ The correct application of those rules, hereinafter collectively referred to as 'Union agri-food chain legislation', contributes to the functioning of the internal market. [Am. 2]

(*) Number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

⁽¹⁾ OJ C 67, 6.3.2014, p. 166.

⁽²⁾ OJ C 114, 15.4.2014, p. 96.

⁽³⁾ Position of the European Parliament of 15 April 2014.

Tuesday 15 April 2014

- (4) The basic Union rules with regard to food and feed law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council⁽¹⁾. In addition to those rules, more specific food and feed law covers different areas such as animal nutrition, including medicated feedingstuffs, food and feed hygiene, zoonoses, animal by-products, residues of veterinary medicinal products, contaminants, control and eradication of animal diseases with a human health impact, food and feed labelling, plant protection products, food and feed additives, vitamins, mineral salts, trace elements and other additives, food contact materials, quality and compositional requirements, drinking water, ionisation, novel foods and GMOs.
- (5) Union legislation on animal health aims to ensure high standards of human and animal health in the Union, the rational development of the agriculture and aquaculture sectors and to increase productivity. That legislation is necessary to contribute to the completion of the internal market in animals and animal products and to avoid the spread of infectious diseases of Union concern. It covers areas such as intra-Union trade, entry into the Union, disease eradication, veterinary controls and notification of diseases, and also contributes to the safety of food and feed.
- (6) Article 13 of the Treaty recognises that animals are sentient beings. Union legislation on animal welfare requires animal owners, animal keepers and competent authorities to respect animal welfare requirements guaranteeing their humane treatment and avoiding their unnecessary pain and suffering. Such rules are based on scientific evidence and may indirectly improve the quality and safety of food and feed.
- (7) Union legislation on plant health regulates the entry, establishment and spread of pests of plants that do not exist, or are not widely present, in the Union. Its objective is to protect the health of Union crops and of public and private green space and forests while simultaneously safeguarding the Union's biodiversity and environment and guaranteeing the quality and safety of food and feed made from plants.
- (8) ~~Union legislation on plant reproductive material regulates the production with a view to placing on the market, and the placing on the market, of plant reproductive material of agricultural, vegetable, forest, fruit and ornamental species and vines. The objective of those rules is to ensure the identity, health and quality of plant reproductive material for its users, and the productivity, diversity, health and quality of the agri-food chain as well as contributing to the protection of biodiversity and the environment. [Am. 3]~~
- (9) Union legislation on organic production and labelling of organic products provides a basis for the sustainable development of organic production and aims to contribute to the protection of natural resources, biodiversity and animal welfare, and the development of rural areas.
- (10) Union legislation on agricultural quality schemes for agricultural products and foodstuffs identifies products and foodstuffs farmed and produced to exact specifications whilst encouraging diverse agricultural production, protecting product names and informing consumers about the specific character of agricultural products and foodstuffs.
- (11) Union agri-food chain legislation is based on the principle that operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that the requirements established by Union agri-food chain legislation and which are relevant to their activities are fulfilled.
- (12) The responsibility to enforce Union agri-food chain legislation lies with Member States, whose competent authorities monitor and verify, through the organisation of official controls, that relevant Union requirements are effectively complied with and enforced.

⁽¹⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and setting out procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Tuesday 15 April 2014

- (13) Regulation (EC) No 882/2004 of the European Parliament and of the Council ⁽¹⁾ has established a single legislative framework for the organisation of official controls. That framework has significantly improved the efficiency of official controls, the enforcement of Union agri-food chain legislation and the level of protection against risks to human, animal and plant health and animal welfare in the Union and the level of protection of the environment from risks that might arise from GMOs and plant protection products. It has also provided a consolidated legal framework to support an integrated approach towards the performance of official controls along the agri-food chain.
- (14) ~~There are a number of provisions in Union agri-food chain legislation, the enforcement of which has not, or has only partially, been governed by Regulation (EC) No 882/2004. In particular, specific official control rules were kept in place in Union legislation on plant reproductive material and in Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 ⁽²⁾. Plant health also largely falls outside the scope of Regulation (EC) No 882/2004 with certain rules on official controls being laid down in Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community ⁽³⁾. [Am. 4]~~
- (15) Council Directive 96/23/EC ⁽⁴⁾ also provides for a very detailed set of rules that establish, inter alia, minimum frequencies of official controls and specific enforcement measures to be adopted in cases of non-compliance.
- (16) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, the rules applicable to official controls ~~in specific areas should be integrated into a single legislative framework for official controls~~ **should be more closely integrated, provided that they pursue the same objective with regard to control activities**. For that purpose, Regulation (EC) No 882/2004 and other acts currently governing official controls in specific areas should be repealed and replaced by this Regulation. [Am. 5]
- (17) This Regulation should seek to establish a harmonised Union framework for the organisation of official controls, and official activities other than official controls, along the entire agri-food chain, taking into account the rules on official controls laid down in Regulation (EC) No 882/2004 and in relevant sectoral legislation, and the experience gained from their application.
- (18) For the verification of compliance with the rules on the common organisation of the markets of agricultural products such as arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey, a well-established and specific control system is already in place. This Regulation should therefore not apply to the verification of compliance with the provisions of Council Regulation (EC) No 1234/2007 ⁽⁵⁾, **with the exception of Part II, Title II, Chapter I of that Regulation**. [Am. 6]
- (19) Certain definitions currently set out in Regulation (EC) No 882/2004 should be adapted to take account of the broader scope of this Regulation, to align them with those set out in other Union acts, and to clarify or, where appropriate, replace terminology having different meanings in different sectors.

⁽¹⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁽²⁾ OJ L 300, 14.11.2009, p. 1.

⁽³⁾ OJ L 169, 10.7.2000, p. 1.

⁽⁴⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

⁽⁵⁾ Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) (OJ L 299, 16.11.2007, p. 1).

Tuesday 15 April 2014

- (20) Union agri-food chain legislation entrusts the competent authorities of the Member States with specialised tasks to be carried out, **not least** for the protection of animal health, plant health and animal welfare and for the protection of the environment in relation to GMOs and plant protection products, ~~and in order to ensure the identity and a high quality of plant reproductive material.~~ Those tasks are the public interest activities which the competent authorities of the Member States are required to carry out for the purpose of eliminating, containing or reducing risks which may arise for human, animal or plant health, animal welfare, or for the environment. Those activities, which include product approval, surveying, surveillance and monitoring, including for epidemiologic purposes, and the eradication and containment of diseases, and other disease control tasks, are governed by the same sectoral rules which are enforced through the official controls. [Am. 7]
- (21) Competent authorities should be designated by the Member States in all the areas falling within the scope of this Regulation. While Member States are best placed to decide which competent authority or authorities to designate for each area, and at which level of the administration, they should also be required to designate a single authority that in each area ensures appropriately coordinated communication with other Member States' competent authorities and with the Commission.
- (22) Member States should be allowed to confer upon designated competent authorities the responsibility for official controls in relation to Union rules, including rules regarding alien species which may harm agricultural production or the environment by their invasive character, other than those falling within the scope of this Regulation.
- (23) For the performance of official controls aimed at verifying the correct application of Union agri-food chain legislation, and of the other official activities entrusted to Member State authorities by Union agri-food chain legislation, Member States should designate competent **public** authorities which act in the public interest, ~~are~~ **and ensure the quality, consistency and effectiveness of official controls. The designated competent authority, or authorities, should be** appropriately resourced and equipped, and ~~offer guarantees of Member States should be able to guarantee their~~ impartiality and professionalism. ~~Competent authorities should ensure the quality, consistency and effectiveness of official controls. by ensuring their independence from any operator operating within the agri-food chain.~~ [Am. 8]
- (24) The correct application and enforcement of the rules falling within the scope of this Regulation requires appropriate knowledge of both such rules and the rules of this Regulation. It is therefore important that the staff performing official controls and other official activities are regularly trained on the applicable legislation, according to their area of competence, as well as on the obligations resulting from this Regulation.
- (24a) *The audits undertaken by the competent authorities, or at the request of the competent authorities, to ensure compliance with this Regulation may be based on international standards, where the requirements of those standards correspond to the requirements of this Regulation.* [Am. 9]
- (25) Operators should have ~~a~~ **the** right to appeal against the decisions taken by the competent authorities, ~~and be informed of such a~~. **The competent authorities are to inform operators of this right.** [Am. 10]
- (26) The competent authorities should ensure that, **with the exception of internal reporting obligations**, staff responsible for official controls do not disclose information acquired during the performance of such controls where that information is covered by professional secrecy. ~~Unless there is an overriding interest justifying disclosure, professional secrecy should include information which would undermine the purpose of inspections, investigations or audits, the protection of commercial interests and the protection of court proceedings and legal advice. However, professional secrecy should not prevent competent authorities from disclosing~~ **Where there is a suspicion of risk to human or animal health or of other serious breaches of food law, the competent authorities should take suitable steps to inform the public. The measures taken should be in proportion to the scale of the infringement, in particular when naming specific products or operators concerned.** Factual information on the outcome of ~~an official controls~~ **control** regarding individual operators **may be divulged** when the operator concerned has been allowed to comment upon it prior to the disclosure and such comments have been taken into account, ~~or~~ **and**

Tuesday 15 April 2014

released alongside **and at the same time as** the information being divulged by the competent authorities. ~~The need to respect professional secrecy is also without prejudice to the obligation to inform the general public where there are reasonable grounds to suspect that food or feed may present a risk for health in accordance with Article 10 of Regulation (EC) No 178/2002.~~ The obligation for competent authorities to inform the general public in cases where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, in accordance with Article 10 of Regulation (EC) No 178/2002, and the right of individuals to the protection of their personal data as provided for in Directive 95/46/EC of the European Parliament and of the Council ⁽¹⁾ should not be affected by this Regulation. [Am. 11]

- (27) Competent authorities should perform official controls regularly, on all the sectors and in relation to all operators, activities, animals and goods governed by Union agri-food chain legislation. The frequency of official controls should be established by the competent authorities having regard to the need to adjust the control effort to the risk and to the level of compliance expected in the different situations. In some cases, however, Union agri-food chain legislation requires that official controls be performed irrespective of the level of risk or expected non-compliance in view of the issuance of an official certificate or attestation which is a pre-requisite for the placing on the market or for the movements of animals or goods. In such cases the frequency of the official controls is dictated by the certification or attestation needs.
- (28) To preserve the effectiveness of official controls in the verification of compliance, no warning should be given prior to performing controls, unless the nature of the official control activities requires otherwise, as is the case in particular for audit activities.
- (29) Official controls should be thorough and effective and should ensure that Union legislation is applied correctly. Given that official controls may represent a burden for operators, competent authorities should organise and conduct official control activities taking their interests into account and limiting the said burden to what is necessary for the performance of efficient and effective official controls.
- (29a) **Official controls should be performed by staff free from any conflict of interests, and in particular not engaged, directly or through a spouse, in an economic activity that is subject to the official controls laid down.** [Am. 12]
- (30) Official controls should be performed with the same level of care by the competent authorities of the Member State irrespective of whether the rules being enforced apply to activities which are only relevant on the territory of that Member State or to activities which will have an impact on the compliance with Union legislation of animals and goods which are to be moved or placed on the market in another Member State or exported outside the Union. In the latter case, competent authorities may also be required, in accordance with Union legislation, to verify the conformity of animals and goods with requirements established by the third country of destination of such animals or goods.
- (31) To ensure that the Union agri-food chain rules are correctly enforced, the competent authorities should have the power to perform official controls at all stages of production, processing and distribution of animals and goods concerned by such rules. To ensure that official controls are thoroughly conducted and effective, the competent authorities should also have the power to perform official controls at all stages of production and distribution of goods, substances, materials or objects which are not governed by agri-food chain rules (for example, of veterinary medicinal products) insofar as this is necessary to fully investigate possible violations of those rules and to identify the cause of any such violation.
- (32) The competent authorities act in the interest of operators and of the general public by ensuring that the high standards of protection established by Union agri-food chain legislation are consistently preserved and protected through appropriate enforcement action, and that compliance with such rules is ascertained across the entire agri-food chain through official controls. The competent authorities should therefore be accountable to the operators and to the general public for the efficiency and effectiveness of the official controls they perform. They should provide access to information concerning the organisation and performance of official controls and other official activities, and regularly publish information concerning official controls and the results therefrom. Competent authorities should also, subject to certain conditions, be entitled to publish or to make available information about the rating of individual operators based on the outcome of official controls.

⁽¹⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

Tuesday 15 April 2014

- (33) It is of the utmost importance that competent authorities ensure and verify the effectiveness and the consistency of the official controls they perform. For that purpose they should act on the basis of written documented procedures and should provide detailed information and instructions to staff performing official controls. They should also have appropriate procedures and mechanisms in place to continuously verify that their own action is effective and consistent, and take corrective action when shortcomings are identified.
- (34) To facilitate the identification of non-compliance and streamline the taking of corrective action by the operator concerned, the outcome of official controls **which identify non-compliance with the rules** should be recorded in a report. A copy of ~~which~~ **that report** should **also** be given to the operator. Where official controls require the continuous or regular presence of the staff of the competent authorities to monitor the operator's activities, a report of each individual inspection or visit to the operator would be disproportionate. In such cases, reports should be prepared with a frequency that enables the competent authorities and the operator to be regularly informed of the level of compliance and immediately notified of any identified shortcomings. **In the interests of reducing the administrative burden, it should also be sufficient to record the outcome of official controls at border control posts in the Common Health Entry Document.** [Am. 13]
- (35) Operators should cooperate fully with competent authorities and delegated bodies to ensure the smooth performance of official controls and to enable the competent authorities to perform other official activities.
- (36) This Regulation establishes a single legislative framework for the organisation of official controls to verify compliance with agri-food chain rules in all the areas that such rules cover. In some of those areas, Union legislation lays down detailed requirements to be complied with which require special skills and specific means for the performance of official controls. To avoid diverging enforcement practices which could generate uneven protection of human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, of the environment, disrupt the functioning of the internal market for animals and goods falling within the scope of this Regulation and distort competition, the Commission should be able to supplement the rules laid down in this Regulation through the adoption of specific official control rules capable of catering for the needs of controls of those areas.

In particular, such rules should lay down specific requirements for the performance of official controls and minimum frequencies for those controls, specific or additional measures to those provided for in this Regulation that competent authorities should take in relation to non-compliances, specific responsibilities and tasks of the competent authorities in addition to those provided for in this Regulation and specific criteria for triggering the administrative assistance mechanisms provided for in this Regulation. In other cases, such additional rules might become necessary in order to provide a more detailed framework for the performance of official controls in relation to food and feed, where new information emerges about risks to human or animal health or, in relation to GMOs and plant protection products to the environment, indicating that in the absence of common specifications for the performance of official controls across the Member States, the controls would fail to deliver the expected level of protection against those risks, as provided for by Union agri-food chain legislation.

- (37) The competent authorities should be able to delegate some of their tasks to other bodies. Appropriate conditions should be laid down to guarantee that the impartiality, quality and consistency of the official controls and of the other official activities are preserved. The delegated body should in particular be accredited according to the ISO standard for the performance of inspections.
- (38) To ensure the reliability and consistency of official controls and other official activities across the Union, the methods used for sampling and for laboratory analyses, tests and diagnoses should meet state-of-the-art scientific standards, satisfy the specific analytical, testing and diagnostic need of the laboratory concerned, and offer sound and reliable analytical, test and diagnostic results. Clear rules should be established for the choice of the method to be used where more than one is available from different sources, such as the International Organisation for Standardisation (ISO), the European and Mediterranean Plant Protection Organisation (EPPO), the International Plant Protection Convention (IPPC), the World Organisation for Animal Health (OIE), European Union and national reference laboratories, or national rules.

Tuesday 15 April 2014

- (39) Operators whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls should have the right to apply for a second expert opinion which should include the taking of a second sample for the purposes of counter-analysis, counter-test or counter-diagnosis unless any such second sampling is technically impossible or irrelevant. Such would be the case, in particular, where the prevalence of the hazard is particularly low in the animal or good or its distribution particularly sparse or irregular. The IPPC for that reason rejects the use of counter-samples for assessing the presence of quarantine organisms in plants or plant products.
- (40) For the purposes of performing official controls on trade which take place through the internet or other remote means, competent authorities should be able to obtain samples through anonymously placed orders, also known as mystery shopping, which can then be analysed, tested or subject to a verification of compliance. All steps should be taken by the competent authorities to preserve the rights of the operators to a second expert opinion.
- (41) Laboratories designated by the competent authorities to carry out analyses, tests and diagnoses on samples taken in the context of official controls and other official activities should possess the expertise, equipment, infrastructure and staff to carry out such tasks to the highest standards. To ensure sound and reliable results, those laboratories should be accredited for the use of these methods according to standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'. The accreditation should be delivered by a national accreditation body operating in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council⁽¹⁾.
- (42) While accreditation is the instrument of choice to ensure state-of-the-art performance by official laboratories, it is also a complex and costly process, which would result in a disproportionate burden for the laboratory in cases where the method of laboratory analysis, test or diagnosis is particularly simple to perform and does not require specialised procedures or equipment, as is the case for the detection of *Trichinella* in the context of the inspection, in cases where the analyses or tests performed only concern qualitative aspects of plant reproductive material, and, under certain conditions, in cases where the laboratory only carries out analyses, tests or diagnoses in the context of other official activities and not of official controls.
- (43) In order to ensure flexibility and proportionality of approach, in particular for animal health or plant health laboratories, provision should be made for the adoption of derogations aimed at allowing certain laboratories not to be accredited for all the methods they use. Moreover, accreditation of a laboratory for all the methods it should use as official laboratory might not be immediately available in certain cases where new or recently modified methods should be used, and in cases of emerging risks or in emergency situations. Under certain conditions, official laboratories should therefore be allowed to carry out analyses, tests and diagnoses for the competent authorities before they obtain the relevant accreditation.
- (44) Official controls performed on animals and goods entering the Union from third countries are of key importance to ensure that they comply with legislation applicable within the Union and, in particular, with the rules established to protect across the Union human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, the environment. Such official controls should take place as appropriate before or after the animals or goods are released for free circulation within the Union. The frequency of official controls should adequately address risks to health, animal welfare and to the environment, that animals and goods entering the Union could pose, taking into account the history of compliance with the requirements provided for in Union agri-food chain rules, the controls already performed on those animals and goods in the third country concerned, and the guarantees given by that third country that animals and goods exported to the Union meet the requirements laid down in Union legislation.

⁽¹⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

Tuesday 15 April 2014

- (45) Given the risks to human, animal or plant health, animal welfare or to the environment that certain animals or goods may pose, those animals or goods should be subject to specific official controls to be performed upon them at their entry into the Union. Current Union rules require the performance of official controls at Union borders to verify that human health, animal health and animal welfare standards applicable to animals, products of animal origin, germinal products and animal by-products are met and that plants and plant products comply with phytosanitary requirements. Increased controls at entry into the Union are also performed on certain other goods where emerging or known risks so warrant. The specificities of such controls, currently governed by the provisions of Council Directive 97/78/EC⁽¹⁾, Council Directive 91/496/EEC⁽²⁾, Council Directive 2000/29/EC⁽³⁾ and Commission Regulation (EC) No 669/2009⁽⁴⁾, should be provided for in this Regulation.
- (46) In order to reinforce the efficiency of the Union's official control system, ensure an optimal allocation of official control resources assigned to border controls and facilitate the enforcement of Union food chain legislation, a common integrated system of official controls at border control posts, replacing the current fragmented control frameworks, should be established to handle all consignments which, given the risk they may carry, should be controlled at their entry into the Union.
- (47) Official controls performed at border control posts should include documentary and identity checks on all consignments and physical checks performed at a frequency dependent on the risk posed by each consignment of animals or goods.
- (48) The frequency of physical checks should be determined and modified on the basis of risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment. This approach should enable the competent authorities to allocate control resources where the risk is highest. The frequency of identity checks should also be subject to reduction or limited to the verification of a consignment's official seal where this is justified by a reduced risk of the consignments entering the Union. The risk-based approach to identity and physical checks should be pursued by making full use of available data sets and information, and of computerised data collection and management systems.
- (49) In certain cases, and as long as high levels of human, animal and plant health, animal welfare and protection of the environment in relation to GMOs and plant protection products are guaranteed, official controls normally performed by competent authorities at border control posts could be performed at other control points or by other authorities.
- (50) For the purpose of organising an efficient system of official controls, consignments arriving from third countries which require controls at their entry into the Union should be accompanied by a common health entry document (CHED), to be used for the prior notification of the arrival of consignments at the border control post, and to record the result of official controls performed and of decisions taken by the competent authorities in relation to the consignment which they accompany. The same document should be used by the operator to obtain clearance by customs authorities once all official controls have been performed.

⁽¹⁾ Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

⁽²⁾ Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ L 268, 24.9.1991, p. 56).

⁽³⁾ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

⁽⁴⁾ Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and the Council as regards the increased level of official controls on imports of certain food and feed of non-animal origin and amending Decision 2006/504/EC (OJ L 194, 25.7.2009, p. 11).

Tuesday 15 April 2014

- (51) Official controls on animals and goods entering the Union from third countries should be performed at border control posts designated by Member States in accordance with a set of minimum requirements. The designation of such entities should be withdrawn or suspended when they no longer comply with those requirements or when their activities may pose a risk to human, animal or plant health, animal welfare or, in the case of GMOs and plant protection products, to the environment.
- (52) To guarantee the uniform application of official control rules on consignments arriving from third countries, common rules should be established to govern the actions that the competent authorities and operators should take in case of suspicion of non-compliance, and in relation to non-compliant consignments and of consignments which could pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment.
- (53) In order to avoid inconsistencies and duplications of the official controls effort, to allow consignments which are subject to official controls at border control posts to be timely identified, and to guarantee that controls are performed in an efficient manner, the cooperation and exchange of information amongst competent authorities, customs authorities and other relevant authorities dealing with consignments arriving from third countries should be ensured.
- (54) Member States should be required to ensure that adequate financial resources are always available in order to appropriately staff and equip the competent authorities performing official controls and other official activities. Although operators are primarily responsible for ensuring that their activities are carried out in compliance with Union agri-food chain rules, the system of own controls that they put in place for that purpose needs to be complemented by a dedicated system of official controls maintained by each Member State to ensure effective market surveillance along the agri-food chain. Such a system is, by its very nature, complex and resource-demanding and should be provided with a stable influx of resources for official controls, at a level appropriate to the enforcement needs at any given moment. To reduce the dependency of the official control system from public finances, competent authorities should **be able to** collect fees **or contributions to costs** to cover the costs they incur when performing official controls on certain operators and for certain activities for which Union agri-food chain legislation requires registration or approval in accordance with Union rules on the hygiene of food and feed or rules governing plant health ~~and plant reproductive material~~. Fees **or contributions to costs** should also be collected from operators to compensate the costs of official controls performed in view of issuing an official certificate or attestation, and costs of official controls performed by the competent authorities at border control posts. [Am. 14]
- (55) Fees should cover, but not exceed, the costs incurred by the competent authorities to perform official controls. Such costs should be calculated on the basis of each individual official control or on the basis of all official controls performed over a given period of time. Where fees are applied on the basis of the actual cost of individual official controls, operators with a good record of compliance should bear lower overall charges than non-compliant ones, as they should be subject to less frequent official controls. In order to promote compliance with Union legislation by all operators irrespective of the method, based on actual costs or on a flat rate, that each Member States will chose for the calculation of the fees, when these are calculated on the basis of overall costs incurred by the competent authorities over a given period of time, and charged on all operators irrespective of whether they are subject to an official control during the reference period, those fees should be calculated so as to reward operators with a consistent good record of compliance with Union food chain legislation.
- (56) The direct or indirect refund of fees collected by the competent authorities should be prohibited as it would put operators not benefitting from the refund at a disadvantage and potentially create distortions of competition. However, in order to provide support to micro-enterprises, these should be exempted from the payment of the fees collected in accordance with this Regulation.
- (57) The financing of official controls through fees collected from operators should occur in full transparency, so as to enable citizens and businesses to understand the method and data used to establish fees and be informed on the use of fees revenue.

Tuesday 15 April 2014

- (58) Union agri-food chain rules establish the cases where the placing on the market or the movement of certain animals or goods should be accompanied by an official certificate signed by the certifying officer. It is appropriate to establish a common set of rules laying down the obligations of the competent authorities and the certifying officers with regard to the issuance of official certificates as well as the characteristics that official certificates should have to ensure their reliability.
- (59) In other cases, the rules falling within the scope of this Regulation provide that the placing on the market or the movement of certain animals or goods should be accompanied by an official label, official mark or other official attestation issued by the operators under the official supervision of the competent authorities or by the competent authorities themselves. It is appropriate to lay down a minimum set of rules ensuring that also the issuance of official attestations is performed according to appropriate guarantees of reliability.
- (60) Official controls and other official activities should be based on analytical, testing and diagnostic methods that meet state-of-the-art scientific standards and offer sound, reliable and comparable results across the Union. The methods used by official laboratories as well as the quality and uniformity of analytical, testing and diagnostic data generated by them should therefore be improved continuously. For that purpose, the Commission should be able to designate, and rely on the expert assistance of European Union reference laboratories in all those areas of the food chain where there is the need for precise and reliable analytical, testing and diagnostic results. The European Union reference laboratories should in particular ensure that national reference laboratories and official laboratories are provided with up-to-date information on available methods, organise or participate actively in inter-laboratory comparative tests and offer training courses for national reference laboratories or official laboratories.
- (60a) *Regulations (EC) No 1829/2003 ⁽¹⁾ and (EC) No 1831/2003 ⁽²⁾ of the European Parliament and of the Council confer respectively on the European Union reference laboratory for genetically modified food and feed and on the European Union reference laboratory for feed additives, specific tasks as part of the authorisation procedure for genetically modified food or feed, or feed additives, relating, in particular, to the testing, evaluation and validation of the method of detection or analysis proposed by applicants. Experience shows that knowledge and expertise in the testing, evaluation and validation of methods in the context of the authorisation procedure is crucial in order to provide a high-level, state-of-the-art contribution to the efficiency of official controls. Laboratories designated as such under Regulations (EC) No 1829/2003 and (EC) No 1831/2003 should therefore act as European Union reference laboratories for the purposes of this Regulation. [Am. 16]*
- (61) For the performance of official controls and other official activities ~~on the production and marketing of plant reproductive material, and~~ in the field of animal welfare, the competent authorities should have access to updated, reliable and consistent technical data, to research findings, new techniques and expertise necessary for the correct application of Union legislation applicable in those areas. For that purpose the Commission should be able to designate, and rely on the expert assistance of, European Union reference centres for ~~plant reproductive material and~~ ~~for~~ animal welfare. [Am. 17]
- (62) In order to pursue the objectives of this Regulation and contribute to the smooth functioning of the internal market, ensuring consumer confidence in it, non-compliances with Union food chain legislation requiring enforcement action in more than one Member State should be pursued efficiently and consistently. The Rapid Alert System for Food and Feed (RASFF) established by Regulation (EC) No 178/2002 already enables competent authorities to rapidly exchange and disseminate information on serious direct or indirect risks to human health in relation to food or feed, or serious risks to human or animal health or to the environment in relation to feed, **or in the case of food fraud**, for the purpose of enabling rapid measures to be taken to counter those risks. However, that instrument, while allowing for timely action across all Member States concerned to counter certain serious risks along the food chain, cannot serve the purpose of enabling effective cross border assistance and cooperation between competent

⁽¹⁾ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

⁽²⁾ Regulation (EC) No 1831/2003 of the European Parliament and the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

Tuesday 15 April 2014

authorities to ensure that cases of non-compliance with Union agri-food chain legislation which have a cross-border dimension are effectively pursued not only in the Member State where the non-compliance is first detected but also in the Member State where the non-compliance originated. In particular, administrative assistance and cooperation should enable competent authorities to share information, detect, investigate and take effective and proportionate action to pursue cross-border violations of agri-food chain rules. **[Am. 18]**

- (63) Requests for administrative assistance and all notifications should be given appropriate follow-up. In order to facilitate administrative assistance and cooperation, Member States should be required to designate one or more liaison bodies to assist and coordinate communication flows between competent authorities in different Member States. In order to streamline and simplify cooperation amongst Member States the Commission should adopt implementing acts establishing the specifications of the technical tools to be used, the procedures for communication between liaison bodies and a standard format for requests for assistance, notifications and responses.
- (64) Each Member State should be required to set up and regularly update a multi-annual national control plan (MANCP) covering all the areas governed by Union agri-food chain legislation and containing information on the structure and organisation of its system of official controls. Such MANCPs are the instrument through which each Member State should ensure that official controls are performed in a risk-based and efficient manner across their territory and across the entire agri-food chain, and in compliance with this Regulation.
- (65) In order to guarantee the coherence and completeness of MANCPs Member States should designate a single authority responsible for their coordinated preparation and implementation. In order to promote a consistent, uniform and integrated approach to official controls, the Commission should have the power to adopt rules concerning MANCPs which should identify priorities for official controls, effective control procedures, criteria for risk categorisation and performance indicators for assessing MANCPs.
- (66) Member States should be required to submit an annual report to the Commission with information on control activities and the implementation of the MANCPs. In order to facilitate the collection and transmission of comparable data, the subsequent compilation of such data into Union-wide statistics and the preparation of reports by the Commission on the operation of official controls across the Union, the Commission should be able to adopt implementing acts in respect of establishing standard model forms for annual reports.
- (67) Commission experts should be able to perform controls in Member States to verify the application of Union legislation and the functioning of national control systems and competent authorities. Commission controls should also serve to investigate and collect information on enforcement practices or problems, emergencies and new developments in Member States.
- (68) Animals and goods from third countries should comply with the same requirements which apply to Union animals and goods, or with requirements which are recognised to be at least equivalent in relation to the objectives pursued by Union agri-food chain rules. This principle is enshrined in Regulation (EC) No 178/2002, which requires that food and feed imported into the Union comply with the relevant requirements of the Union's food law or with requirements considered to be at least equivalent thereto. Specific requirements to apply that principle are provided for in Union rules on protective measures against pests of plants, which prohibit the introduction into the Union of certain pests which are not present, or only present to a limited extent, in the Union, in Union rules laying down animal health requirements, which allow the entry of animals and of certain products of animal origin into the Union only from third countries which are included in a list set up for that purpose, and in Union rules for the organisation of official controls on products of animal origin intended for human consumption, which also provide for the establishment of a list of third countries from which those products can enter the Union. Concerning plant reproductive material, an equivalence system is in place whereby third countries from which plant reproductive material can be imported are authorised and listed.
- (69) In order to ensure that animals and goods entering the Union from third countries comply with all the requirements laid down in Union agri-food chain legislation or with requirements considered equivalent, in addition to the requirements established by Union rules on protective measures against pests of plants, Union rules laying down

Tuesday 15 April 2014

animal health requirements, and Union rules laying down specific hygiene rules for food of animal origin to ensure that the requirements laid down in Union agri-food legislation in relation to phytosanitary and veterinary concerns are met, the Commission should be allowed to establish conditions for the entry of animals and goods into the Union to the extent necessary to ensure that those animals and goods comply with all relevant requirements of Union agri-food chain legislation or equivalent requirements. Such conditions should apply to animals or goods or categories of animals or goods from all third countries or from certain third countries or regions thereof.

- (70) Where, in specific cases, there is evidence that certain animals or goods originating from a third country, a group of third countries, or regions thereof, give rise to risks to human, animal or plant health or, as regards GMOs and plant protection products, to the environment or where there is evidence that widespread serious non-compliance with Union agri-food chain legislation might be taking place, the Commission should be able to adopt measures to contain such risks.
- (71) The performance of effective and efficient official controls and other official activities, and ultimately the safety and health of humans, animals and plants, and the protection of the environment, also depends on the availability to the control authorities of well trained staff possessing an appropriate knowledge of all the matters relevant for the correct application of Union legislation. Appropriate, dedicated training should be provided by the Commission to promote a uniform approach to official controls and other official activities by the competent authorities. To promote the knowledge of Union agri-food chain legislation and requirements in third countries, such training should be also addressed to staff of the competent authorities in third countries.
- (72) To promote the sharing of experience and best practices among competent authorities, the Commission should also be able to organise, in cooperation with the Member States, programmes for the exchange of staff tasked with official controls or other official activities.
- (73) It is important for the performance of effective official controls and other official activities that the competent authorities in the Member States, the Commission and, where relevant, operators be able to exchange data and information related to official controls or results therefrom rapidly and efficiently. Several information systems are established by Union legislation and managed by the Commission to allow such data and information to be handled and managed through Union wide computerised and internet-based tools. A system dedicated to recording and tracing official control results is the Trade Control and Expert System (TRACES system), established by Commission Decision 2003/24/EC ⁽¹⁾ and currently used for the management of data and information on animals and products of animal origin and official controls thereon. That system should be upgraded **and adapted** so as to allow its use for all goods for which Union agri-food chain legislation establishes specific requirements or official control modalities. Dedicated computerised systems also exist for the rapid exchange of information between Member States and with the Commission on risks which might arise in the food chain or for animal and plant health. Regulation (EC) No 178/2002 establishes the RASFF, Regulation (EU) .../... (*) a system for the notification and reporting on the measures on listed diseases **and on food fraud**, and Regulation (EU) .../... (**) a system for the notification and reporting of the presence of pests and the notification of non-compliances. All such systems should work in a harmonious, consistent manner that makes use of synergies between the different systems, avoids duplications, simplifies their operation and makes them more efficient. [Am. 19]
- (74) To support a more efficient management of official controls, a computerised information system integrating and upgrading as necessary all relevant existing information systems should be set up by the Commission, allowing for the use of advanced communication and certification tools, and for the most efficient use of the data and

⁽¹⁾ Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).

(*) Number, date, title and, in a footnote, the OJ reference for the Regulation on animal health.

(**) Number, date, title and, in a footnote, the OJ reference for the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

information related to official controls. In view of avoiding unnecessary duplications of information requirements, the design of such computerised system should take into account the need to ensure, wherever appropriate, the compatibility of such computerised system with other information systems operated by public authorities and through which relevant data is exchanged or made available. Moreover, the possibility to use the electronic signatures within the meaning of Directive 1999/93/EC of the European Parliament and the Council⁽¹⁾ should be laid down, in line with the Digital Agenda for Europe.

- (74a) ***In order to minimise administrative burdens and control costs and in order to allow the Union and its Member States to effectively communicate electronically in trade relations with third countries, it is necessary that when exchanging electronic certificates or other electronic data, the Commission and the competent authorities of the Member States use internationally standardised language, message structure and exchange protocols based on guidance for electronic certification in standardised World Wide Web Consortium (WC3) Extensible Markup Language (XML schemas) as well as secure exchange mechanisms between competent authorities as is provided by the UN Centre for Trade Facilitation and Electronic Business (UN/CEFACT).*** [Am. 20]
- (75) The competent authorities should investigate cases where there is a suspicion of non-compliance with Union agri-food legislation and, where non-compliance is established, determine its origin and extent as well as the operators' responsibilities. They should also take appropriate measures to ensure that the operators concerned remedy the situation and to prevent further non-compliance.
- (76) The verification of compliance with agri-food chain legislation through official controls is of fundamental importance to ensure that, across the Union, the objectives of that legislation are effectively achieved. Failures in a Member State's control systems can in certain cases substantially hinder the achievement of those objectives and lead to the emergence of risks to human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, to the environment, independently of the involvement or responsibility of operators or other actors, or lead to situations of serious widespread non-compliance with food chain rules. The Commission should therefore be able to react to serious failures in a Member State's control system by adopting measures aimed at containing or eliminating those risks from the agri-food chain pending the necessary action to be taken by the concerned Member State to make good the failure in the control system.
- (77) Infringements of the rules should be subject to effective, dissuasive and proportionate sanctions at national level throughout the Union. For financial penalties applicable to intentional infringements to be sufficiently dissuasive, they should be set at a level ~~which is likely to offset~~ **of at least double** the economic advantage sought by the perpetrator through the violation. Member States should also be required to apply appropriate criminal or administrative penalties, or both, in cases where operators fail to cooperate during an official control. [Am. 21]
- (77a) ***Account should be taken of the specific needs of the developing countries, in particular the least developed countries, which should be given support in organising their official controls so that they can meet the criteria for the import of animals and goods into the Union.*** [Am. 22]

⁽¹⁾ Directive 1999/93/EC of the European Parliament and the Council of 13 December 1999 on a Community framework for electronic signatures (OJ L 13, 19.1.2000, p. 12).

Tuesday 15 April 2014

- (78) This Regulation covers areas that are already covered in certain acts currently in force. To avoid duplications and to establish a coherent legislative framework, the following acts should be repealed and replaced by the rules of this Regulation: Council Directive 89/608/EEC⁽¹⁾, Council Directive 89/662/EEC⁽²⁾, Council Directive 90/425/EEC⁽³⁾, Council Directive 91/496/EEC, Council Decision 92/438/EEC⁽⁴⁾, Council Directive 96/23/EC, Council Directive 96/93/EC⁽⁵⁾, Council Directive 97/78/EC and Regulation (EC) No 882/2004; ~~and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption⁽⁶⁾. [Am. 23]~~
- (79) In order to ensure consistency, amendments should also be effected to the following acts: Regulation (EC) No 999/2001 of the European Parliament and of the Council⁽⁷⁾, Council Regulation (EC) No 1/2005⁽⁸⁾, Regulation (EC) No 396/2005 of the European Parliament and of the Council⁽⁹⁾, Council Regulation (EC) No 834/2007⁽¹⁰⁾; ~~Regulation (EC) No 1069/2009~~; Council Regulation (EC) No 1099/2009⁽¹¹⁾, Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁽¹²⁾, Regulation (EU) No 1151/2012 of the European Parliament and of the Council⁽¹³⁾, Council Directive 98/58/EC⁽¹⁴⁾, Council Directive 1999/74/EC⁽¹⁵⁾, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Council Directive 2007/43/EC⁽¹⁶⁾, Council Directive 2008/119/EC⁽¹⁷⁾, Council Directive 2008/120/EC⁽¹⁸⁾ and Directive 2009/128/EC of the European Parliament and of the Council⁽¹⁹⁾. [Am. 24]

- ⁽¹⁾ Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters (OJ L 351, 21.12.1989, p. 34).
- ⁽²⁾ Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 395, 30.12.1989, p. 13).
- ⁽³⁾ Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29).
- ⁽⁴⁾ Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC (OJ L 243, 25.8.1992, p. 27).
- ⁽⁵⁾ Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products (OJ L 13, 16.1.1997, p. 28).
- ⁽⁶⁾ ~~OJ L 139, 30.4.2004, p. 206.~~
- ⁽⁷⁾ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).
- ⁽⁸⁾ Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).
- ⁽⁹⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum levels of pesticides in or on food and feed of plant of animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).
- ⁽¹⁰⁾ Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).
- ⁽¹¹⁾ Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).
- ⁽¹²⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).
- ⁽¹³⁾ Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).
- ⁽¹⁴⁾ Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23).
- ⁽¹⁵⁾ Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens (OJ L 203, 3.8.1999, p. 53).
- ⁽¹⁶⁾ Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production (OJ L 182, 12.7.2007, p. 19).
- ⁽¹⁷⁾ Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7).
- ⁽¹⁸⁾ Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs (OJ L 47, 18.2.2009, p. 5).
- ⁽¹⁹⁾ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

Tuesday 15 April 2014

- (80) Regulation (EU) No .../... (*) provides a framework for the Union's financing of actions and measures across the agri-food chain in those areas under the multi-annual financial framework 2014-2020. Some of those acts and measures aim to improve the performance of official controls and other official activities across the Union. Regulation (EU) No .../... (**) should be amended to take account of the changes introduced by this Regulation to Regulation (EC) No 882/2004.
- (81) In order to amend the references to European standards, and Annexes II and III to this Regulation to take into account of legislative and technical and scientific developments, and to supplement this Regulation with specific rules governing official controls and other official activities in the areas it covers, including, *inter alia*, rules on the qualification and training of staff, on additional responsibilities and tasks of the competent authorities, on the cases where the accreditation of laboratories is not required, on certain exemptions from official controls at the borders, on the criteria to be used to determine the frequency of identity and physical checks, on the establishment of conditions to be met by certain animals or goods entering the Union from third countries, on additional requirements and tasks of European Union reference laboratories and centres, on additional requirements for national reference laboratories, on criteria for risk categorisation and for performance indicators for the MANCPs, and on the contingency plans for food and feed provided for in Regulation (EC) No 178/2002, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (82) In order to ensure uniform conditions for the implementation of this Regulation regarding the designation of European Union reference laboratories and of the European Union reference centres for plant reproductive material and for animal welfare, the adoption of the programme of the Commission controls in the Member States, and the performance of increased official controls in the event of violations of agri-food chain rules which require coordinated assistance and follow-up by the Commission, implementing powers should be conferred on the Commission.
- (83) In order to ensure uniform conditions for the implementation of this Regulation, including, *inter alia*, rules and modalities in respect of audits, the format of certificates and other documents, the establishment of computerised information management systems, the cooperation between operators and competent authorities and amongst competent authorities, customs authorities and other authorities, the methods of sampling and of laboratory analysis, test and diagnosis as well as their validation and interpretation, traceability, the listing of products or goods subject to controls as well the listing of countries or regions that can export certain animals and goods to the Union, prior notification of consignments, exchanges of information, border control posts, isolation and quarantine, approval of pre-export controls performed by third countries, measures to contain a risk or put an end to a widespread serious non-compliance relating to certain animals or goods originating from a third country or a region thereof, the recognition of third countries or regions that offer equivalent guarantees to those applied in the Union and its repeal, training activities and exchange programmes of staff amongst Member States, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.

(*) Number, date, title and, in the footnote, the OJ reference for the Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

(**) Number of the Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Tuesday 15 April 2014

- (84) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to official controls and other official activities performed in view of ensuring the application of Union agri-food chain rules, cannot be sufficiently achieved by the Member States but can therefore, by reason of its effect, complexity, trans-border and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not exceed what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

Title I

Subject matter, scope and definitions

Article 1

Subject matter and scope

1. This Regulation lays down rules for:
 - (a) the performance of official controls and other official activities performed by the competent authorities of the Member States;
 - (b) the financing of official controls;
 - (c) the administrative assistance and cooperation between Member States in view of the correct application of the rules referred to in paragraph 2;
 - (d) the performance of Commission controls in Member States and in third countries;
 - (e) the adoption of conditions to be met by animals and goods entering the Union from a third country;
 - (f) the establishment of a computerised information system to manage information and data in relation to official controls.
2. This Regulation shall apply to the official controls performed for the verification of compliance with the following rules, whether established at Union level or by the Member States to apply Union legislation in those areas:
 - (a) governing food ~~and~~ food safety, **food quality and food wholesomeness**, at any stage of production, the processing and distribution of food, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food;
 - (b) governing the deliberate release into the environment ~~and the contained use~~ of GMOs;
 - (c) governing feed and feed safety, at all stages of production, processing and distribution of feed and the use of feed, including rules aimed at guaranteeing fair practices in trade and protecting consumer **health**, interests and information;
 - (d) laying down animal health requirements;
 - (e) aiming at preventing and minimising risks to human and animal health arising from animal by-products and derived products;
 - (ea) aiming at preventing and minimising antimicrobial resistance in animals and humans, as well as in the environment;**
 - (f) laying down welfare requirements for animals;

Tuesday 15 April 2014

- (g) on protective measures against pests of plants;
- ~~(h) on the production, with a view to placing on the market, and placing on the market of plant reproductive material;~~
- (i) laying down requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides;
- (j) governing organic production and labelling of organic products;
- (k) on the use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed;

(ka) laying down requirements on monitoring certain substances and residues thereof in live animals and animal products. [Ams. 25, 26 and 27]

3. This Regulation shall also apply to official controls performed for the verification of compliance with requirements laid down in the rules referred to in paragraph 2 applicable to animals and goods:

- (a) entering the Union from third countries;
- (b) to be exported to third countries.

4. This Regulation shall not apply to official controls for the verification of compliance with:

- (a) Regulation (EC) No 1234/2007 **in areas other than those under Part II, Title II, Chapter I of that Regulation. However, this Regulation shall apply to official controls on protected designations of origin and protected geographical indications for wine.** [Am. 28]
- (b) Directive 2010/63/EU of the European Parliament and of the Council ⁽¹⁾;

(ba) Directive 2001/82/EC of the European Parliament and of the Council ⁽²⁾. [Am. 29]

5. Articles 3 to 5, Article 7, Article 11(2) and (3), Article 14, Articles 30 to 33, Articles 36 to 41, Article 76, Titles III and IV, and Articles 129 and 136 of this Regulation shall also apply to other official activities performed by the competent authorities in accordance with this Regulation or with the rules referred to in paragraph 2 of this Article.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'official control' means any form of control, **also including controls of requirements for animals and goods from third countries intended for export to third countries**, that the competent authorities perform for the verification of compliance with: [Am. 30]
 - (a) this Regulation;
 - (b) the rules referred to in Article 1(2);
- (2) 'other official activities' means any activity, other than an official control, which is performed by competent authorities in accordance with:
 - (a) this Regulation;

⁽¹⁾ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

⁽²⁾ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

Tuesday 15 April 2014

- (b) the rules referred to in article 1(2), **except letter (g)**, to ensure the application of those rules; [Am. 31]
- (3) 'food law' means food law as defined in point (1) of Article 3 of Regulation (EC) No 178/2002;
- (4) 'feed law' means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Union or national level; it covers all stages of production, processing and distribution of feed and the use of feed;
- (5) 'competent authorities' means:
- (a) the central authorities of a Member State responsible for ~~the organisation of~~ **organising and carrying out** official controls and of other official activities, ~~in accordance with~~ **such as issuing certificates and attestations, appointing laboratories, exchanging information in the interest of cooperation between authorities, and taking decisions on measures to remedy breaches of** this Regulation and the rules referred to in Article 1(2); [Am. 32]
- (b) any other authority to which that responsibility has been conferred;
- (c) where appropriate, the corresponding authorities of a third country;
- (6) 'animals' means animals as defined in point (1) of Article 4(1) of Regulation (EU) No .../... (*) **with the exception of 'pets'**; [Am. 33]
- (7) 'goods' means any good subject to one or more of the rules referred to in Article 1(2), excluding animals;
- (8) 'food' means food as defined in Article 2 of Regulation (EC) No 178/2002;
- (9) 'feed' means feed as defined in point (4) of Article 3 of Regulation (EC) No 178/2002;
- (10) 'animal by-products' means animal by-products as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009;
- (11) 'derived products' means derived products as defined in point (2) of Article 3 of Regulation (EC) No 1069/2009;
- (12) 'pests' means pests as defined in Article 1(1) of Regulation (EU) No .../... (**);
- (13) 'plants' means plants as defined in point (1) of Article 2 of Regulation (EU) No .../... (**);
14. ~~'plant reproductive material' means plant reproductive material as defined in point (2) of Article 3 of Regulation (EU) No XXX/XXXX [number, date, title and, in a footnote, the O] reference for the Regulation on the production and making available on the market of plant reproductive material;~~ [Am. 34]
- (15) 'plant protection products' means plant protection products as referred to in Article 2(1) of Regulation (EC) No 1107/2009; **for the purposes of this Regulation, 'plant protection products' also refers to the active substances referred to in Article 2(2) of Regulation (EC) No 1107/2009 and other substances or preparations referred to in Article 2(3) of that Regulation;** [Am. 35]
16. ~~'alien species' means a species, subspecies or lower taxon, introduced outside its natural past or present distribution and includes any part, gametes, seeds, eggs, or propagules of such species, as well as any hybrids, varieties or breeds, that might survive and subsequently reproduce;~~ [Am. 36]

(*) Number of the Regulation on animal health.

(**) Number of the Regulation on protective measures against pests of plants.

(***) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

- (17) 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽¹⁾;
- (18) 'germinal products' means germinal products as defined in point (25) of Article 4(1) of Regulation (EU) No .../.... (*);
- (19) 'plant products' means plant products as defined in point (2) of Article 2 of Regulation (EU) No .../.... (**);
- (20) 'other objects' means other objects as defined in point (4) of Article 2 of Regulation (EU) No .../.... (**);
- (21) 'risk assessment' means risk assessment as defined in point (11) of Article 3 of Regulation (EC) No 178/2002;
- (22) 'certifying officer' means:
- (a) any official of the competent authorities authorised to sign official certificates by such authorities;
 - (b) where provided for by the rules referred to in Article 1(2), any other person, who is authorised to sign official certificates by the competent authorities;
- (23) 'official certificate' means any paper or electronic document signed by the certifying officer and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2);
- (24) 'non-compliance' means non-compliance with:
- (a) this Regulation;
 - (b) rules referred to in Article 1(2);
- (25) 'official attestation' means any label, mark or other form of attestation issued by ~~the operators under the supervision, through dedicated official controls, of~~ the competent authorities, or by the competent authorities themselves, and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2); **[Am. 37]**
- (26) 'operator' means any natural and legal person subject to one or more obligations provided for in the rules referred to in Article 1(2), except the competent authorities and the other bodies in charge of official controls and other official activities;
- (27) 'consignment' means a number of animals or quantity of goods of the same type, class, or description, covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport and having the same origin; it may consist of one or more lots;
- (28) 'inspection' means a form of official control involving the examination of:
- (a) animals or goods;
 - (b) activities under the control of operators falling within the scope of the rules referred to in Article 1(2) and equipment, means of transport, substances ~~and~~ materials, **plant protection products and precautionary measures** used to perform those activities; **[Am. 38]**
 - (c) places where operators perform their activities;
- (ca) the documentation referred to in points (a), (b) and (c); [Am. 39]**
- (29) 'border control post' means ~~a place~~ **an inspection centre**, and the facilities belonging to it, designated by a Member State to perform the official controls provided for in Article 45(1); **[Am. 40]**

⁽¹⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

(*) Number of the Regulation on animal health.

(**) Number of the Regulation on protective measures against pests of plants.

(***) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

- (30) 'audit' means a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve objectives;
- (31) 'rating' means a classification of operators based on an assessment of their conformity with rating criteria;
- (32) 'official veterinarian' means a veterinarian appointed by the competent authorities and appropriately qualified to perform ~~the~~ official controls and other official activities in accordance with: [Am. 42]
- (a) this Regulation;
- (b) the rules referred to in Article 1(2);
- (33) 'hazard' means any agent or condition with the potential to have an adverse effect on human, animal or plant health, animal welfare or the environment;
- (34) 'specified risk material' means tissues as defined in point (g) of Article 3(1) of Regulation (EC) No 999/2001;
- (35) 'long journey' means a journey as defined in point (m) of Article 2 of Regulation (EC) No 1/2005;
- (36) 'exit point' means a border control post or any other place designated by a Member State where animals, falling within the scope of Regulation (EC) No 1/2005, leave the customs territory of the Union;
- (37) 'pesticide application equipment' means any apparatus as defined in point (4) of Article 3 of Directive 2009/128/EC;
- (38) 'delegated body' means **an independent** third party, to which the competent authorities have delegated specific ~~official control~~ tasks **relating to official controls and other official activities**; [Am. 43]
- (39) 'control authority for organic ~~products~~ **production**' means a public administrative organisation of a Member State to which the competent authorities have conferred, in whole or in part, their competences **for inspections and certification in the organic production sector**, in relation to Regulation (EC) No 834/2007, including, where appropriate, the corresponding authority of a third country or operating in a third country; [Am. 44]
- (40) 'control verification procedures' means the arrangements put in place and actions performed by the competent authorities for the purpose of ensuring that official controls and other official activities are consistent and effective;
- (41) 'screening' means a form of official control performed by conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with this Regulation and the rules referred to in Article 1(2);
- (42) 'targeted screening' means a form of official control involving observation of one or more operators or their activities;
- (43) 'control system' means a system comprising the competent authorities and the resources, structures, arrangements and procedures set up in a Member State to ensure that official controls are performed in accordance with this Regulation and with the rules provided for in Articles 15 to 24;
- (44) 'equivalence' or 'equivalent' means: **systems that are broadly the same and meet the same objectives**; [Am. 45]
- ~~(a) the capability of different systems or measures to meet the same objectives; [Am. 46]~~
- ~~(b) different systems or measures capable of meeting the same objectives; [Am. 47]~~
- (45) 'entry into the Union' means the action of bringing animals and goods into one of the territories listed in Annex I;

Tuesday 15 April 2014

- (46) 'documentary check' means the examination of the official certificates, official attestations and other document or documents including documents of a commercial nature, which are required to accompany the consignment as provided for by the rules referred to in Article 1(2), Article 54(1), or by implementing acts adopted in accordance with Articles 75(3), 125(4), 127(1) and 128(1);
- (47) 'identity check' means a visual inspection to verify that the content and the labelling of a consignment, including the marks on animals, seals and means of transport, correspond with the information provided in the official certificates, official attestations and other documents accompanying it;
- (48) 'physical check' means a check on animals or goods and, as appropriate, checks on packaging, the means of transport, labelling and temperature, the sampling for analysis, testing or diagnosis and any other check necessary to verify compliance with the rules referred to in Article 1(2);
- (49) 'transhipment' means the movement of goods **or animals** subject to the official controls provided for in Article 45(1) which arrive by sea or by air transport from a third country from a vessel or aircraft and are transported under customs supervision to another vessel or aircraft in the same port or airport in preparation for onward travel; **[Am. 48]**
- (50) 'transit' means movement from one third country to another third country passing under customs supervision through one of the territories listed in Annex I or from one of the territories listed in Annex I to another territory listed in Annex I passing through the territory of a third country;
- (51) 'supervision by the customs authorities' means action as defined in Article 4(13) of Council Regulation (EEC) No 2913/92 ⁽¹⁾;
- (52) 'control by the customs authorities' means customs controls as defined in Article 4(14) of Regulation (EEC) No 2913/92;
- (53) 'official detention' means the procedure by which the competent authorities ensure that animals and goods subject to official controls are not moved or tampered with pending a decision on their destination; it includes storage by operators **in accordance with the instructions and** under the control of the competent authorities; **[Am. 49]**
- (54) 'additional official controls' means those controls which were not originally planned and which were decided on the basis of the findings of previous official controls, or other official activities;
- (55) 'official certification' means the procedure by which assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2) is provided by the competent authorities;
- (56) 'control plan' means a description established by the competent authorities containing information on the structure and organisation of the official control system, and of its operation and the detailed planning of official controls to be performed in each of the areas referred to in Article 1(2) over a period of time;
- (57) 'journey log' means the document set out in points 1 to 5 of Annex II to Regulation (EC) No 1/2005;
- (57a) 'Official auxiliary' means a person qualified, in accordance with Annex IIIa to this Regulation, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian. [Am. 50]**

⁽¹⁾ Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

Tuesday 15 April 2014

Title II

Official controls and other official activities in Member States

Chapter I

Competent authorities

Article 3

Designation of competent authorities

1. For each of the areas governed by the rules referred to in Article 1(2), Member States shall ~~designate the~~ **have one or more** competent ~~authority or authorities on which they confer the responsibility to perform~~ **responsible for planning, organising and where necessary performing** official controls and other official activities. [Am. 51]
2. Where, for the same area, a Member State ~~confers the responsibility to perform official controls or other official activities on~~ **has** more than one competent authority, at national, regional or local level, or where the competent authorities designated in accordance with paragraph 1 are allowed ~~by that designation~~ to transfer specific responsibilities for official controls or other official activities to other public authorities, the Member State ~~care~~ shall **be taken to ensure that**: [Am. 52]
 - (a) ~~put in place~~ procedures **are put in place** to ensure efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls or other official activities across **the whole of** its territory; [Am. 53]
 - (b) designation of a single authority responsible to coordinate the cooperation and the contacts with the Commission and other Member States in relation to the official controls and other official activities performed in ~~that area~~ **each of the sectors defined by the Member State, in such a way as to cover all the areas referred to in Article 1(2)**. [Am. 54]
3. Competent authorities responsible for the verification of compliance with the rules referred to in point (j) of Article 1(2) may confer specific official control tasks to one or more control authorities for organic ~~products~~ **production**. In such cases, they shall attribute a code number to each of them. [Am. 55]
4. Member States shall inform the Commission and other Member States of, and of any changes to, the contact details of:
 - (a) the competent authorities designated in accordance with paragraph 1;
 - (b) the single authorities designated in accordance with point (b) of paragraph 2;
 - (c) the control authorities for organic products referred to in paragraph 3;
 - (d) the delegated bodies referred to in Article 25(1).

The information referred to in the first subparagraph shall also be made available to the public.

5. Member States may confer to the competent authorities referred to in paragraph 1 the responsibility to carry out controls for the verification of compliance with, or for the application of, rules, ~~including those regulating specific risks which may arise from the presence of alien species in the Union~~, other than those referred to in Article 1(2). [Am. 56]
6. The Commission may, by means of implementing acts, determine the means by which the information referred to in paragraph 4 is to be made available to the public. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2). **The means by which the information referred to in paragraph 4 is to be made available to the public shall in any case include publication on the internet**. [Am. 57]

Tuesday 15 April 2014

Article 4

General obligations of the competent authorities

1. The competent authorities shall have:
 - (a) procedures and arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities;
 - (b) arrangements in place to ensure the impartiality, **independence**, quality, consistency and **unity of purposes** of official controls and other official activities at all levels; **they should be in no way connected to or dependent of the operators that they control**;
 - (c) arrangements in place to ensure that staff performing official controls and other official activities are **independent, impartial, and** free from any conflict of interest, **and have no improper connection from which they stand to make economic gain or which might jeopardise their impartiality**;
 - (d) or have access to, an adequate laboratory capacity for analysis, testing and diagnosis;
 - (e) or have access to, a sufficient number of **independent**, suitably qualified **and experienced staff with regard to the control requirements under Article 1(1) and (2)**, so that official controls and other official activities can be performed **fully**, efficiently and effectively;
 - (f) appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls and other official activities efficiently and effectively;
 - (g) the legal powers to perform official controls and other official activities and to take the action provided for in this Regulation and in the rules referred to in Article 1(2);
 - (h) legal procedures in place in order to ensure that staff have access to the premises of and documents kept by operators so as to be able to accomplish their tasks properly;
 - (i) contingency plans in place, and be prepared to operate such plans in the event of an emergency, where appropriate in accordance with the rules referred to in Article 1(2).
2. Staff performing official controls and other official activities shall:
 - (-a) be officials employed by the competent authorities or by an independent public body delegated by the competent authority to perform official controls or other official activities;**
 - (a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to perform official controls and other official activities in a consistent manner;
 - (b) keep up-to-date in their area of competence and receive regular additional training as necessary;
 - (c) receive training in the subject matters set out in Chapter I of Annex II and on the obligations of the competent authorities resulting from this Regulation.

Competent authorities shall develop and implement training programmes for the purpose of ensuring that staff performing official controls and official activities receive the training referred to in points (a), (b) and (c) of the first subparagraph.

~~3. For the purpose of ensuring that the staff of the competent authorities referred to in point (c) of paragraph 1 and in paragraph 2 have the necessary qualifications, skills and knowledge, the Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules for the specific qualification and training requirements of such staff, having regard to the scientific and technical knowledge necessary to perform official controls and other official activities in each of the areas referred to in Article 1(2).~~

4. When, within the ~~services of~~ **activities carried out by** a competent authority, more than one unit is competent to perform official controls or other official activities, efficient and effective coordination and cooperation shall be ensured between the different units. [Ams 58 and 341]

Tuesday 15 April 2014

Article 5

Audits of the competent authorities

1. Competent authorities shall carry out internal audits or have audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are complying with this Regulation.

Those audits shall be:

- (a) subject to independent scrutiny;
- (b) carried out in a transparent manner.

2. Competent authorities shall make available the results of the audits referred to in paragraph 1 to the Commission upon **justified** request. [Am. 59]

3. The Commission may, by means of implementing acts, lay down rules for the conduct of the audits provided for in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 6

Decisions of the competent authorities concerning natural and legal persons

The decisions taken by the competent authorities in accordance with Article 53, Article 64(3) and (5), Articles 65, Article 134(2) and Article 135(1) and (2) concerning natural or legal persons shall be subject to the right of appeal of such persons against those decisions in accordance with national law.

Article 7

Confidentiality obligations of the staff of the competent authorities

1. Competent authorities shall require members of their staff not to disclose, **except within the competent authority**, information acquired when undertaking their duties in the context of official controls and other official activities which by its nature is covered by professional secrecy, ~~subject to paragraph 2.~~

2. Unless there is an overriding public interest in its disclosure, **or disclosure is required by other Union legislation**, information covered by professional secrecy as referred to in paragraph 1 shall include information whose disclosure would undermine:

- (a) the purpose of inspections, investigations or audits;
- (b) the protection of commercial interests of a natural or legal person;
- (c) ~~the protection of~~ **ongoing** court proceedings and legal advice;

(ca) the decision-making process of competent authorities.

2a. The competent authorities, when determining whether there is an overriding public interest to disclose, shall take into account inter alia the following elements:

- (a) possible risks to human, animal or plant health, or to the environment;**
- (b) the nature, severity and extent of such risks, so as to ensure that disclosure is proportionate in the circumstances.**

Tuesday 15 April 2014

3. **Without prejudice to** paragraphs 1 and 2 ~~shall not prevent~~, the competent authorities ~~from publishing~~ **shall publish** or ~~making make~~ otherwise available to the public information about the outcome of official controls regarding individual operators, provided that the following conditions are met:

- (a) the operator concerned is given the opportunity to comment on the information that the competent authority intends to publish or make otherwise available to the public, prior to the publication or release;
- (b) the information which is published or made otherwise available to the public takes into account the comments expressed by the operator concerned or is published or released **simultaneously and** together with such comments.

3a. Competent authorities shall ensure that any information published or made available to the public pursuant to this Article is accurate and that, if any such information subsequently proves to be inaccurate, it is appropriately rectified. [Am. 60]

Chapter II

Official Controls

Article 8

General rules on official controls

1. Competent authorities shall perform official controls on all ~~operators~~ **undertakings** regularly, on a risk basis and with appropriate frequency, taking account of: [Am. 61]

- (a) identified risks associated with:
 - (i) animals and goods;
 - (ii) the activities **and precautionary measures** under the control of operators; [Am. 62]
 - (iii) the location of the activities or operations of operators;
 - (iv) the use of products, processes, materials, **feed additives** or substances that may influence food ~~or safety and wholesomeness~~, feed safety, animal health or animal welfare, plant health ~~or plant reproductive material identity and quality~~, or, in the case of GMOs and plant protection products, may adversely impact on the environment; [Am. 63]
 - (iva) **the potential for consumers to be misled as to the nature, quality or substance of a product or the potential for consumers to incur financial loss as a result of receiving misleading information from the operator;** [Am. 64]
 - (ivb) **the process requirements according to point (j) of Article 1(2);** [Am. 65]
- (b) ~~operators~~ **undertakings'** past record as regards the results of official controls performed on them and their compliance with the rules referred to in Article 1(2); [Am. 66]
- (c) the reliability and results of own controls that have been performed by the operators, or by a third party at their request, for the purpose of ascertaining compliance with the rules referred to in Article 1(2). **Transfer of information on these own controls shall be utilised as much as possible, in a manner that minimizes the burden on operators;** [Am. 67]
- (ca) **consumer expectations regarding nature, quality and composition of foods and goods;** [Am. 68]
- (d) any information that might indicate non-compliance with the rules referred to in Article 1(2);

Tuesday 15 April 2014

(da) private quality assurance schemes put in place by operators, which are certified and audited by independent and recognised certification bodies. [Am. 69]

2. Competent authorities shall perform official controls on a regular basis and with appropriate frequency to identify possible intentional violations of the rules referred to in Article 1(2), **to verify compliance with the requirements and process criteria according to point (j) of Article 1(2)**, taking into account, in addition to the criteria referred to in paragraph 1, information regarding such possible intentional violations shared through the mechanisms of administrative assistance provided for in Title IV and any other information pointing to the possibility of such violations. **[Am. 70]**

2a. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 in order to establish a uniform minimum frequency for carrying out the controls referred to in paragraphs 1 and 2. Where necessary, such minimum frequency, based on risk, shall be established differently for each product, process or activity that is subject to official controls pursuant to this Regulation. [Am. 71]

3. Official controls performed prior to the placing on the market or the movement of certain animals and goods in view of the issuance of the official certificates or official attestations required by the rules referred to in Article 1(2) as a condition for the placing on the market or the movement of the animals or goods shall be performed in accordance with:

(a) the rules referred to in Article 1(2);

(b) the delegated acts adopted by the Commission in accordance with Articles 15 to 24.

4. Official controls shall be performed without prior warning, except where:

~~(a) prior notification of the operator is necessary;~~ **[Am. 72]**

(b) the operator has requested such official controls. **Such announced controls shall not replace standard controls without prior warning;** **[Am. 73]**

(ba) audits for verification of requirements in accordance with point (j) of Article 1(2) are performed. [Am. 74]

5. Official controls shall be performed as much as possible in a manner that ~~minimises~~ **the administrative burden on the and operational disruption for operators is kept to the necessary minimum, but without this affecting the quality of the control negatively; to that end, where the same operator is subject to various official controls over the same period, the competent authority shall aggregate them. Where various official controls are applied to operators, Member States shall ensure a coordinated approach with the aim of combining existing control measures.****[Am. 75]**

6. Competent authorities shall perform official controls with the same care irrespective of whether the animals and goods concerned are:

(a) available on the Union market, whether originating in the Member State where the official controls are performed or in another Member State;

(b) to be exported from the Union;

(c) entering the Union from third countries.

7. To the extent ~~strictly~~ necessary for the organisation of the official controls, Member States of destination ~~may~~ **shall** require operators who have animals or goods delivered to them from another Member State to report the arrival of such animals or goods. **[Am. 76]**

Tuesday 15 April 2014

Article 9

Persons, processes ~~and~~, activities, **methods and techniques** subject to official controls [Am. 77]

To the extent necessary to ascertain compliance with the rules referred to in Article 1(2), competent authorities shall perform official controls:

- (a) on animals and goods at all stages of production, processing, **marketing**, and distribution; [Am. 78]
- (b) on substances, materials or **other** objects which may influence the characteristics **or health** of animals and goods, at all stages of production, processing and distribution; [Am. 79]
- (c) on operators and the activities and operations under their control, on their premises, **land, crops** and processes, on the storage, transport, and the use of goods and **on** the keeping of animals; [Am. 80]
- (ca) **on all documentation, including documentation kept in electronic form, linked to the activity being performed, or to operations including transport.** [Am. 81]

Article 10

Transparency of official controls

1. Competent authorities shall perform official controls with a high level of transparency and make available to the public relevant information concerning the organisation and the performance of official controls.

They shall also ensure the regular publication of information, **at least once a year**, on the following:

- (a) type, number and **final** outcome of official controls;
- (b) type and the number of non-compliances detected;
- (c) **type and number of** cases where measures were taken by the competent authorities in accordance with Article 135;
- (d) **type and number of** cases where the penalties referred to in Article 136 were imposed. [Am. 82]

2. To ensure the uniform implementation of the rules provided for in paragraph 1 of this Article, the Commission shall, ~~by means of implementing acts, lay down and update as necessary the format in which the information referred to in that paragraph shall be published. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2)~~ **provide Member States with appropriate guidance documents, including a proposal for a standardised reporting format, which shall in any case include publication of those guidance documents on the internet.** [Am. 83]

3. Competent authorities shall be entitled to publish or make otherwise available to the public information about the rating of individual operators based on the outcome of **the last four** official controls, provided that the following conditions are met:

- (a) the rating criteria are objective, transparent and publicly available;
- (b) appropriate arrangements are in place to ensure the consistency and transparency of the rating process;

(ba) subsequent inspections are carried out without delay if the findings are unfavourable. [Am. 84]

3a. To enable rating systems to be compared between one Member State and another, the Commission shall, by means of delegated acts and in consultation with the stakeholders, lay down guidelines to establish objective criteria which shall be made available to the Member States and which they may use on a voluntary basis. [Am. 85]

Tuesday 15 April 2014

Article 11

Documented control and control verification procedures

1. Competent authorities shall perform official controls in accordance with documented procedures.

Those procedures shall cover the subject areas for control procedures set out in Chapter II of Annex II and contain detailed instructions for staff performing official controls.

2. Competent authorities shall have procedures in place to verify the consistency and effectiveness of official controls and other official activities that they perform.

3. Competent authorities shall:

- (a) take corrective actions in all cases where the procedures provided for in paragraph 2 identify shortcomings in the consistency and effectiveness of official controls and other official activities;
- (b) update the documented procedures provided for in paragraph 1 as appropriate.

Article 12

Recording of, and reports on, official controls [Am. 86]

1. Competent authorities shall ~~draw up reports on~~ **keep documentary records of** every official control that they perform ~~have performed. They shall draw up reports on controls in which this Regulation or the provisions referred to in Article 1(2) were found to have been infringed.~~ [Am. 87]

Those reports shall contain:

- (a) a description of the purpose of the official controls;
- (b) the control methods applied;
- (c) the results of the official controls;
- (d) where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls.

2. Competent authorities shall provide the operator subject to an official control with a copy of the report provided for in paragraph 1.

3. Where official controls require the continuous or regular presence of staff or representatives of the competent authorities in the operator's premises, the reports provided for in paragraph 1 shall be produced with a frequency that enables the competent authorities and the operator to be:

- (a) regularly informed of the level of compliance;
- (b) immediately informed of any shortcoming or non-compliance identified through the official controls.

3a. The outcome of official controls performed at a border control post shall be recorded in the Common Health Entry Document in accordance with Article 54(2)(b). [Am. 88]

Article 13

Official controls, methods and techniques

1. Competent authorities shall perform official controls using control methods and techniques that shall, as appropriate, include screening, targeted screening, verification, inspections, audits, sampling, analysis, diagnosis and tests.

2. Official controls shall include the following ~~as appropriate:~~ [Am. 89]

- (a) an examination of the control systems that operators have put in place and of the results obtained;

Tuesday 15 April 2014

- (b) an inspection of:
- (i) primary producers' installations and other businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport and their animals and goods;
 - (ii) raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals;
 - (iii) materials intended to come into contact with food; [Am. 90]**
 - (iii) semi-finished goods;
 - (iv) cleaning and maintenance products and processes, plant protection products;
 - (v) labelling, presentation and advertising;
- (c) controls on the hygiene conditions in the operators' premises;
- (d) an assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and hazard analysis critical control points (HACCP);
- (e) an examination of documents, **traceability records** and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2); **[Am. 91]**
- (f) interviews with operators and with their staff;
- (g) a reading of values recorded by operators' measuring instruments;
- (h) controls performed with the competent authorities' own instruments to verify measurements taken by operators;
- (i) any other activity required to identify non-compliance.

2a. Specific rules for the performance of official controls shall always take into account not only potential health risks, but also consumer expectations with regard to food composition and the likelihood of fraudulent practices. [Am. 326]

Article 14

Obligations of operators

1. To the extent that this is necessary for the performance of official controls or of other official activities, operators shall, where required by the competent authorities, give staff of the competent authorities **and staff of the delegated bodies, where specific official control tasks have been delegated in accordance with the provisions of Article 25**, access to: **[Am. 92]**

- (a) their premises;
- (b) their computerised information management systems;
- (c) their animals and goods;
- (d) their **relevant** documents and any other ~~relevant~~ information, **including the results of potential own tests, that is relevant for the purpose of performing such controls or activities and the control subjects listed in Article 13(2). Every operator shall be able to indicate at least each operator he is supplied by and each operator he is supplying. [Am. 93]**

2. During official controls and other official activities, operators shall assist the staff of the competent authorities **and the delegated bodies, pursuant to Article 25**, in the accomplishment of their **control** tasks. **Operators shall supply sufficient quantities of samples free of charge to the competent authorities. [Am. 94]**

Tuesday 15 April 2014

3. The operator responsible for the consignment shall:
 - (a) cooperate fully with the competent authorities to ensure the efficient performance of official controls or other official activities;
 - (b) make available **without delay** all **requested** information concerning the consignment on paper or electronically. [Am. 95]
4. The Commission may, by means of implementing acts, lay down rules:
 - (a) establishing the modalities for access by the competent authorities **and the delegated bodies, pursuant to Article 25**, to the computerised information management systems referred to in paragraph 1(b); [Am. 96]
 - (b) on the cooperation between operators and competent authorities as referred to in paragraph 3.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 15

Specific rules on official controls and on action to be taken by the competent authorities in relation to the production of products of animal origin intended for human consumption

-1. Official controls performed to verify compliance with the rules referred to in Article 1(2) in relation to products of animal origin intended for human consumption shall always include the verification of compliance with Regulations (EC) No 852/2004⁽¹⁾, (EC) No 853/2004 and (EC) No 1069/2009 as applicable, and at least of the following, as appropriate:

- (a) **the design and maintenance of premises and equipment;**
- (b) **personal hygiene;**
- (c) **HACCP-based procedures;**
- (d) **own-controls procedures;**
- (e) **verification of compliance by the staff with applicable requirements;**
- (f) **verification of the operator's records and of documents accompanying food, feed and any substance or material entering and leaving the establishment;**
- (g) **consideration of any evidence of the presence of fraudulent practices.**

1. **The official controls ~~on~~ referred to in paragraph 1 performed in relation to the production of meat shall include:**

- (a) **the verification by ~~or under the responsibility of~~ an official veterinarian, of the health and welfare of the animals prior to the slaughter ~~or by an official auxiliary working under an official veterinarian's responsibility~~;**
- (b) **official controls by ~~or under the responsibility of~~ an official veterinarian ~~or by an official auxiliary working under an official veterinarian's responsibility~~, in slaughterhouses, cutting **and processing** plants and game handling establishments, to verify compliance with the requirements applicable to:**
 - (i) the hygiene of meat production;
 - (ii) the presence of residues of veterinary medicinal products in products of animal origin intended for human consumption;

⁽¹⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

Tuesday 15 April 2014

- (iii) the handling and disposal of animal by-products and of specified risk material;
- (iv) the health and welfare of the animals.

1a. For the purposes of the official controls referred to in paragraph 2:

- (a) *at least one official veterinarian shall be present during both the ante-mortem and post-mortem inspection or, in the case of game-handling establishments, during the post-mortem inspection;*
- (b) *an official veterinarian or an official auxiliary shall be present, with a frequency appropriate to achieving the objectives of this Regulation, in cutting plants when meat is being worked on.*

1b. Following the official controls referred to in paragraph 2, actions and measures in accordance with Article 135 in relation to the animals, their welfare and the destination of meat shall be taken by or under the responsibility of the official veterinarian.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning specific rules for the performance of official controls on products of animal origin intended for human consumption and on animals intended for the production of such products to verify compliance with the rules referred to in points (a), (c), (d) and (e) of Article 1(2) applicable to those products and animals, and on action to be taken by the competent authorities following official controls. Those delegated acts shall lay down rules on:

- (a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in paragraph 1 and in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;
- (b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks which exist in relation to each product of animal origin and the different processes it undergoes;
- (c) the cases where and the conditions under which slaughterhouse staff ~~may be involved in official controls~~ **appropriately qualified and trained, and employed under the control of the official veterinarian in a unit which is segregated and independent from the production units of the establishment, may assist the official veterinarian when performing the official controls referred to in paragraph 2 in relation to the production of meat from poultry and largomorphs,** and the design and application of tests to assess their performance;
- (d) the circumstances in which the competent authorities in relation to specific cases of non-compliance are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph;
- (e) criteria to determine ~~when~~, on the basis of a risk analysis, the **conditions and the frequency of the official control tasks to be carried out by the official veterinarian is not required to be present in low throughput slaughterhouses and in game handling establishments, during the official controls referred to respecting the minimum requirement laid down in paragraph 1a (a).**

Where, in cases of risks which cannot be effectively addressed in the absence of common specifications for the official controls or for the action to be taken by the competent authorities following such official controls, imperative grounds of urgency so require, the procedure provided for in Article 140 shall apply to delegated acts adopted pursuant to this paragraph.

3. The Commission shall take into account the following when adopting delegated acts as provided for in paragraph 2:

- (a) the experience gained by **competent authorities and** food business operators on the application of the procedures referred to in Article 5 of Regulation (EC) No 852/2004;
- (b) scientific and technological developments;
- (c) ~~consumer expectations with regard to food composition and changes in patterns of consumption of food;~~

Tuesday 15 April 2014

- (d) risks to human health and animal health associated with meat and other products of animal origin intended for human consumption;

(da) consideration of any evidence of the presence of fraudulent practices.

4. Insofar as this does not prevent the achievement of the objectives of human health and animal health pursued by the rules referred to in points (a), (c), (d) and (e) of Article 1(2), applicable to products of animal origin intended for human consumption and to animals intended for the production of such products, the Commission shall also take into account the following elements, when adopting delegated acts as provided for in paragraph 2:

- (a) the need ~~to facilitate the application of~~ **for the delegated acts ~~in~~ to be commensurate with the nature and the size of small businesses to ensure an effective application;** [Am. 97]
- (b) the need to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;
- (c) the needs of food businesses situated in regions that are subject to special geographic constraints.

Article 16

Specific rules on official controls and on action to be taken by the competent authorities in relation to the residues of certain substances in food and feed

The Commission shall be empowered to adopt ~~delegated acts in accordance with Article 139~~ **legislative proposals** concerning rules on official controls to be performed to verify compliance with the rules referred to in point (a) of Article 1 (2) applicable to certain substances whose use on crops or animals or to produce or process food or feed may result in residues of those substances in food or feed, and on action to be taken by the competent authorities following official controls. Such ~~delegated acts~~ **legislative proposals** shall take account of the need to ensure a minimum level of official controls to prevent the use of those substances in violation of point (a) of Article 1(2), and lay down rules on: [Am. 327]

- (a) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks related to non-authorised substances and to the non-authorised use of authorised substances;
- (b) specific additional criteria and specific additional content to those provided for in Article 108, for the preparation of the relevant parts of the multi-annual national control plan provided for in Article 107(1);
- (c) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.

Article 17

Specific rules on official controls and on action to be taken by the competent authorities in relation to animals, products of animal origin, **and** germinal products, ~~animal by-products and derived products~~ [Am. 98]

1. Official controls in relation to animals shall include:

- (a) **verification of measures for protection against biological and chemical hazards to human and animal health;**

Tuesday 15 April 2014

(b) verification of animal welfare measures, without prejudice to Article 18;

(c) verification of disease control or eradication measures. [Am. 99]

2. The Commission shall be empowered to adopt ~~delegated acts in accordance with Article 139~~ **legislative proposals** concerning rules for the performance of official controls on animals, on products of animal origin, on germinal products, on animal by-products and on derived products to verify compliance with the Union rules referred to in points (d) and (e) of Article 1(2) and on action to be taken by the competent authorities following official controls. Such ~~delegated acts~~ **legislative proposals** shall take account of animal health risks related to animals, products of animal origin and germinal products, ~~and of human and animal health risks related to animal by-products and derived products~~, and lay down rules on: **[Am. 100]**

- (a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article ~~4, 8, 9, 10(1), Articles 11 and 12, 13,~~ **and** Article 34(1) and (2) ~~and 36;~~ **[Am. 101]**
- (b) uniform specific requirements for the performance of official controls, and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the need to address specific hazards and risks to animal health by means of official controls performed to verify compliance with disease prevention and control measures laid down in accordance with the rules referred to in point (d) of Article 1(2);
- (c) the cases where the competent authorities in relation to cases of specific non-compliance are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.

Article 18

Specific rules on official controls and action to be taken by the competent authorities in relation to the welfare requirements for animals

1. **In addition to the general rules on official controls provided for in Article 8,** official controls to verify compliance with the rules laying down welfare requirements for animals in case of their transport shall include: **[Am. 102]**

- (a) in case of long journeys between Member States and with third countries, official controls performed prior to the loading to check the fitness of the animals for transport;
- (b) in case of long journeys between Member States and with third countries of domestic equidae other than registered equidae and domestic animals of the bovine, ovine, caprine and porcine species, prior to the journey:
 - (i) official controls on journey logs to verify that the journey log is realistic and indicates compliance with Regulation (EC) No 1/2005;
 - (ii) official controls to verify that the transporter indicated in the journey log has a valid transporter authorisation, certificate of approval for the means of transport for long journeys and certificates of competence for drivers and attendants;
- (c) at border control posts provided for in Article 57(1) and at exit points:
 - (i) official controls on the fitness of the animals being transported and on the means of transport **to verify compliance with Chapter II and where applicable Chapter VI of Annex I to Regulation (EC) No 1/1005;** **[Am. 103]**

Tuesday 15 April 2014

- (ii) official controls to verify that transporters comply with applicable international agreements, **including the European Convention for the protection of animals during international transport** and have valid transporter authorisations and certificates of competence for drivers and attendants; [Am. 104]
 - (iii) official controls to verify whether domestic equidae and domestic animals of bovine, ovine, caprine and porcine species have been or are to be transported over long journeys;
 - (iiia) **following official controls under point (c) (i) of this paragraph, where the view of the competent authority is that animals are unfit for transport, they shall be unloaded, watered, fed and rested and veterinary assistance must be sought if necessary, until fit to continue their journey;** [Am. 105]
 - (ca) **in case of long journeys between Member States and with third countries, official controls performed at any stage of the long journey on a random or targeted basis to verify that declared journey times are realistic and that the journey complies with Regulation (EC) No 1/2005 and in particular that travel times and rest periods have complied with the limits set out in Chapter V of Annex I to Regulation (EC) No 1/2005.** [Am. 106]
2. Where the rules referred to in point (f) of Article 1(2) require that certain non-quantifiable standards of animal welfare be met, or where those rules require the adoption of certain practices whose adherence to which cannot be effectively verified through the sole use of the official control methods and techniques referred to in Article 13, official controls performed to verify compliance with those rules may include the use of specific indicators of animal welfare, in the cases and under the conditions that shall be adopted in accordance with point (f) of paragraph 3.
3. The Commission shall be empowered to adopt ~~delegated acts in accordance with Article 139~~ **legislative proposals** concerning rules for the performance of official controls to verify compliance with Union rules referred to in point (f) of Article 1(2). Those ~~delegated acts~~ **legislative proposals** shall take into account the animal welfare risk related to the farming activities and to the transport, slaughter and killing of animals, and shall lay down rules on: [Am. 107]
- (a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in paragraph 1 and Article 4, Articles 8 and 9, Article 10(1) and Articles 11 to 13, ~~34(1) and (2), and 36;~~ [Am. 108]
 - (b) uniform specific requirements for the performance of official controls, and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the risk associated with different animal species and means of transport, and the need to prevent non-compliant practices and to limit the suffering of animals;
 - (c) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph;
 - (d) the verification of animal welfare requirements at border control posts and at exit points and the minimum requirements applicable to such exit points;
 - (e) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;
 - (f) the cases and conditions where official controls to verify compliance with animal welfare requirements ~~may~~ **shall** include the use of specific animal welfare indicators based on measurable performance criteria, and the design of such indicators on the basis of scientific and technical evidence. [Am. 109]

Tuesday 15 April 2014

Article 19

Specific rules on official controls and action to be taken by the competent authorities in relation to plant health

The Commission shall be empowered to adopt ~~delegated acts in accordance with Article 139~~ **legislative proposals** concerning rules for the performance of official controls on plants, plant products and other objects in order to verify compliance with Union rules referred to in point (g) of Article 1(2) applicable to such goods and on action to be taken by the competent authorities following such official controls. Those ~~delegated acts~~ **legislative proposals** shall take account of plant health risks associated with plants, plant products and other objects in relation to specific pests of plants or operators and lay down rules on: [**Am. 328**]

- (a) specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;
- (b) uniform specific requirements for the performance of official controls on the introduction into and movement in the Union of particular plants, plant products and other objects subject to the rules referred to in point (g) of Article 1(2) and uniform minimum frequencies of such official controls having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks to plant health in relation to specific plants, plant products and other objects of a particular origin or provenance;
- (c) uniform frequencies of official controls performed by competent authorities on operators authorised to issue plant passports in accordance with Article 79(1) of Regulation (EU) No .../....(*) having regard, in addition to the criteria referred to in Article 8(1), to whether those operators have implemented a phytosanitary risk management plan as referred to in Article 86 of Regulation (EU) No .../....(**) for the plants, plant products and other objects they produce;
- (d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.

Article 20

~~Specific rules on official controls and action to be taken by the competent authorities in relation to plant reproductive material~~

~~The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules for the performance of official controls on plant reproductive material in order to verify compliance with the rules referred to in point (h) of Article 1(2) applicable to such goods and on action to be taken by the competent authorities following such official controls. Those delegated acts shall lay down rules on:~~

- ~~(a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Articles 4, 8, 9, 10(1), 11, 12, 13, 34(1) and (2), and 36;~~
- ~~(b) uniform specific requirements for the performance of official controls having regard, in addition to the criteria referred to in Article 8(1), to the risks to the health, identity, quality and traceability of certain categories of plant reproductive material or of specific genera or species;~~
- ~~(c) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;~~
- ~~(d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph. [**Am. 110**]~~

(*) Number of the Regulation on protective measures against pests of plants.

(**) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

Article 21

Specific rules on official controls and action to be taken by the competent authorities in relation to GMOs and genetically modified food and feed

The Commission shall be empowered to adopt ~~delegated acts in accordance with Article 139~~ **legislative proposals** concerning rules for the performance of official controls on GMOs and genetically modified food and feed performed to verify compliance with the rules referred to in points (a), (b) and (c) of Article 1(2) and on action to be taken by the competent authorities following such official controls. Those ~~delegated acts~~ **legislative proposals** shall take into account the need to ensure a minimum level of official controls to prevent practices in violation with those rules, and lay down rules on: **[Am. 111]**

- (a) specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;
- (b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls on:
 - (i) the presence on the market of GMOs and of genetically modified food and feed which have not been authorised in accordance with Directive 2001/18/EC of the European Parliament and the Council⁽¹⁾ or Regulation (EC) No 1829/2003;
 - (ii) the cultivation of GMOs and the correct application of the monitoring plan referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, **including minimum measures for monitoring and surveillance of potential effects on health, animal health and the environment; [Am. 112]**
 - (iii) the contained use of genetically modified micro-organisms;
 - (iiia) minimum measures as regards controls and reporting which aim at avoiding the unintended presence of GMOs, in accordance with Article 26a of Directive 2001/18/EC; [Am. 113]**
- (c) the circumstances in which the competent authorities in relation to specific cases of non-compliance are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.

Article 22

Specific rules on official controls and on action to be taken by the competent authorities in relation to plant protection products

The Commission shall be empowered to adopt ~~delegated acts in accordance with Article 139~~ **legislative proposals** concerning rules for the performance of official controls to verify compliance with the rules referred to in point (i) of Article 1(2). **[Am. 114]**

Those ~~delegated acts~~ **legislative proposals** shall take into account the risks that plant protection products may represent for human health, animal health or the environment, and shall lay down rules on: **[Am. 115]**

- (a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;

⁽¹⁾ Directive 2001/18/EC of the European Parliament and the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

Tuesday 15 April 2014

- (b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, concerning the manufacture, placing on the market, entry into the Union, labelling, packaging, transport, storage, **parallel trade** and use of plant protection products, having regard, in addition to the criteria referred to in Article 8(1), to the need to ensure the safe and sustainable use of plant protection products and to combat illegal trade of such products; [Am. 116]
- (c) uniform specific requirements for inspections on pesticide application equipment and uniform minimum frequency of such controls;
- (ca) **uniform specific requirements for the establishment of a register or database concerning production, packaging and storage facilities;** [Am. 117]
- (d) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph;
- (e) the design of certification systems to assist the competent authorities in the inspections of pesticide application equipment;
- (f) the collection of information, monitoring and reporting on suspected poisonings from plant protection products;
- (g) the collection of information, and the monitoring of and reporting on counterfeited plant protection products and illegal trade of plant protection products.

Article 23

Specific rules on official controls and on action to be taken by the competent authorities in relation to organic products and to protected designations of origin, protected geographical indications and traditional specialties guaranteed

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 139 concerning rules for the performance of official controls to verify compliance with the rules referred to in points (j) and (k) of Article 1(2) and on action to be taken by the competent authorities following such official controls.

2. ~~In relation to~~ **The Commission shall be empowered to adopt delegated acts, in accordance with Article 27(2) of Regulation (EC) No 834/2007, to verify compliance with the rules referred to in point (j) of Article 1(2), the delegated acts referred to in paragraph 1 and on action to be taken by the competent authorities following such official controls. Those delegated acts** shall lay down rules on: [Am. 118]

- (a) the specific responsibilities and tasks of the **operators, the competent authorities, the delegated bodies to ensure compliance with the provisions of Regulation (EC) No 834/2007**, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36, and in addition to Articles 25, 29, 30 and 32 for the approval and supervision of delegated bodies; [Am. 119]
- (b) additional requirements to those referred to in Article 8(1) for risk assessment, and for the establishment of the frequency of official controls, and of sampling as appropriate, taking into account the risk of the occurrence of non-compliance;
- (c) the minimum frequency of official controls on operators as defined in point (d) of Article 2 of Council Regulation (EC) No 834/2007, and the cases where and the conditions under which certain such operators are to be exempted from certain official controls;
- (d) additional methods and techniques for official controls to those referred to in Article 13 and Article 33(1) to (5) and specific requirements for the performance of official controls aimed at ensuring the traceability of organic products at all stages of the production, preparation and distribution, and at providing assurances as to compliance with the rules referred to in point (j) of Article 1(2);

Tuesday 15 April 2014

- (e) additional criteria to those referred to in the second subparagraph of Article 135(1) and in Article 30(1) of Regulation (EC) No 834/2007, relating to the measures to be taken in case of the occurrence of non-compliance, and additional measures to those provided for in Article 135(2);
 - (f) additional requirements to those provided for in point (f) of Article 4(1) in relation to the facilities and equipment necessary to carry out official controls and additional conditions and obligations to those referred to in Articles 25 to 30 and Article 32 for the delegation of official control tasks;
 - (g) additional reporting obligations to those referred to in Articles 12 and 31 for the competent authorities, the control authorities for organic products, and the delegated bodies in charge of official controls;
 - (h) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV.
3. In relation to the rules referred to in point (k) of Article 1(2), the delegated acts referred to in paragraph 1 shall lay down rules on:
- (a) additional requirements, methods and techniques to those referred to Articles 11 and 13 for official controls performed to verify compliance with product specifications and labelling requirements;
 - (b) additional methods and techniques to those referred in Article 13 for the performance of official controls aimed at ensuring the traceability of products falling within the scope of the rules referred to in point (k) of Article 1(2) at all stages of production, preparation and distribution, and at providing assurances as to compliance with those rules;
 - (c) specific additional criteria and specific additional content to those provided for in Article 108, for the preparation of the relevant parts of the multi-annual national control plan provided for in Article 107(1), and specific additional content of the report provided for in Article 112;
 - (d) specific criteria and conditions for the activation of the mechanisms of administrative assistance provided for in Title IV;
 - (e) specific measures to be taken, in addition to those referred to in Article 135(2) in case of non-compliance and of serious or recurrent non-compliance.

4. ~~Where appropriate, the delegated acts referred to in paragraphs 2 and 3 shall derogate from the provisions of this Regulation referred to in those paragraphs. [Am. 120]~~

Article 24

Specific rules on official controls and on action to be taken by the competent authorities in cases of newly identified risks in relation to food and feed

1. The Commission shall be empowered to adopt ~~delegated acts in accordance with Article 139~~ **legislative proposals** concerning specific rules on official controls performed on certain categories of food or feed to verify compliance with the rules referred to in points (a) to (e) of Article 1(2) and on action to be taken by the competent authorities following such official controls. Those ~~delegated acts~~ **legislative proposals** shall address newly identified risks which may be posed through food or feed to human or animal health or, in relation to GMOs and plant protection products to the environment, or any such risks emerging from new patterns of production or consumption of food or feed, or which cannot be effectively addressed in the absence of common specifications for the official controls and for the action to be taken by the competent authorities following such official controls, and shall lay down rules on: **[Am. 121]**

- (a) the specific responsibilities and tasks of the competent authorities, in addition to those provided for in Article 4, Articles 8 and 9, Article 10(1), Articles 11 to 13, Article 34(1) and (2), and Article 36;

Tuesday 15 April 2014

- (b) uniform specific requirements for the performance of official controls and uniform minimum frequency of such official controls, having regard, in addition to the criteria referred to in Article 8(1), to the specific hazards and risks which exist in relation to each category of food and feed and the different processes it undergoes;
- (c) the cases where the competent authorities in relation to specific non-compliances are to take one or more of the measures referred to in Article 135(2) or additional measures to those provided for in that paragraph.
2. Where, in the case of serious risks to human or animal health or to the environment, imperative grounds of urgency so require, the procedure provided for in Article 140 shall apply to delegated acts adopted pursuant to paragraph 1.

Article 24a

Specific rules on official controls and on action to be taken by the competent authorities in relation to materials and articles intended to come into contact with food.

The Commission may be empowered to adopt delegated acts in accordance with Article 139 concerning rules on the application of the official controls and on action to be taken by the competent authorities in relation to materials and articles intended to come into contact with food. [Am. 122]

Chapter III

Delegation of specific tasks of the competent authorities

Article 25

Delegation by the competent authorities of specific official control tasks

1. Competent authorities may delegate specific official control tasks to one or more delegated bodies or natural persons in accordance with the conditions provided for in Articles 26 and 27 respectively. ***Competent authorities shall not delegate specific official control tasks to natural persons concerning official controls performed to verify compliance with the rules referred to in point (j) of Article 1(2). [Am. 123]***
2. Competent authorities shall not delegate the decision concerning the measures provided for in point (b) of Article 135 (1) and in Article 135 (2) and (3).

~~The first subparagraph shall not apply to the measures to be taken in accordance with Article 135 or with the rules provided for in point (e) of Article 23(2) following official controls performed to verify compliance with the rules referred to in point (j) of Article 1(2). [Am. 124]~~

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 establishing specific official control tasks that may not be delegated in order to preserve the independence or the core functions of the competent authorities.
4. Where competent authorities delegate specific official control tasks for the verification of compliance with the rules referred to in point (j) of Article 1(2) to one or more delegated bodies, they shall attribute a code number to each delegated body and designate authorities responsible for their approval and supervision.

Article 26

Conditions for delegating specific official control tasks to delegated bodies

The delegation of specific control tasks to a delegated body referred to in Article 25(1) shall be in writing and shall comply with the following conditions:

- (a) the delegation contains a precise description of:
- (i) the specific official control tasks that the delegated body may perform;

Tuesday 15 April 2014

- (ii) the conditions under which it may perform those tasks;
- (b) the delegated body:
 - (i) has the expertise, equipment and infrastructure required to perform the specific official control tasks delegated to it;
 - (ii) has a sufficient number of suitably qualified and experienced staff;
 - (iii) is impartial, **independent, not directly nor indirectly employed by the operator on which it is performing control activities**, and **otherwise** free from any conflict of interest as regards the exercise of the specific official control tasks delegated to it; [Am. 125]
 - (iv) works and is accredited in accordance with standard EN ISO/IEC 17020 'Requirements for the operation of various types of bodies performing inspection' or another standard if more relevant to the delegated tasks in question;
- (iva) has sufficient powers to perform the official controls delegated to it; [Am. 126]**
- (c) there are arrangements in place ensuring efficient and effective coordination between the delegating competent authorities and the delegated body.

Article 27

Conditions for delegating specific official control tasks to natural persons

Competent authorities may delegate specific official control tasks to one or more natural persons where the rules provided for in Articles 15 to 24 so allow. Such delegation shall be in writing.

Article 26 shall apply to the delegation of specific official control tasks to natural persons, with the exception of points (b) (ii) and (b)(iv).

Article 28

Obligations of the delegated body and natural person to which specific official control tasks are delegated

Delegated bodies or natural persons to whom specific official control tasks have been delegated in accordance with Article 25(1) shall:

- (a) communicate the results of the official controls performed by them to the competent authorities which have delegated the specific official control tasks on a regular basis and whenever those competent authorities so request;
- (b) immediately inform the competent authorities which have delegated the specific official control tasks whenever the results of the official controls indicate non-compliance or point to the likelihood of non-compliance.

Article 29

Obligations of the competent authorities delegating specific official control tasks

Competent authorities that have delegated specific official control tasks to delegated bodies or natural persons in accordance with Article 25(1) shall:

- (a) organise **periodic and unannounced** audits or inspections of such bodies or persons ~~as necessary~~; [Am. 127]
- (b) fully or partly withdraw the delegation without delay where:
 - (i) following an audit or an inspection as provided in point (a), there is evidence that such delegated bodies or natural persons are failing to properly perform the official control tasks delegated to them;

Tuesday 15 April 2014

- (ii) the delegated body or the natural person fails to take appropriate and timely action to remedy the shortcomings identified during the audits and inspections provided for in point (a);

(iii) *the independence or impartiality of the delegated body or natural person have been shown to be compromised.*
[Am. 128]

Article 30

Conditions for delegating specific tasks related to other official activities

1. The competent authorities may delegate specific tasks related to other official activities to one or more delegated bodies subject to compliance with the following conditions:

- (a) the rules referred to in Article 1(2) do not prohibit such delegation;
- (b) the conditions laid down in Article 26 are fulfilled with the exception of point (b)(iv).

2. The competent authorities may delegate specific tasks related to other official activities to one or more natural persons subject to compliance with the following conditions:

- (a) the rules referred to in Article 1(2) allow such delegation;
- (b) the conditions laid down in Article 26 are fulfilled with the exception of points (b)(ii) and (b)(iv).

Article 31

Obligations of the delegated body and natural person to which specific tasks related to other official activities are delegated

The delegated body or the natural person to whom specific tasks related to other official activities have been delegated in accordance with Article 30 shall:

- (a) communicate the results of the other official activities performed by it to the competent authorities which have delegated the specific tasks related to other official activities on a regular basis and whenever the competent authorities so request;
- (b) immediately inform the competent authorities which have delegated the specific tasks related to other official activities whenever the results of the other official activities indicate non-compliance or point to the likelihood of non-compliance.

Article 32

Obligations of the competent authorities delegating specific tasks related to other official activities

Competent authorities that have delegated specific tasks related to other official activities to delegated bodies or natural persons in accordance with Article 30 shall:

- (a) organise audits or inspections of such bodies or persons ~~as necessary~~; [Am. 129]
- (b) fully or partly withdraw the delegation without delay where:
 - (i) following an audit or an inspection as provided for in point (a), there is evidence that such delegated bodies or natural persons are failing to properly perform the tasks related to other official activities delegated to them;
 - (ii) the delegated bodies or natural persons fail to take appropriate and timely action to remedy the shortcomings identified during the audits and inspections provided for in point (a).

Tuesday 15 April 2014

Chapter IV

Sampling, analyses, tests and diagnoses

Article 33

Methods used for sampling, analyses, tests and diagnoses

1. Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.
2. In the absence of the Union rules referred to in paragraph 1, **in the context of official controls**, official laboratories shall use state-of-the-art methods for their specific analytical, testing and diagnostic needs, taking into account, **in the following order**: [Am. 130]
 - (a) the most recent available methods complying with relevant internationally recognised rules or protocols, including those that the European Committee for Standardisation (CEN) has accepted;
 - (b) in the absence of the rules or protocols referred to in point (a), the relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols;
 - (c) in the absence of the rules or protocols referred to in point (a) and the methods referred to in point (b), the methods which comply with relevant rules established at national level;
 - (d) in the absence of the rules or protocols referred to in point (a), the methods referred to in point (b) and the national rules referred to in point (c), the relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or,
 - (e) in the absence of the rules or protocols referred to in point (a), the methods referred to in point (b), the national rules referred to in point (c) and the methods referred to in point (d), the relevant methods validated in accordance with internationally accepted scientific protocols.
3. **By way of derogation from paragraph 2**, in the context of screening, targeted screening and of other official activities, any of the methods referred to in paragraph 2 may be used in the absence of Union rules referred to in paragraph 1. **The same rule shall apply to the other official activities**. [Am. 131]
4. Where laboratory analyses, tests or diagnoses are urgently needed **in exceptional cases due to a developing emergency situation**, and none of the methods referred to in paragraphs 1 and 2 exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 36(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols. [Am. 132]
5. Wherever possible, methods used for laboratory analyses shall be characterised by the appropriate criteria set out in Annex III.
6. Samples shall be taken, handled and labelled in such a way as to guarantee their legal, scientific and technical validity. **The size of the sample taken must be such as to enable a second expert opinion to be given, where necessary, should an operator so request under Article 34**. [Am. 133]
 - 6a. **As regards products of animal origin, methods have to be developed and mandatorily established aimed at identifying and tracing breeding material from cloned animals as well as descendants from cloned animals and products derived thereof**. [Am. 134]

Tuesday 15 April 2014

7. The Commission may, by means of implementing acts, *insofar as these matters are not otherwise regulated*, lay down rules for: [Am. 135]

- (a) the methods to be used for sampling and for laboratory analyses, tests and diagnoses;
- (b) performance criteria, analysis, test or diagnosis parameters, measurement uncertainty and procedures for the validation of those methods;
- (c) the interpretation of analytical, testing and diagnostic results.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 34

Second expert opinion

1. The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to apply for a second expert opinion, *where this is relevant and technically feasible. The operator shall bear the costs of that expert opinion.* [Am. 136]

Such a right:

- (a) shall always entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another expert *designated by the reference laboratory or, failing that, by another official laboratory which is at least equivalent;* [Am. 137]
- (b) where relevant and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, shall entitle the operator to request *and oblige the competent authorities to ensure:* [Am. 138]
 - (i) that a sufficient number of ~~other~~ samples be taken ~~for~~ *and divided into three parts for the purpose of an initial analysis and, if appropriate, a second expert opinion; or, at the request of the operator, and then another final analysis, if there is a discrepancy between the two previous ones;* [Am. 139]
 - (ii) where it is not possible to take a sufficient number of samples as referred to in point (i), that an independent second analysis, test or diagnosis on the sample be carried out.

1a. Samples shall be handled and labelled in such a way as to guarantee their legal and technical validity. [Am. 140]

2. The application by the operator for a second expert opinion in accordance with paragraph 1 shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health, or for animal welfare or, as regards GMOs and plant protection products, for the environment, in accordance with the rules referred to in Article 1(2) and with this Regulation.

3. The Commission may, by means of implementing acts, lay down procedures for the uniform application of the rules provided for in paragraph 1 and for the presentation and handling of applications for a second expert opinion. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 35

Sampling of animals and goods offered for sale by means of distance communication

1. In the case of animals and goods offered for sale by means of distance communication, samples ordered from operators by the competent authorities without identifying themselves may be used for the purposes of an official control.

Tuesday 15 April 2014

2. Competent authorities, **once they are in possession of the samples**, shall take all steps to ensure that the operators from whom ~~the~~ **those** samples are ordered in accordance with paragraph 1: **[Am. 141]**
 - (a) are informed that such samples are being taken in the context of an official control and, where appropriate, analysed or tested for the purposes of such official control; and,
 - (b) where the samples referred to in paragraph 1 are analysed or tested, are entitled to exercise the right to apply for a second expert opinion provided for in Article 34(1).

Article 36

Designation of official laboratories

1. The competent authorities shall designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities, in the Member State in whose territory those competent authorities operate or in another Member State.
2. Competent authorities may designate as official laboratory a laboratory located in another Member State subject to compliance with the following conditions:
 - (a) appropriate arrangements are in place under which they are enabled to perform the audits and inspections referred to in Article 38(1) or delegate the performance of such audits and inspections to the competent authorities of the Member State where the laboratory is located;
 - (b) that laboratory is already designated as an official laboratory by the competent authorities of the Member State on whose territory it is located.
3. The designation shall be in writing and shall include a detailed description of:
 - (a) the tasks that the laboratory shall carry out as official laboratory;
 - (b) the conditions under which it shall carry out those tasks;
 - (c) the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities.
4. The competent authorities may only designate as official laboratory a laboratory which:
 - (a) has the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;
 - (b) has a sufficient number of suitably qualified, trained and experienced staff;
 - (c) is **independent**, impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory; **[Am. 142]**
 - (d) can deliver timely the results of the analysis, test or diagnosis carried out on the samples taken during official controls and other official activities;
 - (e) operates in accordance with the standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' and is ~~assessed and~~ accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008. **[Am. 143]**
5. The scope of the ~~assessment and~~ accreditation of an official laboratory referred to in point (e) of paragraph 4: **[Am. 144]**
 - (a) shall include all the methods of laboratory analysis, test or diagnosis required to be used by the laboratory for analyses, tests or diagnoses when it operates as an official laboratory;

Tuesday 15 April 2014

- (b) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;
- (c) may be defined in a flexible manner, so as to allow the accreditation scope to include modified versions of the methods used by the official laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods.

Where no official laboratory designated in the Union in accordance with paragraph 1 has the expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses, the competent authorities may request a laboratory or diagnostic centre which does not comply with one or more of the requirements of paragraphs 3 and 4 of this Article to carry out those analyses, tests and diagnoses.

Article 37

Obligations of official laboratories

1. Official laboratories shall immediately inform the competent authorities where the results of an analysis, test or diagnosis carried out on samples indicate non-compliance or point to the likelihood of non-compliance by an operator.
2. Upon request by the European Union reference laboratory or national reference laboratory, official laboratories shall take part in inter-laboratory comparative tests organised for the analyses, tests or diagnoses they perform as official laboratories.
3. Official laboratories shall make available to the public the list of methods used for analyses, tests or diagnoses performed in the context of official controls and other official activities.

Article 38

Audits and inspections of official laboratories

1. The competent authorities shall organise audits or inspections of the official laboratories they have designated in accordance with Article 36(1):
 - (a) on a regular basis;
 - (b) any time they consider that an audit or inspection is necessary.
2. The competent authorities shall immediately withdraw the designation of an official laboratory, either completely or for certain tasks, where it fails to take appropriate and timely remedial action following the results of an audit or an inspection provided for in paragraph 1 which disclose any of the following:
 - (a) it no longer complies with the conditions provided for in Article 36(4) and (5);
 - (b) it does not comply with the obligations provided for in Article 37;
 - (c) it is underperforming at inter-laboratory comparative tests referred to in Article 37(2).

Article 39

Derogations from the condition for the mandatory ~~assessment and~~ accreditation for certain official laboratories [**Am. 145**]

1. By derogation from point (e) of Article 36(4), competent authorities may designate the following as official laboratories irrespective of whether they fulfil the condition provided for in that point:
 - (a) laboratories:
 - (i) whose sole activity is the detection of *Trichinella* in meat;

Tuesday 15 April 2014

- (ii) that only use for the detection of *Trichinella* the methods referred to in Article 6 of Commission Regulation (EC) No 2075/2005 ⁽¹⁾;
 - (iii) that carry out the detection of *Trichinella* under the supervision of the competent authorities or of an official laboratory designated in accordance with Article 36(1), and ~~assessed and~~ accredited in accordance with the standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' for the use of the methods referred to in point (a)(ii) of this paragraph; **[Am. 146]**
 - ~~(b) laboratories carrying out analyses or tests to verify compliance with the rules on plant reproductive material referred to in point (h) of Article 1(2); **[Am. 147]**~~
 - (c) laboratories which only carry out analyses, tests or diagnoses in the context of other official activities, provided that they:
 - (i) only use the methods of laboratory analysis, test and diagnosis referred to in Article 33(1) and points (a), (b) and (c) of Article 33(2);
 - (ii) carry out the analyses, tests or diagnoses under the supervision of the competent authorities or of the national reference laboratories for the methods they use;
 - (iii) participate regularly in the inter-laboratory comparative tests organised by the national reference laboratories for the methods they use;
 - (iv) have a quality assurance system in place to ensure sound and reliable results from the methods for laboratory analysis, test and diagnosis used.
2. Where the methods used by the laboratories referred to in point (c) of paragraph 1 require confirmation of the result of the laboratory analysis, test or diagnosis, the confirmatory laboratory analysis, test or diagnosis shall be carried out by an official laboratory which complies with the requirements of point (e) of Article 36(4).
3. The official laboratories designated in accordance with points (a) and (c) of paragraph 1 shall be located in the Member States in whose territory the competent authorities which have designated them are located.

Article 40

Powers to adopt derogations from the condition for the mandatory ~~assessment and~~ accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories **[Am. 148]**

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories in accordance with Article 36(1) laboratories which do not fulfil the conditions referred to in point (e) of Article 36(4) in relation to all the methods they use, provided that such laboratories comply with the following conditions:

- (a) they operate, are assessed and accredited in accordance with the standard EN ISO/IEC 17025 for the use of one or more methods which are similar to and representative of the other methods they use;
- (b) they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (a).

Article 41

Temporary derogations from the condition for the mandatory ~~assessment and~~ accreditation of official laboratories **[Am. 149]**

1. By derogation from point (a) of Article 36(5), the competent authorities may temporarily designate an existing official laboratory as official laboratory in accordance with Article 36(1) for the use of a method of laboratory analysis, test or diagnosis for which it has not obtained the accreditation referred to in point (e) of Article 36(4):

- (a) when the use of that method is newly required by Union rules;

⁽¹⁾ Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat (OJ L 338, 22.12.2005, p. 60).

Tuesday 15 April 2014

- (b) when changes to a method in use require a new accreditation or an extension of the scope of the accreditation obtained by the official laboratory;
- (c) in cases where the need for the use of the method results from an emergency situation or an emerging risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment; or

(ca) pending the assessment by, and decision of, the accreditation body. [Am. 150]

2. The temporary designation referred to in paragraph 1 shall be subject to the following conditions:

- (a) the official laboratory is already accredited in accordance with the standard EN ISO/IEC 17025 for the use of a method which is similar to the one not included within the scope of its accreditation;
- (b) a quality assurance system is in place in the official laboratory to ensure sound and reliable results from the use of the method which is not included within the scope of the existing accreditation;
- (c) the analyses, tests or diagnoses are carried out under the supervision of the competent authorities or the national reference laboratory for that method.

3. The temporary designation provided for in paragraph 1 shall not exceed a period of one year, and may be renewed once for a further period of one year.

4. The official laboratories designated in accordance with paragraph 1 of this Article shall be located in the Member States in whose territory the competent authorities which have designated them are located.

Article 41a

Official controls on animals and goods entering the Union shall be organised according to risk, and may take place at border control posts in accordance with Section II of this chapter, with a view to checking compliance with the regulatory provisions specific to certain animals or goods, or at an appropriate place in accordance with Section I of this chapter. [Am. 151]

Chapter V

Official controls on animals and goods entering the Union

Section I

Animals and goods not subject to specific official controls at borders

Article 42

Official controls on animals and goods not subject to specific official controls at borders

1. The competent authorities shall perform official controls regularly on animals and goods entering the Union to ascertain compliance with the rules referred to in Article 1(2).

On animals and goods to which Article 45 does not apply, those official controls shall be performed with appropriate frequency, taking into account:

- (a) the risks to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment, associated with different types of animals and goods;

(aa) the likelihood of fraudulent practices which might deceive consumer expectation regarding nature, quality and composition of foods and goods; [Am. 152]

- (b) the history of compliance with the requirements established by the rules referred to in Article 1(2) applicable to the animals or goods concerned:

- (i) of the third country and establishment of origin;

Tuesday 15 April 2014

- (ii) of the exporter;
- (iii) of the operator responsible for the consignment;
- (c) the controls that have already been performed on the animals and goods concerned;
- (d) the guarantees that the competent authorities of the third country of origin has given with regard to compliance of the animals and goods with the requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto.

2. The official controls provided for in paragraph 1 shall be performed at an appropriate place within the customs territory of the Union, including:

- (a) the point of entry into the Union;
- (b) a border control post;
- (c) the point of release for free circulation in the Union;
- (d) the warehouses and the premises of the operator responsible for the consignment.

3. The competent authorities at border control posts and other points of entry into the Union shall perform official controls on the following whenever they have reason to believe that their entry into the Union may pose a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment:

- (a) means of transport, including where empty;
- (b) packaging.

4. The competent authorities may also perform official controls on goods that are placed under one of the customs procedures defined in points (a) to (g) of Article 4(16) of Regulation (EEC) No 2913/92.

Article 43

Types of official controls on animals and goods not subject to specific official controls at borders

1. The official controls referred to in Article 42(1) shall:

- (a) always include a documentary check;
- (b) include identity and physical checks depending on the risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment.

2. The competent authorities shall carry out the physical checks referred to in point (b) of paragraph 1 under appropriate conditions allowing investigations to be conducted properly.

3. Where the documentary, identity and physical checks referred to in paragraph 1 show that animals and goods do not comply with the rules referred to in Article 1(2), Article 64(1), (3), (4) and (5), Articles 65 to 67, Article 69(1) and (2) and Article 70(1) and (2) shall apply.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where and the conditions under which competent authorities may request operators to notify the arrival of certain goods entering the Union.

Article 44

Samples taken on animals and goods not subject to specific official controls at borders

1. Where samples on animals and goods are taken, the competent authorities shall:

- (a) inform the customs authorities and the operators concerned;

Tuesday 15 April 2014

(b) decide whether or not the animals or goods can be released before the results of the analysis, test or diagnosis carried out on the samples are available, provided that the traceability of the animals or goods is ensured.

2. The Commission shall, by means of implementing acts:

- (a) establish the mechanisms necessary to ensure the traceability of the animals or goods referred to in point (b) of paragraph 1;
- (b) identify the documents that must accompany the animals or goods referred to in paragraph 1 when samples have been taken by the competent authorities.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Section II

Official controls at border Control Posts on animals and goods

Article 45

Animals and goods subject to official controls at border control posts

1. To ascertain compliance with the rules referred to in Article 1(2), the competent authorities shall perform official controls, at the border control post of first arrival to the Union, on each consignment of the following categories of animals and goods entering the Union from third countries:

- (a) animals;
- (b) **products of animal origin, foods that contain** products of animal origin, germinal products and animal by-products; [Am. 153]
- (c) plants, plant products, and other objects and materials capable of harbouring or spreading pests of plants as referred to in the lists established pursuant to Articles 68(1) and 69(1) of Regulation (EU) No .../... (*);
- (d) goods originating from certain third countries for which the Commission has decided, by means of implementing acts provided for in point (b) of paragraph 2, that a measure requiring a temporary increase of official controls at their entry into the Union is necessary due to a known or emerging risk or because there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) might be taking place;
- (e) animals and goods which are subject to an emergency measure provided for in acts adopted in accordance with Article 53 of Regulation (EC) No 178/2002, Article 249 of Regulation (EU) No .../... (**), or Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No .../... (***) requiring consignments of those animals or goods, identified by means of their codes from the Combined Nomenclature, to be subject to official controls at their entry into the Union;
- (f) animals and goods in relation to whose entry into the Union conditions or measures have been established by acts adopted in accordance with Articles 125 or 127 respectively, or with the rules referred to in Article 1(2), which require that compliance with those conditions or measures be ascertained at the entry of the animals or goods into the Union.

2. The Commission shall, by means of implementing acts:

- (a) establish lists detailing the animals and goods belonging to the categories referred to in points (a) and (b) of paragraph 1, indicating their codes from the Combined Nomenclature;

(*) Number of the Regulation on protective measures against pests of plants.

(**) Number of the Regulation on animal health.

(***) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

- (b) establish the list of goods belonging to the category referred to in point (d) of paragraph 1, indicating their codes from the Combined Nomenclature, and update it as necessary in relation to the risks referred to in that point.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning amendments of the categories of consignments referred to in paragraph 1, to include other products which may give rise to risks to human, animal or plant health or, as regards GMOs and plant protection products, to the environment.

4. Unless otherwise provided by the acts establishing the measures or conditions referred to in points (d), (e) and (f) of paragraph 1, this Article shall also apply to consignments of the categories of animals and goods referred to in points (a), (b) and (c) of paragraph 1 when they are of a non-commercial nature.

Article 46

Animals and goods exempted from official controls at border control posts

The Commission shall be empowered to adopt delegated acts in accordance with Article 139, concerning rules establishing the cases where and the conditions under which the following categories of animals and goods are exempted from Article 45:

- (a) ~~goods sent as commercial or trade samples or as display items for exhibitions, which are not intended to be placed on the market;~~ [Am. 154]
- (b) ~~animals and goods intended for scientific purposes;~~ [Am. 155]
- (c) goods that are on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers;
- (d) goods which form part of passengers personal luggage and are intended for personal consumption;
- (e) small consignments of goods sent to natural persons which are not intended to be placed on the market;
- (f) ~~pet animals as defined in point (10) of Article 4(1) of Regulation (EU) No XXX/XXXX [number of the Regulation on animal health];~~ [Am. 156]
- (g) goods which have undergone heat treatment and do not exceed quantities to be defined in those delegated acts;
- (h) any other category of animals or goods for which controls at border control posts are not necessary given the risks they pose.

Article 47

Official controls at border control posts

1. The competent authorities shall perform official controls on the consignments of the categories of animals and goods referred to in Article 45(1) upon arrival of the consignment at the border control post. Those official controls shall include documentary, identity and physical checks.

2. All consignments of the categories of animals and goods referred to in Article 45(1) shall be subject to documentary and identity checks.

3. Physical checks shall be performed on consignments of the categories of animals and goods referred to in Article 45(1) at a frequency dependent on the risk posed by each animal, good or category of animals or goods to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment.

Tuesday 15 April 2014

4. Physical checks to verify compliance with animal health and welfare requirements or with plant health requirements laid down in the rules referred to in Article 1(2) shall be performed by, or under the supervision of, staff possessing appropriate qualifications in veterinary or phytosanitary matters respectively, designated by the competent authorities for that purpose.

Where such checks are performed on animals **or on products of animal origin**, they shall be carried out by an official veterinarian ~~or under his supervision~~, **who may be assisted by specially trained support staff whilst retaining responsibility for the checks carried out.** [Am. 157]

5. The competent authorities at border control posts shall systematically perform official controls on consignments of animals being transported and on means of transport to verify compliance with the animal welfare requirements laid down in the rules referred to in Article 1(2). Arrangements shall be put in place by competent authorities to give priority to official controls on animals being transported and to reduce delays on such controls.

6. The Commission may, by means of implementing acts establish the modalities of presentation of consignments of the categories of goods referred to in Article 45(1), the sub-entities which can constitute an individual consignment and the maximum number of such sub-entities in each consignment, taking into account the need to guarantee the rapid and efficient handling of the consignments and the official controls to be performed by the competent authorities.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 48

Certificates and documents accompanying consignments and split consignments

1. The original official certificates or documents, or electronic equivalents, which are required by the rules referred to in Article 1(2) to accompany consignments of the categories of animals and goods referred in Article 45(1) shall be presented to, and kept by, the competent authorities of the border control post.

2. The competent authorities of the border control post shall issue the operator responsible for the consignment with an authenticated paper or electronic copy of the official certificates or documents referred to in paragraph 1 or, if the consignment is split, with individually authenticated paper or electronic copies of such certificates or documents.

3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 54 has been finalised in accordance with Articles 54(4) and 55(1).

Article 49

Specific rules for official controls at border control posts

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules to establish:

- (a) the cases where and the conditions under which the competent authorities of a border control post may authorise the onward transportation of consignments of the categories of animals and goods referred to in Article 45(1) to the place of final destination pending the availability of the results of physical checks, where such checks are required;
- (b) the time limits and modalities for carrying out documentary, identity and physical checks on transhipped consignments of the categories of goods referred to in Article 45(1);
- (c) the cases where and the conditions under which identity and physical checks of transhipped consignments and of animals arriving by air or sea and staying on the same means of transport for onward travel may be performed at a border control post other than the one of first arrival into the Union;
- (d) the cases where and the conditions under which the transit of consignments of the categories of animals and goods referred to in Article 45(1) may be authorised and the specific official controls to be performed at border control posts on such consignments, including the cases and conditions for their storage in specially approved free or customs warehouses.

Tuesday 15 April 2014

Article 50

Details of documentary, identity and physical checks

For the purposes of ensuring the uniform implementation of the rules laid down in Articles 47, 48 and 49, the Commission shall by means of implementing acts, lay down the details of the operations to be carried out during and after the documentary, identity and physical checks referred to in those rules to ensure the efficient performance of those official controls. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 51

Official controls not performed at border control posts of first arrival

1. Competent authorities may perform the identity and physical checks of the animals and goods entering the Union from third countries referred to in Article 45(1) at control points other than border control posts, provided that those control points comply with the requirements provided for in Article 62(3) and in the implementing acts adopted in accordance with Article 62(4). [Am. 158]

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the cases where and the conditions under which:

- ~~(a) identity and physical checks on consignments of the categories of animals and goods referred to in Article 45(1) may be performed by competent authorities at control points other than border control posts provided that those control points comply with the requirements provided for in Article 62(3) and in the implementing acts adopted in accordance with Article 62(4); [Am. 159]~~
- (b) physical checks on consignments which have undergone documentary and identity checks at a border control post of first arrival may be performed at another border control post in a different Member State;
- (c) specific control tasks relating to the following may be attributed by competent authorities to customs authorities or other public authorities:
 - (i) consignments referred to in Article 63(2);
 - (ii) passengers personal luggage;
 - (iii) ~~goods ordered by~~ **small consignments sent to private individuals or acquired at a distance selling by telephone, post or internet; [Am. 160]**
 - (iiia) pet animals which meet the conditions laid down in Article 5 of Regulation (EU) No 576/2013 of the European Parliament and of the Council⁽¹⁾. [Am. 161]**

2. Point (b) of Article 54(2), point (a) of Article 55(2) and Article 57 and 58, Articles 60 and 61, and Article 62(3) and (4), shall apply to the control points referred to in point (a) of paragraph 1.

Article 52

Frequency of identity and physical checks

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the categories of animals and goods and the conditions under which, by derogation from Article 47(2) and account taken of the reduced risk, identity checks on consignments of animals and goods referred to in Article 45(1) shall be:

- (a) performed at a reduced frequency;
- (b) limited to the verification of a consignment's official seal, where any such seal is present.

⁽¹⁾ **Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).**

Tuesday 15 April 2014

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing:

- (a) the criteria and the procedures for determining and modifying the **minimum** frequency rates of physical checks to be performed on consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 45(1) and to adjust them to the level of risk associated with those categories, having regard to: [**Am. 162**]
 - (i) information collected by the Commission in accordance with Article 124(1);
 - (ii) the outcome of controls performed by Commission experts in accordance with Article 115(1);
 - (iii) operators' past record as regards compliance with the rules referred to in Article 1(2);
 - (iv) data and information collected via the information management system referred to in Article 130;
 - (v) available scientific assessments; and,
 - (vi) any other information regarding the risk associated to the categories of animals and goods;
- (b) the conditions under which Member States may increase the frequency rates of physical checks established in accordance with point (a) so as to take account of local risk factors;
- (c) the procedures for ensuring that the **minimum** frequency rates of physical checks established in accordance with point (a) are applied in a timely and uniform manner. [**Am. 163**]

3. The Commission shall, by means of implementing acts, lay down rules establishing:

- (a) the **minimum** frequency of physical checks for the categories of goods referred to in point (d) of Article 45(1); [**Am. 164**]
- (b) the **minimum** frequency of physical checks for the categories of animals and goods referred to in points (e) and (f) of Article 45(1) as long as this is not already provided for in the acts referred to therein. [**Am. 165**]

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 53

Decisions on consignments

1. A decision shall be taken by the competent authorities on each consignment of the categories of animals and goods referred to in Article 45(1) following the performance of official controls, indicating whether the consignment is in compliance with the rules referred to in Article 1(2) and, where relevant, the applicable customs procedure.

2. Decisions taken following a physical check to verify compliance with animal health and welfare requirements or with plant health requirements shall be taken by staff possessing appropriate qualifications in veterinary or phytosanitary matters respectively, and designated by the competent authorities for that purpose.

Decisions on consignments of animals **and products of animal origin** shall be taken by an official veterinarian ~~or under his supervision~~ **who may be assisted by specially trained support staff whilst retaining responsibility for the checks carried out.** [**Am. 166**]

2a. Decisions on consignments of animals and products of animal origin shall be recorded in the CHED. [**Am. 167**]

Article 54

Use of the Common Health Entry Document by the operator and by the competent authorities

1. For each consignment of the categories of animals and goods referred to in Article 45(1) the operator responsible for the consignment shall complete a CHED, providing the information necessary for the immediate and complete identification of the consignment and its destination.

Tuesday 15 April 2014

2. The CHED shall be used:
 - (a) by the operators responsible for consignments of the categories of animals and goods referred to in Article 45(1) in order to give prior notification to the competent authorities of the border control post of the arrival of those consignments;
 - (b) by the competent authorities of the border control post, in order to:
 - (i) record the outcome of the official controls performed and any decisions taken on that basis, including the decision to reject a consignment;
 - (ii) communicate the information referred to in point (i) through **or in electronic exchange with** the TRACES system. **[Am. 168]**

2a. The operators and competent authorities referred to in paragraph 2 may also use a national information system to feed data into the TRACES system. [Am. 169]

3. Operators shall give prior notification in accordance with point (a) of paragraph 2 by completing and submitting the relevant part of the CHED into the TRACES system for transmission to the competent authorities of the border control post prior to the physical arrival of the consignment into the Union.
4. The competent authorities of the border control post shall ~~finalise the CHED~~ **record the decision on the consignment in the Common Health Entry Document** as soon as: **all official controls required by Article 47(1) have been performed.**
 - ~~(a) all official controls required by Article 47(1) have been performed;~~
 - ~~(b) the results from physical checks, where such checks are required, are available;~~
 - ~~(c) a decision on the consignment has been taken in accordance with Article 53 and recorded on the CHED. [Am. 170]~~

Article 55

Use of the Common Health Entry Document by customs authorities

1. The placing of consignments of the categories of animals and goods referred to in Article 45(1) under supervision or control by the customs authorities, including the entry or handling in free zones or customs warehouses, shall be subject to the presentation by the operator to the customs authorities of the CHED, or its electronic equivalent, duly finalised in the TRACES system by the competent authorities of the border control post.
2. Customs authorities shall:
 - (a) not allow the placing of the consignment under a customs procedure different from the one indicated by the competent authorities of the border control post;
 - (b) only allow the release for free circulation of a consignment upon presentation of a duly finalised CHED which confirms that the consignment is in compliance with the rules referred to in Article 1(2).
3. Where a customs declaration is made for a consignment of the categories of animals or goods referred to in Article 45(1) and the CHED is not presented, the customs authorities shall detain the consignment and immediately notify the competent authorities of the border control post. The competent authorities shall take the necessary measures in accordance with Article 64(5).

Article 56

Format, time requirements and specific rules for the use of the Common Health Entry Document

1. The Commission shall, by means of implementing acts, lay down rules establishing:
 - (a) the format of the CHED and the instructions for its presentation and use;

Tuesday 15 April 2014

- (b) the minimum time requirements for prior notification of consignments by operators as provided for in point (a) of Article 54(2) in order to enable the competent authorities of the border control post to perform official controls in a timely and effective manner.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules establishing the cases where and the conditions under which the CHED is required to accompany consignments of the categories of animals and goods referred to in Article 45(1) to the place of destination. **A copy of the CHED shall in any case accompany consignments of the categories of animals and goods referred to in Article 45(1) to the place of destination.** [Am. 171]

Article 57

Designation of border control posts

1. Member States shall designate border control posts for the purpose of performing official controls on one or more of the categories of animals and goods referred to in Article 45(1).
2. Member States shall notify the Commission at least three months before designating a border control post. That notification shall include all the information necessary for the Commission to verify that the proposed border control post complies with the minimum requirements laid down in Article 62.
3. Within three months of receiving the notification referred to in paragraph 2, the Commission shall inform the Member State:
 - (a) whether the designation of the proposed border control post is dependent upon the favourable outcome of a control performed by Commission experts in accordance with Article 115 in order to verify compliance with the minimum requirements laid down in Article 62;
 - (b) of the date of such a control.
4. The Member State shall delay designating the border control post until the favourable outcome of the control has been communicated to it by the Commission.

Article 58

Listing of border control posts

1. Each Member State shall make available on the internet up-to-date lists of border control posts on its territory, providing the following information for each border control post:
 - (a) its contact details and opening hours;
 - (b) its exact location and whether it is a port, airport, rail or road entry point;
 - (c) the categories of animals and goods referred to in Article 45(1) which are included in the scope of its designation;
 - (d) the equipment and premises available for performing official controls on each of the categories of animals and goods for which it is designated;
 - (e) the volume of the animals and goods handled per calendar year for each of the categories of animals and goods referred to in Article 45(1) for which it is designated.
2. The Commission shall, by means of implementing acts, establish the format, categories, abbreviations for designations and other information to be used by Member States in the lists of border control posts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Tuesday 15 April 2014

Article 59

Withdrawal of approvals for, and re-designation of, existing border control entities

1. The approval of border inspection posts in accordance with Article 6 of Directive 97/78/EC and Article 6 of Directive 91/496/EEC and the designation of points of entry in accordance with Article 5 of Regulation (EC) No 669/2009 and with Article 13(c)(4) of Directive 2000/29/EC shall be withdrawn.
2. Member States may re-designate border inspection posts, designated points of entry and points of entry referred to in paragraph 1 as border control posts in accordance with Article 57(1) provided that the minimum requirements referred to in Article 62 are complied with.
3. Article 57(2) and (3) shall not apply to the re-designation referred to in paragraph 2.

Article 60

Withdrawal of the designation of border control posts

1. Where border control posts cease to comply with the requirements referred to in Article 62, the Member States shall:
 - (a) withdraw the designation provided for in Article 57(1) for all or for certain categories of animals and goods for which the designation was made;
 - (b) remove them from the lists referred to in Article 58(1), for the categories of animals and goods for which the designation is withdrawn.
2. Member States shall inform the Commission and the other Member States of the withdrawal of the designation of a border control post as provided for in paragraph 1 and of the reasons for such withdrawal.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where, and the procedures by which, border control posts whose designation has only been partially withdrawn in accordance with point (a) of paragraph 1 may be re-designated by derogation from Article 57.

Article 61

Suspension of the designation of border control posts

1. A Member State shall immediately suspend the designation of a border control post and order its activities to be stopped, for all or for certain categories of animals and goods for which the designation was made, in cases where such activities may result in a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products or to the environment. **[Am. 172]**
2. Member States shall immediately inform the Commission and the other Member States of any suspension of the designation of a border control post and the reasons for such a suspension.
3. Member States shall indicate the suspension of the designation of a border control post in the lists referred to in Article 58(1).
4. Member States shall remove the suspension provided for in paragraph 1 as soon as:
 - (a) the competent authorities are satisfied that the risk referred to in paragraph 1 no longer exists;
 - (b) they have communicated to the Commission and to the other Member States the information on the basis of which the suspension is removed.
5. The Commission may, by means of implementing acts, establish procedures for the exchanges of information and communications referred to in paragraph 2 and in point (b) of paragraph 4.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Tuesday 15 April 2014

Article 62

Minimum requirements for border control posts

1. Border control posts shall be located in the immediate vicinity of the point of entry into the Union and in a place **that is** suitably equipped ~~to be designated by the customs authorities~~, in accordance with Article 38(1) of Regulation (EEC) No 2913/92. [**Am. 173**]
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the cases where and conditions under which a border control post can be situated at a certain distance from the point of entry into the Union given specific geographical constraints.
3. Border control posts shall have:
 - (a) a sufficient number of suitably qualified staff;
 - (b) premises appropriate for the nature and volume of the categories of animals and goods handled;
 - (c) equipment and premises to allow the performance of official controls for each of the categories of animals and goods for which the border control post has been designated;
 - (d) arrangements in place to guarantee, as appropriate, access to any other equipment, premise and service necessary to apply the measures taken in accordance with Articles 63, 64 and 65 in cases of suspicion, non-compliant consignments or consignments presenting a risk;
 - (e) contingency arrangements to ensure the smooth operation of official controls and the effective application of the measures taken in accordance with Articles 63, 64 and 65 in cases of unforeseeable and unexpected conditions or events;
 - (f) the technology and equipment necessary for the efficient operation of the TRACES system and, as appropriate, of other computerised information management systems necessary for the handling and exchange of data and information;
 - (g) access to the services of official laboratories capable of providing analytical, testing and diagnostic results within appropriate deadlines and equipped with the information technology tools necessary to ensure the introduction of the results of analyses, tests or diagnoses carried out into the TRACES system as appropriate;
 - (h) appropriate arrangements for the proper handling of different categories of animals and goods and to prevent risks which may result from cross-contamination;
 - (i) arrangements to comply with relevant biosecurity standards in order to prevent the spread of diseases into the Union.
4. The Commission may, by means of implementing acts, detail the requirements laid down in paragraph 3 to take into account specific features and logistic needs related to the performance of official controls and to the application of the measures taken in accordance with Article 64(3) and (5) and Article 65 in relation to the different categories of animals and goods referred to in Article 45(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Section III

Action in case of suspicion of non-compliance and of non-compliance of animals and goods from third countries

Article 63

Suspicion of non-compliance and intensified official controls

1. In case of suspicion of non-compliance of consignments of the categories of animals and goods referred to in Article 45(1) with the rules referred to in Article 1(2), the competent authorities shall perform official controls **or delegate the responsibility to other competent authorities** in order to confirm or to eliminate that suspicion. [**Am. 174**]

Tuesday 15 April 2014

2. Consignments of animals and goods which are not declared by operators to consist of the categories of animals and goods referred to in Article 45(1), shall be subject to official controls by the competent authorities where there is reason to believe that such categories of animals or goods are present in the consignment.

3. The competent authorities shall place the consignments referred to in paragraphs 1 and 2 under official detention until they obtain the results of the official controls provided for in those paragraphs.

Where appropriate, those consignments shall be isolated or quarantined and animals shall be sheltered, fed, watered and treated pending the results of the official controls.

4. Where the competent authorities have reasons to suspect fraudulent behaviour by an operator or official controls give grounds to believe that the rules referred to in Article 1(2) have been seriously or repeatedly infringed, they shall, ~~where appropriate, and~~ in addition to the measures provided for in Article 64(3), intensify official controls on consignments with the same origin or use ~~as appropriate.~~ [Am. 175]

5. The competent authorities shall notify the Commission and the Member States through the TRACES system of their decision to perform intensified official controls, as provided for in paragraph 4, indicating the purported fraudulent behaviour or serious or repeated infringement.

6. The Commission shall, by means of implementing acts, establish procedures for the coordinated performance by competent authorities of the intensified official controls referred to in paragraphs 4 and 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 64

Measures to be taken in cases of non-compliant consignments entering the Union from third countries

1. ~~The competent authorities shall place under official detention any consignment of animals or goods entering the Union from third countries which does not comply with the rules referred to in Article 1(2)~~ **When the competent authority ascertains as a result of the official controls performed at the border control posts in accordance with Article 45, that consignments of animals and goods do not comply with the requirements under Article 1(2), it shall issue a report or a decision: 'Non-compliant consignment' or 'Negative control' which shall be recorded in the CHED. Furthermore the competent authorities shall officially detain said consignment of animals or goods** and refuse its entry into the Union. [Am. 176]

As appropriate, any such consignment **or part thereof** shall be isolated or quarantined and animals belonging to it shall be kept and treated under appropriate conditions pending any further decision. **The special needs of other goods shall also be borne in mind.** [Am. 177]

2. The Commission shall, by means of implementing acts, lay down the modalities for the isolation and quarantine provided for in the second subparagraph of paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

3. ~~Having, where possible, heard the competent authorities.~~ **The competent authorities shall hear the operator responsible for the consignment** ~~the competent authorities.~~ **The competent authority may omit this if an immediate decision is necessary either because a delay would be dangerous or such a decision in the public interest.** It shall, without delay, order that the operator: [Am. 178]

(a) destroy the consignment **or part thereof, humanely in the case of live animals,** in compliance, where appropriate, with the rules referred to in Article 1(2); or [Am. 179]

(b) re-dispatch the consignment **or part thereof** outside the Union in accordance with Article 70(1) and (2); or [Am. 180]

(c) subject the consignment **or part thereof** to special treatment in accordance with Article 69(1) and (2) or to any other measure necessary to ensure compliance with the rules referred to in Article 1(2), and, where appropriate, destines the consignment for purposes other than those for which it was originally intended. [Am. 181]

Tuesday 15 April 2014

4. The competent authorities shall immediately notify any decision to refuse entry of a consignment as provided for in paragraph 1 and any order issued pursuant to paragraphs 3 and 5 and Article 65 to:

- (a) the Commission;
- (b) the competent authorities of the other Member States;
- (c) the customs authorities;
- (d) the competent authorities of the third country of origin;
- (e) the operator responsible for the consignment.

That notification shall be performed via the computerised information management system referred to in Article 130(1).

5. If a consignment of the categories of animals or goods referred to in Article 45(1) is not presented for the official controls referred to in that Article, or is not presented in accordance with the requirements laid down in Articles 48(1) and (3) and 54(1), (2) and (3), or with the rules adopted pursuant to Article 46, Article 47(6), Article 49, Article 51(1) and Article 56, the competent authorities shall order that it be retained or recalled, and placed under official detention without delay.

Paragraphs 1, 3 and 4 of this Article shall apply to such consignments.

Article 65

Measures to be taken ~~on animals or goods entering the Union~~ **in cases of an attempt to bring non-compliant consignments into the Union** from third countries presenting a risk [Am. 182]

Where official controls indicate that a consignment of animals or goods presents a risk to human, ~~or animal or plant~~ health, animal welfare or, ~~as regards GMOs and plant protection products,~~ to the environment, such consignment shall be isolated or quarantined and animals belonging to it shall be kept and treated under appropriate conditions pending any further decision. [Am. 183]

The competent authorities shall retain the consignment in question under official detention and shall, without delay:

- (a) order that the operator destroy the consignment, **humanely in the case of live animals**, in compliance, where appropriate, with the rules referred to in Article 1(2), taking all the measures necessary to protect human, animal or plant health, animal welfare or the environment; or [Am. 184]
- (b) subject the consignment to special treatment in accordance with Article 69(1) and (2).

Article 66

Follow up of decisions taken in relation to non-compliant consignments entering the Union from third countries

1. The competent authorities shall:

- (a) invalidate the official certificates and other documents accompanying consignments which have been subject to measures pursuant to Article 64(3) and (5) and Article 65;
- (b) cooperate in accordance with Title IV to take any further measures necessary to ensure that it is not possible to reintroduce consignments into the Union which have been refused entry in accordance with Article 64(1).

2. The competent authorities in the Member State where the official controls were performed shall supervise the application of the measures ordered pursuant to Article 64(3) and (5) and Article 65 to ensure that the consignment does not give rise to adverse effects on human, ~~or animal or plant~~ health, animal welfare, or the environment, during or pending the application of those measures. [Am. 185]

Where appropriate, such application shall be completed under the supervision of the competent authorities of another Member State.

Tuesday 15 April 2014

Article 67

Failure by the operator to apply the measures ordered by the competent authorities

1. The operator shall carry out all the measures ordered by the competent authorities in accordance with Article 64 (3) and (5) and 65 without delay and, at the latest, **in the case of products**, within 60 days from the day on which the competent authorities notified the operator of their decision in accordance with Article 64(4). [**Am. 186**]
2. If, after the expiry of the 60-day period no action has been taken by the operator, the competent authorities shall order:
 - (a) that the consignment be destroyed or subject to any other appropriate measure;
 - (b) in the cases referred to in Article 65, that the consignment be destroyed in suitable facilities located as close as possible to the border control post, taking all measures necessary to protect human, animal or plant health, animal welfare or the environment.
3. The competent authorities may extend the period referred to in paragraphs 1 and 2 of this Article for the time necessary to obtain the results of the second expert opinion referred to in Article 34, provided that this is without adverse effects to human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, to the environment.

Article 68

Consistency of application of Articles 64 and 65

The Commission shall, by means of implementing acts, lay down rules to ensure consistency across all border control posts referred to in Article 57(1) and control points referred to in in point (a) of Article 51(1) of decisions and measures taken and orders issued by the competent authorities pursuant to Articles 64 and 65, in the form of instructions to be followed by the competent authorities when responding to common or recurring situations of non-compliance or risk.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 69

Special treatment of consignments

1. The special treatment of consignments provided for in point (c) of Article 64(3) and point (b) of Article 65 may, as appropriate, include:
 - (a) treatment or processing, including decontamination, where appropriate, but excluding dilution, so that the consignment complies with the requirements of the rules referred to in Article 1(2), or with the requirements of a third country of re-dispatch;
 - (b) treatment in any other manner suitable for safe animal or human consumption or for purposes other than animal or human consumption.
2. The special treatment provided for in paragraph 1 shall:
 - (a) be carried out effectively and ensure the elimination of any risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment;
 - (b) be documented and carried out under the control of the competent authorities;
 - (c) comply with the requirements laid down in the rules referred to in Article 1(2).
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the requirements and the conditions in accordance with which the special treatment provided for in paragraph 1 shall take place.

In the absence of rules adopted by delegated act, such special treatment shall take place in accordance with national rules.

Tuesday 15 April 2014

Article 70

Re-dispatch of consignments

1. The competent authorities shall allow the re-dispatch of consignments subject to compliance with the following conditions:
 - (a) the destination has been agreed with the operator responsible for the consignment;
 - (b) the operator responsible for the consignment has first informed the competent authorities of the third country of origin or third country of destination, if different, of the reasons and circumstances for the refusal of the entry into the Union of the consignment of animals or goods concerned;
 - (c) where the third country of destination is not the third country of origin, the competent authorities of the third country of destination have notified the competent authorities of the Member State that they are prepared to accept the consignment;
 - (d) in the case of consignments of animals the re-dispatch is in compliance with animal welfare requirements.
2. The conditions of points (b) and (c) of paragraph 1 shall not apply to consignments of the categories of goods referred to in point (c) of Article 45(1).
3. The Commission shall, by means of implementing acts, specify the procedures for the information exchanges and notifications referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

3a. Member States receiving imports which have been authorised by pre-export-controls shall regularly check if the imports actually comply with Union requirements. [Am. 187]

Article 71

Approval of pre-export controls performed by third countries

1. The Commission may, by means of implementing acts, approve specific pre-export controls that a third country carries out on consignments of animals and goods prior to export to the Union with a view to verifying that the exported consignments satisfy the requirements of the rules referred to in Article 1(2). The approval shall only apply to consignments originating in the third country concerned and may be granted for one or more categories of animals or goods.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).
2. The approval provided for in paragraph 1 shall specify:
 - (a) the maximum frequency of official controls to be performed by the competent authorities of Member States at the entry of the consignments into the Union, where there is no reason to suspect non-compliance with the rules referred to in Article 1(2) or fraudulent behaviour;
 - (b) the official certificates that must accompany consignments entering the Union;
 - (c) a model for such certificates;
 - (d) the competent authorities of the third country under the responsibility of which pre-export controls must be performed;
 - (e) where appropriate, any delegated body to which those competent authorities may delegate certain tasks. Such delegation may only be approved if it meets the criteria of Articles 25 to 32 or equivalent conditions.
3. The approval provided for in paragraph 1 may only be granted to a third country if the evidence available and, where appropriate, a Commission control performed in accordance with Article 119, demonstrate that the system of official controls in that third country can ensure that:
 - (a) the consignments of the animals or goods exported to the Union meet the requirements of the rules referred to in Article 1(2), or equivalent requirements;

Tuesday 15 April 2014

- (b) the controls performed in the third country prior to dispatch to the Union are sufficiently effective to replace or reduce the frequency of the documentary, identity and physical checks laid down in the rules referred to in Article 1(2).
4. The competent authorities or a delegated body specified in the approval shall:
- (a) be responsible for contacts with the Union;
 - (b) ensure that the official certificates referred to in point (b) of paragraph 2 accompany each consignment controlled.
5. The Commission shall by means of implementing acts establish detailed rules and criteria for approving pre-export controls performed by third countries in accordance with paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 72

Non-compliance with, and withdrawal of, the approval of pre-export controls performed by third countries

1. When official controls on consignments of categories of animal and goods in respect of which specific pre-export controls have been approved in accordance with Article 71(1) reveal serious and recurrent non-compliances with the rules referred to in Article 1(2), Member States shall immediately:
- (a) notify the Commission and the other Member States and operators concerned via the TRACES system, **including the measures to be applied**, in addition to seeking administrative assistance in accordance with the procedures established in Title IV; [Am. 188]
 - (b) increase the number of official controls on consignments from the relevant third country and, where necessary to allow a proper analytical examination of the situation, detain a reasonable number of samples under appropriate storage conditions.
2. The Commission may, by means of implementing acts, withdraw the approval provided for in Article 71(1) where, following the official controls referred to in paragraph 1, it appears that the requirements laid down in Article 71(3) and (4) are no longer being met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141 (2).

Article 73

Cooperation amongst authorities in relation to consignments entering the Union from third countries

1. Competent authorities, customs authorities and other authorities of the Member States shall cooperate closely to ensure that the official controls performed on consignments of animals and goods entering the Union are performed in accordance with the requirements of this Regulation.

For that purpose, competent authorities, customs authorities and other authorities shall:

- (a) guarantee reciprocal access to information which is relevant for the organisation and conduct of their respective activities in relation to animals and goods entering the Union;
- (b) ensure the timely exchange of such information, including via electronic means.

1a. The customs authorities shall only release those consignments of animals and goods under Article 45 in respect of which the competent authority at the border control post has carried out the official controls provided for in Article 47 and issued a decision recorded in the CHED. [Am. 189]

Tuesday 15 April 2014

2. The Commission shall, by means of implementing acts, adopt uniform rules on the cooperation arrangements that competent authorities, customs authorities and other authorities referred to in paragraph 1 are required to put in place to ensure:

- (a) access by competent authorities to the information necessary for the immediate and complete identification of the consignments of animals and goods entering the Union that are subject to official controls at a border control post in accordance with Article 45(1);
- (b) the reciprocal update, through exchanges of information or synchronisation of relevant data sets, of information gathered by competent authorities, customs authorities and other authorities on consignments of animals and goods entering the Union;
- (c) the swift communication of decisions taken by such authorities on the basis of the information referred to in points (a) and (b).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 74

Cooperation amongst authorities in relation to consignments not subject to specific controls at borders

1. In the case of consignments of animals and goods other than those subject to controls at entry into the Union as required by Article 45(1) and for which a customs declaration for release for free circulation has been made in accordance with Article 4(17) and Articles 59 to 83 of Regulation (EEC) No 2913/92, paragraphs 2, 3 and 4 shall apply.

2. Customs authorities shall suspend release for free circulation when they have reason to believe that the consignment may present a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment and immediately notify the competent authorities of such suspension.

3. A consignment whose release for free circulation has been suspended pursuant to paragraph 2 shall be released if, within three working days of the suspension of release, the competent authorities have not requested customs authorities to continue the suspension or have informed customs authorities that no risk is present.

4. Where the competent authorities consider that a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment, is present:

- (a) they shall instruct the customs authorities not to release the consignment for free circulation and to include the following statement on the commercial invoice accompanying the consignment and on any other relevant accompanying document:

‘Product presents a risk — release for free circulation not authorised — Regulation (EU) No .../... (*)’;

- (b) no other customs procedure shall be permitted without the consent of the competent authorities;

- (c) Article 64(1), (3), (4) and (5), Articles 65 to 67, Article 69(1) and (2) and Article 70(1) and (2) shall apply.

5. In the case of consignments of animals and goods other than those subject to controls at entry into the Union as required by Article 45(1) and for which no customs declaration for release for free circulation has been made, customs authorities, where they have reason to believe that the consignment may present a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment, shall transmit all relevant information to the customs authorities in the Member States of final destination.

(*) Number of this Regulation.

Tuesday 15 April 2014

Article 75

Rules for specific official controls and for measures to be taken following the performance of such controls

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning rules for the performance of specific official controls and for the adoption of measures in cases of non-compliance, to account for the specificities of the following categories of animals and goods or their transport modalities and means:

- (a) consignments of fresh fishery products directly landed in ports designated by Member States in accordance with Article 5(1) of Council Regulation (EC) No 1005/2008 ⁽¹⁾ from a fishing vessel flying a third country flag;
- (b) consignments of unskinned, furred wild game;
- (c) consignments of the categories of goods referred to in point (b) of Article 45(1) which are delivered, with or without storage in a specially approved free or customs warehouse, to vessels leaving the Union and intended for ship supply or consumption by the crew and passengers;
- ~~(d) wood packaging material; [Am. 190]~~
- (e) feed and food accompanying animals and intended for the feeding of those animals;
- (f) animals and goods ordered by distance selling and delivered from a third country to an address in the Union, and the notification requirements necessary to allow the proper performance of official controls;
- (g) plant products which, on account of their subsequent destination, may give rise to the risk of spreading infectious or contagious animal diseases;
- (h) consignments of the categories of animals and goods referred to in points (a), (b) and (c) of Article 45(1) originating from, and returning to, the Union following a refusal of entry by a third country;
- (i) goods entering the Union in bulk from a third country, irrespective of whether they all originate from that third country;
- (j) consignments of goods referred to in Article 45(1) coming from the territory of Croatia and transiting through the territory of Bosnia and Herzegovina at Neum ('Neum corridor') before re-entering the territory of Croatia via the points of entry at Klek or Zaton Doli;
- (k) animals and goods exempted from the provisions of Article 45 in accordance with Article 46.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the conditions for monitoring the transport and arrival of consignments of certain animals and goods, from the border control post of arrival to the establishment at the place of destination in the Union or the border control post of exit.

3. The Commission may, by means of implementing acts, lay down rules concerning:

- (a) model official certificates and rules for the issuance of such certificates;
- (b) the format of documents that must accompany the categories of animals or goods referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

⁽¹⁾ Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 (OJ L 286, 29.10.2008, p. 1).

Tuesday 15 April 2014

Chapter VI

Financing of official controls and other official activities

Article 76

General rules

1. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official activities. **With that aim in view they shall collect fees or contributions to the costs or make resources available from general tax revenue.**
2. ~~In addition to the fees collected in accordance with Article 77, Member States may collect fees to cover costs occasioned by official controls other than those referred to in Article 77(1) and (2).~~
3. This Chapter also applies in the case of delegation of specific official control tasks in accordance with Article 25.
4. Member States shall consult the operators concerned on the methods used to calculate the fees **or contributions to the costs.** [Am. 191]

Article 77

Mandatory fees **or contributions to the costs**

1. For the purpose of ensuring that competent authorities are provided with adequate resources for the performance of official controls, the competent authorities ~~shall~~ **may** collect fees **or contributions to the costs** to recover, **some or all of** the costs they incur in relation to:
 - (a) official controls performed to verify that the following operators comply with the rules referred to in Article 1(2):
 - (i) food business operators as defined in Article 3(3) of Regulation (EC) No 178/2002 that are either registered or approved, or registered and approved, in accordance with Article 6 of Regulation (EC) No 852/2004;
 - (ii) feed business operators as defined in Article 3(6) of Regulation (EC) No 178/2002 registered or approved in accordance with Articles 9 and 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council ⁽¹⁾;
 - (iii) professional operators as defined in point (7) of Article 2 of Regulation (EU) No .../... (*);
 - ~~(iv) professional operators as defined in point (6) of Article 3 of Regulation (EU) No XXX/XXXX [number of the Regulation on the production and making available on the market of plant reproductive material];~~
 - (b) the official controls performed in view of the issuance of official certificates or to supervise the issuance of official attestations;
 - (c) official controls performed to verify that the conditions are met:
 - (i) to obtain and maintain the approval provided for in Article 6 of Regulation (EC) No 852/2004 or in Articles 9 and 10 of Regulation (EC) No 183/2005;
 - (ii) to obtain and maintain the authorisation referred to in Articles 84, 92 and 93 of Regulation (EU) No .../... (**);
 - ~~(iii) to obtain and maintain the authorisation referred to in Article 25 of Regulation (EU) No XXX/XXXX [number of the Regulation on the production and making available on the market of plant reproductive material];~~

⁽¹⁾ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

(*) Number of the Regulation on protective measures against pests of plants.

(**) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

(d) official controls performed by the competent authorities at the border control posts or at the control points referred to in point (a) of Article 51(1).

2. For the purposes of paragraph 1, the official controls referred to in point (a) of that paragraph shall include official controls performed to verify compliance with measures adopted by the Commission in accordance with Article 137 of this Regulation, Article 53 of Regulation (EC) No 178/2002, Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No .../... (*), ~~Articles 41 and 144 of Regulation (EU) No XXX/XXXX [number of the Regulation on the production and making available on the market of plant reproductive material]~~ and Part VI of Regulation (EU) No .../... (**), unless the decision establishing the measures requires otherwise.

3. For the purposes of paragraph 1:

(a) the official controls referred to in point (a) of that paragraph shall not include official controls performed to verify compliance with temporary restrictions, requirements or other disease control measures adopted by the competent authorities in accordance with Article 55(1), Article 56, Articles 61 and 62, Articles 64 and 65, Article 68(1) and Article 69, and rules adopted pursuant to Article 55(2), Article 63, Article 67 and Article 68(2) of Regulation (EU) No .../... (***) and Article 16 of Regulation (EU) No .../... (****);

(aa) the official controls referred to in point (a) of that paragraph shall not include controls performed at the level of primary production as defined in Article 3(17) of Regulation (EC) No 178/2002, including on farm processing. That includes controls to verify compliance with statutory management requirements in the area of public health, animal health, plant health, and animal welfare in accordance with Article 93 of Regulation (EU) No 1306/2013; [Ams 192, 343, 314 and 316]

(b) the official controls referred to in point (a) and (b) of that paragraph shall not include official controls performed to verify compliance with the rules referred to in Article 1(2)(j) and (k).

Article 78

Costs

1. The competent authorities shall ~~collect fees~~ **be entitled, when calculating the fees or contributions to the cost** in accordance with Article 77, to ~~recover~~ **take the following costs criteria into account:**

(a) the salaries of the staff, including support staff, ~~involved in the performance~~ **insofar as they correspond to the actual costs** of official controls, **in accordance with point (b) of Article 79(1), excluding** their social security, pension and insurance costs;

~~(b) the cost of facilities and equipment, including maintenance and insurance costs;~~

(c) the cost of consumables, services and tools;

(*) Number of the Regulation on protective measures against pests of plants.

(**) Number of the Regulation on animal health.

(***) Number of the Regulation on animal health.

(****) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

- (d) ~~the cost of training of staff referred to in point (a), with the exclusion of the training necessary to obtain the qualification necessary to be employed by the competent authorities;~~
- (e) the cost of travel of the staff **for the performance of the official controls** referred to in point (a), and associated subsistence costs, **calculated in accordance with Article 79(2)**;
- (f) the cost of sampling and of laboratory analysis, testing and diagnosis.

2. If the competent authorities collecting **mandatory fees or contributions to the costs** in accordance with Article 77 also perform other activities, only the fraction of the cost elements referred to in paragraph 1 of this Article which results from the official controls referred to in Article 77(1) shall be considered for the calculation of the **mandatory fees or contribution to the costs**. [Am. 193]

Article 79

Calculation of **mandatory fees or contributions to the costs**

1. **The fees or contributions to the costs** collected in accordance with Article 77 shall be:

- (a) ~~established at a flat rate on the basis of the overall costs of official controls borne by the competent authorities over a given period of time, and applied to all operators irrespective of whether any official control is performed during the reference period in relation to each operator charged; in establishing the level of the fees to be charged on each sector, activity and category of operators, the competent authorities shall take into consideration the impact that the type and the size of the activity concerned and the relevant risk factors have on the distribution of the overall costs of those official controls; or,~~
- (b) calculated on the basis of the actual costs of each individual official control, and applied to the operators subject to such official control; such fee shall not exceed the actual costs of the official control performed and may be partly or entirely expressed as a function of the time employed by the staff of the competent authorities to perform the official controls.

2. Travel costs as referred to in point (e) of Article 78(1) shall be considered for the calculation of the fees **or contributions to the costs** referred to in Article 77(1) in a manner that does not discriminate between operators on the basis of the distance of their premises from the location of the competent authorities.

3. Where **the fees or contributions to the costs** are calculated in accordance with point (a) of paragraph 1, the fees **or contribution to the costs** collected by competent authorities in accordance with Article 77 shall not exceed the overall costs incurred for the official controls performed over the period of time referred to in point (a) of paragraph 1. [Am. 194]

Article 80

Reduction of fees **or contributions to the costs** for consistently compliant operators

Where fees **or contributions to the costs** are established in accordance with ~~point (a)~~ of Article 79(1), the rate of the fee to be applied to each operator shall be determined taking into account the operators' record of compliance with the rules referred to in Article 1(2) as ascertained through official controls, so that fees or contribution to the costs applied to consistently compliant operators are lower than those applied to other operators. [Am. 195]

Article 81

Application of fees **or contributions to the costs**

1. Operators shall receive proof of the payment of fees **or contributions to the costs** provided for in Article 77(1).
2. Fees **or contributions to the costs** collected in accordance with point (d) of Article 77(1) shall be paid by the operator responsible for the consignment or its representative. [Am. 196]

Tuesday 15 April 2014

Article 82

Fees refunds and exemption for microenterprises

- ~~1. Fees provided for in Article 77 shall not directly or indirectly be refunded, unless unduly collected.~~
- ~~2. Enterprises employing fewer than 10 persons and whose annual turnover or annual balance sheet total does not exceed EUR 2 million shall be exempted from the payment of the fees provided for in Article 77.~~
- ~~3. The costs referred to in Articles 77, 78 and 79 shall not include those incurred for the performance of official controls on the enterprises referred to in paragraph 2.~~

Member States may exempt small and medium-sized enterprises that fulfil certain objective and non-discriminatory criteria from the payment of fees or cost contributions provided for in Article 77. [Ams 197, 315 and 348]

Article 83

Transparency

1. The competent authorities shall ensure the highest level of transparency of:
 - (a) the method and data used to establish the fees **or contributions to the costs** provided for in Article 77(1);
 - (b) the use of resources collected through such fees **or contributions to the costs, including the number of controls performed;**
 - (c) the arrangements in place to ensure an efficient and thrifty use of the resources collected through such fees **or contributions to the costs.**
2. Each competent authority shall make available to the public the following information for each reference period:
 - (a) the costs to the competent authority for which a fee is due in accordance with Article 77(1), indicating the breakdown of such costs per activity referred to in Article 77(1) and per cost element referred to in Article 78(1);
 - (b) the amount of the fees **or contributions to the costs** provided for in Article 77(1) applied to each category of operators, and for each category of official controls;
 - (c) the method used to establish the fees **or contributions to the costs** provided for in Article 77(1), including the data and estimates used for the establishment of the flat rate fees **or contribution to the costs** referred to in point (a) of Article 79(1);
 - (d) where point (a) of Article 79(1) applies, the method used to adjust the level of the fees **or contributions to the costs** in accordance with Article 80;
 - (e) the overall amount of fees **or contributions to the costs** corresponding to the exemption referred to in Article 82(2). **[Am. 198]**

Article 84

Expenses arising from additional official controls and from enforcement measures

Competent authorities shall charge fees **or contributions to the costs** to cover the additional costs they have incurred as a result of: **[Am. 199]**

- (a) additional official controls:
 - (i) which have become necessary following the detection of a non-compliance during an official control performed in accordance with this Regulation;

Tuesday 15 April 2014

- (ii) performed to assess the extent and the impact of the non-compliance or to verify that the non-compliance has been remedied;
- (b) official controls performed at the request of the operator;
- (c) corrective action taken by the competent authorities, or by a third party upon request by the competent authorities, where an operator has failed to carry out corrective action ordered by the competent authorities in accordance with Article 135 to remedy the non-compliance;
- (d) official controls performed and action taken by the competent authorities in accordance with Articles 64 to 67, 69 and 70, and corrective action taken by a third party upon request by the competent authorities, in cases where the operator has failed to carry out corrective action ordered by the competent authorities in accordance with Article 64(3) and (5), Article 65 and Article 67.

Chapter VII

Official certification

Article 85

General requirements concerning official certification

1. In accordance with rules referred to in Article 1(2), official certification shall take the form of:
 - (a) official certificates; or,
 - (b) official attestations,
- (ba) official health attestations. [Am. 200]**
2. Where the competent authorities delegate specific tasks related to the issuance of official certificates or official attestations, or to the official supervision referred to in Article 90(1) such delegation shall comply with Articles 25 to 32.

Article 86

Official certificates

1. When the rules referred to in Article 1(2) require the issuance of an official certificate, Articles 87, 88 and 89 shall apply.
2. Articles 87 to 89 shall also apply to official certificates which are necessary for the purposes of exporting consignments of animals and goods to third countries.

2a. Regarding the issuance of an official certificate for products referred to in point (j) of Article 1(2), in addition to compliance with Article 85(2), the delegated body shall work and be accredited in accordance with standard EN ISO/IEC 17065: 2012. [Am. 201]

Article 87

Signature and issuance of official certificates

1. Official certificates shall be issued by the competent authorities **or delegated bodies pursuant to Articles 25 to 32. [Am. 202]**
2. Competent authorities shall designate the certifying officers who are authorised to sign official certificates. Certifying officers shall:
 - (a) be free from conflict of interest in relation to what is being certified and act **independently and** impartially; **[Am. 203]**
 - (b) receive appropriate training on the rules with which compliance is certified by the official certificate as well as on the provisions of this Chapter.

Tuesday 15 April 2014

3. Official certificates shall be signed by the certifying officer and issued on one of the following grounds:
 - (a) direct knowledge by the certifying officer of facts and data relevant for the certification, obtained through:
 - (i) an official control; or
 - (ii) the acquisition of another official certificate issued by the competent authorities;
 - (b) facts and data relevant for the certification, knowledge of which was ascertained by another person authorised for that purpose by, and acting under the control of, the competent authorities, provided that the certifying officer can verify the accuracy of such facts and data;
 - (c) facts and data relevant for the certification which were obtained from the operators' own-control systems, complemented and confirmed by results from regular official controls, where the certifying officer is thus satisfied that the conditions for issuing the official certificate are met.
4. Official certificates shall be signed by the certifying officer and issued only on the basis of point (a) of paragraph 3 when rules referred to in Article 1(2) so require.

Article 88

Guarantees of reliability for official certificates

1. Official certificates shall:
 - (a) not be signed by the certifying officer where they are blank or incomplete;
 - (b) be drawn up in one of the official languages of the institutions of the Union that is understood by the certifying officer and, where relevant, in one of the official languages of the Member State of destination;
 - (c) be authentic and accurate;
 - (d) enable the identification of the person who signed them *and the date of issue*; [Am. 204]
 - (e) allow the *easy* verification of the link between the certificate, *the issuing authority* and the consignment, lot or individual animal or good covered by the certificate. [Am. 205]
2. The competent authorities shall take all measures necessary to prevent and penalise the issuance of false or misleading official certificates or the abuse of official certificates. Such measures shall include where appropriate:
 - (a) the temporary suspension of the certifying officer from its duties;
 - (b) the withdrawal of the authorisation to sign official certificates;
 - (c) any other necessary measure to prevent that the offence referred to in the first sentence of this paragraph is repeated.

Article 89

Implementing powers for official certificates

The Commission may, by means of implementing acts, lay down rules for the uniform application of Articles 87 and 88 concerning:

- (a) model official certificates and rules for the issuance of such certificates;
- (b) the mechanisms and the legal and technical arrangements to ensure the issuance of accurate and reliable official certificates and prevent risk of fraud;
- (c) the procedures to be followed in the case of withdrawals of official certificates and for the production of replacement certificates;
- (d) rules for the production of certified copies of official certificates;

Tuesday 15 April 2014

- (e) the format of documents that must accompany animals and goods after official controls have been performed;
- (f) rules for the issuance of electronic certificates and for the use of electronic signatures.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 90

Official attestations

1. When the rules referred to in Article 1(2) require the issuance of official attestations by the operators under the official supervision of the competent authorities, or by the competent authorities themselves, paragraphs 2, 3 and 4 of this Article shall apply.
2. Official attestations shall:
 - (a) be authentic and accurate;
 - (b) be drawn up in one of the official languages of the institutions of the Union **or in any of the official languages of a Member State**; [Am. 206]
 - (c) where they relate to a consignment or a lot, allow the verification of the link between the official attestation and that consignment or lot.
3. Competent authorities shall ensure that the staff performing official controls to supervise the certification procedure or, where the official attestations are issued by the competent authorities, the staff involved in the issuance of those official attestations:
 - (a) are **independent**, impartial and free from any conflict of interest in relation to what is being certified by the official attestations; [Am. 207]
 - (b) receive appropriate training on:
 - (i) the rules with which compliance is certified by the official attestations;
 - (ii) the rules laid down in this Regulation.
4. Competent authorities shall perform regular official controls to verify that:
 - (a) the operators issuing the attestations comply with the conditions laid down in the rules referred to in Article 1(2);
 - (b) the attestation is issued on the basis of relevant, correct and verifiable facts and data.

Title III

Reference laboratories and centres

Article 91

Designation of European Union reference laboratories

1. The Commission ~~may~~ **shall**, by means of implementing acts, designate European Union reference laboratories in the areas governed by the rules referred to in Article 1(2) where the effectiveness of official controls also depends on the quality, uniformity and reliability of: [Am. 208]
 - (a) the methods of analysis, test or diagnosis employed by the official laboratories designated in accordance with Article 36 (1);

Tuesday 15 April 2014

(b) the results of the analyses, tests and diagnoses performed by those official laboratories.

2. The designations provided for in paragraph 1 shall:

(a) follow a public selection process;

(b) be reviewed regularly *every five years*; [Am. 209]

(ba) be made only to laboratories that hold a supporting letter from the authority competent in the field in question.
[Am. 317]

2a. The Commission may, where it considers appropriate, designate more than one reference laboratory for the same disease and thus promote the rotation of national laboratories meeting the requirements of paragraph 3 of this Article.
[Am. 210]

3. European Union reference laboratories shall:

(a) operate in accordance with the standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' and be assessed and accredited in accordance with that standard by a national accreditation body, operating in accordance with Regulation (EC) No 765/2008;

(b) be *independent*, impartial and free of conflict of interests as regards the exercise of its tasks as European Union reference laboratories; [Am. 211]

(c) have suitably qualified staff with adequate training in analytical, testing and diagnostic techniques applied in their area of competence, and support staff as appropriate;

(d) possess or have access to the infrastructure, equipment and products necessary to carry out the tasks assigned to them;

(e) ensure that their staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;

(f) be equipped to perform their tasks in emergency situations;

(g) where relevant, be equipped to comply with relevant biosecurity standards;

(ga) where relevant, cooperate with Union research centres and Commission services to develop high standards in methods of laboratory analysis, testing and diagnosis; [Am. 212]

(gb) be able to receive a financial contribution from the Union in accordance with Council Decision 90/424/EEC ⁽¹⁾;
[Am. 213]

(gc) ensure that their staff respect the confidential nature of certain subjects, results or communications. [Am. 214]

3a. By way of derogation from paragraphs 1 and 2 of this Article, the reference laboratories referred to in Article 32 (1) of Regulation (EC) No 1829/2003 and Article 21(1) of Regulation (EC) No 1831/2003 shall be European Union reference laboratories having the tasks and responsibilities set out in Article 92 of this Regulation, as regards, respectively:

(a) GMOs and genetically modified food and feed;

(b) feed additives. [Am. 215]

⁽¹⁾ Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (OJ L 224, 18.8.1990, p. 19).

Tuesday 15 April 2014

Article 92

Responsibilities and tasks of European Union reference laboratories

1. European Union reference laboratories shall contribute to the improvement and harmonisation of methods of analysis, test or diagnosis to be used by official laboratories designated in accordance with Article 36(1) and of the analytical, testing and diagnostic data generated by them.
2. European Union reference laboratories shall be responsible, in accordance with annual or multiannual work programmes approved by the Commission, for the following tasks:
 - (a) providing national reference laboratories with details of methods of laboratory analysis, test or diagnosis, including reference methods;
 - (aa) **providing reference material free of charge and for unrestricted use, in respect of animal health, strains and serums, to the national reference laboratories to facilitate the adjustment and harmonisation of methods of analysis, testing and diagnosis; [Am. 216]**
 - (b) coordinating the application by the national reference laboratories ~~and, if necessary, by other official laboratories~~ of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing and by ensuring appropriate follow-up of such comparative testing in accordance, where available, with internationally accepted protocols; **they shall inform the competent authorities of the follow-up and results of such inter-laboratory comparative testing; [Am. 217]**
 - (c) coordinating practical arrangements necessary to apply new methods of laboratory analysis, test or diagnosis, and informing national reference laboratories of advances in this field;
 - (d) conducting training courses **free of charge** for the benefit of staff from national reference laboratories and, if needed, **conducting training courses for the benefit of staff** from other official laboratories, as well as of experts from third countries; **[Am. 218]**
 - (e) providing scientific and technical assistance to the Commission within the scope of their mission;
 - (f) providing information on relevant Union, national and international research activities to national reference laboratories;
 - (g) collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority, the European Medicines Agency and the European Centre for Disease Prevention and Control;
 - (h) assisting actively in the diagnosis of outbreaks in Member States of foodborne, zoonotic or animal diseases, ~~or of pests of plants~~, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens; **[Am. 219]**
 - (i) coordinating or performing tests for the verification of the quality of reagents used for the diagnosis of animal, zoonotic or foodborne diseases;
 - (j) where relevant for their area of competence, establishing and maintaining:
 - (i) ~~reference collections of pests of plants or~~ reference strains of pathogenic agents; **[Am. 220]**
 - (ii) reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories;
 - (iii) up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents.

Tuesday 15 April 2014

2a. Paragraphs 1 and 2 of this Article shall apply without prejudice to Article 32, first paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth paragraphs of Article 32 of that Regulation, in addition to Article 21, first paragraph, of Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation. [Am. 221]

3. European Union reference laboratories shall publish the list of the national reference laboratories designated by the Member States in accordance with Article 98(1).

Article 92a

1. The Commission shall, by means of delegated acts, designate a European Union reference laboratory for food authenticity.

2. Member States may designate national reference laboratories as part of a network of laboratories working within the Union. [Am. 222]

Article 93

Designation of European Union reference centres for plant reproductive material

~~1. The Commission may, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission, the Member States and the European Plant Variety Agency (EPVA) in relation to the application of the rules referred to in point (h) of Article 1(2).~~

~~2. The designations provided for in paragraph 1 shall:~~

~~(a) follow a public selection process;~~

~~(b) be reviewed regularly.~~

~~3. European Union reference centres for plant reproductive material shall:~~

~~(a) possess a high level of scientific and technical expertise in inspection, sampling and testing of plant reproductive material;~~

~~(b) have suitably qualified staff with adequate training in the areas referred to in point (a) and support staff as appropriate;~~

~~(c) possess or have access to the infrastructure, the equipment and the products necessary to carry out the tasks assigned to them;~~

~~(d) ensure that their staff have good knowledge of international standards and practices in the areas referred to in point (a) and that the latest developments in research at national, Union and international level in those areas are taken into account in their work. [Am. 223]~~

Article 94

Responsibilities and tasks European Union reference centres for plant reproductive material

~~The European Union reference centres designated in accordance with Article 93(1) shall be responsible, in accordance with annual or multiannual work programmes approved by the Commission for the following tasks:~~

~~(a) providing scientific and technical expertise, within the scope of their mission, on:~~

~~(i) field inspection, sampling and testing performed for the certification of plant reproductive material;~~

Tuesday 15 April 2014

- ~~(ii) post-certification tests of plant reproductive material;~~
- ~~(iii) tests on standard material categories of plant reproductive material;~~
- ~~(b) organising comparative tests and field trials on plant reproductive material;~~
- ~~(c) conducting training courses for the benefit of staff of the competent authorities and of experts from third countries;~~
- ~~(d) contributing to the development of certification and post-certification test protocols for plant reproductive material, and of performance indicators for the certification of plant reproductive material;~~
- ~~(e) disseminating research findings and technical innovations in the fields within the scope of their mission. [Am. 224]~~

Article 95

Designation of European Union reference centres for animal welfare

1. The Commission ~~may~~ **shall**, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission and of the Member States in relation to the application of the rules referred to in point (f) of Article 1(2). [Am. 225]
2. The designations provided for in paragraph 1 shall:
 - (a) follow a public selection process;
 - (b) be reviewed regularly.
3. European Union reference centres for animal welfare shall:
 - (a) have **suitably qualified staff with** a high level of scientific and technical expertise in human-animal relationship, animal behaviour, animal physiology, animal health and nutrition related to animal welfare, and animal welfare aspects related to the commercial and scientific use of animals, **taking ethical aspects into consideration**; [Am. 226]
 - ~~(b) have suitably qualified staff with adequate training in the areas referred to in point (a) and in ethical issues related to animals and support staff as appropriate; [Am. 227]~~
 - (c) possess or have access to the infrastructure, the equipment and products necessary to carry out the tasks assigned to them;
 - (d) ensure that their staff have good knowledge of international standards and practices in the areas referred to in point (a) and that the latest developments in research at national, Union and international level in those areas are taken into account in their work.

Article 96

Responsibilities and tasks of European Union reference centres for animal welfare

The European Union reference centres designated in accordance with Article 95(1) shall be responsible, in accordance with annual or multiannual work programmes approved by the Commission for the following tasks:

- (a) providing scientific and technical expertise within the scope of their mission to the national scientific support networks or bodies provided for in Article 20 of Regulation (EC) No 1099/2009;
- (b) providing scientific and technical expertise for the development and application of the animal welfare indicators referred to in point (f) of Article 18(3);

Tuesday 15 April 2014

- (ba) **coordinating a network of institutions with recognised knowledge on animal welfare that could assist the competent authorities and stakeholders in implementing relevant Union legislation;** [Am. 228]
- (c) ~~developing or coordinating the development of~~ **helping to develop and coordinate** methods for the assessment of the level of welfare of animals and ~~of~~ methods for the improvement of the welfare of animals; [Am. 229]
- (d) **coordinating the** carrying out **of** scientific and technical studies on the welfare of animals used for commercial or scientific purposes; [Am. 230]
- (e) conducting training courses for the benefit of staff of the national scientific support networks or bodies referred to in point (a), of staff of the competent authorities and of experts from third countries;
- (f) disseminating research findings and technical innovations and collaborating with Union research bodies in the fields within the scope of their mission.

Article 96a

Designation of European Union reference centres for the authenticity and integrity of the agri-food chain

1. *The Commission may, by means of implementing acts, designate European Union reference centres that shall support the activities of the Commission and of the Member States to prevent, detect and combat any intentional violations of the rules referred to in Article 1(2).*
2. *The designations provided for in paragraph 1 shall follow a public selection process and be reviewed regularly.*
3. *European Union reference centres for the authenticity and integrity of the agri-food chain shall:*
 - (a) *possess a high level of scientific and technical expertise in the sectors governed by the rules referred to in Article 1(2) and in applied forensic science in those sectors, thus having the ability to carry out or coordinate research at the highest levels on the authenticity and integrity of goods and to develop, apply and validate the methods to be used for the detection of intentional violations of the rules referred to in Article 1(2);*
 - (b) *have suitably qualified staff with adequate training in the areas referred to in point (a) and the necessary support staff;*
 - (c) *possess or have access to the infrastructure, the equipment and the products necessary to carry out the tasks assigned to them;*
 - (d) *ensure that their staff have good knowledge of international standards and practices in the subjects referred to in point (a) and that the latest research developments at national, Union and international level in those areas are taken into account in their work.* [Am. 231]

Article 96b

Responsibilities and tasks of European Union reference centres for the authenticity and integrity of the agri-food chain

The European Union reference centres designated under Article 96a(1) shall be responsible, in accordance with the annual or multiannual work programmes approved by the Commission, for the following activities:

- (a) *providing specific knowledge of the authenticity and integrity of goods and methods for detecting intentional violations of the rules referred to in Article 1(1), in relation to the forensic science applied to the areas governed by these rules;*

Tuesday 15 April 2014

- (b) *providing specific analyses designed to identify the segments of the agri-food chain that are potentially subject to intentional violations, for economic reasons, of the rules referred to in Article 1(2) and helping to develop specific official control techniques and protocols;*
- (c) *where necessary, performing the tasks referred to in points (a) to (g) of Article 92(2);*
- (d) *where necessary, establishing and storing collections or databases of authenticated reference materials, to be used to verify the authenticity or integrity of goods;*
- (e) *disseminating research findings and technical innovations in the fields within the scope of their missions.*
[Am. 232]

Article 97

Obligations of the Commission

1. The Commission shall publish and update, whenever necessary, the list of:
 - (a) European Union reference laboratories provided for in Article 91;
 - ~~(b) European Union reference centres for plant reproductive material provided for in Article 93; [Am. 233]~~
 - (c) European Union reference centres for animal welfare provided for in Article 95.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of requirements, responsibilities and tasks for the European Union reference laboratories, ~~the European Union reference centres for plant reproductive material~~ and the European Union reference centres for animal welfare in addition to those laid down in Article 91(3), Article 92, ~~93(3)~~, Article 95(3) and Article 96. [Am. 234]
3. European Union reference laboratories and European Union reference centres shall be subject to Commission controls to verify compliance with the requirements of Article 91(3), Article 92, ~~93(3)~~, Article 95(3) and Article 96. [Am. 235]
4. If the Commission controls referred to in paragraph 3 show non-compliance with the requirements laid down in Article 91(3), Article 92, Article 95(3) and Article 96, the Commission shall, after having received the comments of the European Union reference laboratory or European Union reference centre:
 - (a) withdraw the designation of that laboratory or centre; or,
 - (b) take any other appropriate measure.

Article 98

Designation of national reference laboratories

1. Member States shall designate one or more national reference laboratories for each European Union reference laboratory designated in accordance with Article 91(1).

A Member State may designate a laboratory situated in another Member State or in a third country that is a Contracting Party to the European Free Trade Association (EFTA).

A single laboratory may be designated as a national reference laboratory for more than one Member State.

2. The requirements provided for in point (e) of Article 36(4), Article 36(5), Article 38, Article 41(1), points (a) and (b) of Article 41(2) and Article 41(3) shall apply to national reference laboratories.
3. National reference laboratories shall:
 - (a) be **independent**, impartial and free of conflict of interests as regards the exercise of its tasks as national reference laboratories; [Am. 236]

Tuesday 15 April 2014

- (b) have suitably qualified staff with adequate training in analytical, testing and diagnostic techniques in their area of competence, and support staff as appropriate;
- (c) possess or have access to the infrastructure equipment and products needed to carry out the tasks assigned to them;
- (d) ensure that their staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;
- (e) be equipped to perform their tasks in emergency situations;
- (f) where relevant, be equipped to comply with biosecurity standards.

4. Member States shall:

- (a) communicate the name and address of each national reference laboratory to the Commission, the relevant European Union reference laboratory and other Member States;
- (b) make that information available to the public;
- (c) update that information whenever necessary.

5. Member States that have more than one national reference laboratory for a European Union reference laboratory shall ensure that such laboratories work closely together, so as to ensure efficient coordination between them, with other national laboratories and with the European Union reference laboratory.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of requirements for national reference laboratories in addition to those laid down in paragraphs 2 and 3.

6a. This Article shall apply without prejudice to Article 32, second paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth paragraphs of Article 32 of that Regulation, in addition to Annex II to Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation. [Am. 237]

Article 99

Responsibilities and tasks of national reference laboratories

1. National reference laboratories shall, in their area of competence:

- (a) collaborate with the European Union reference laboratories, and participate in training courses and in inter-laboratory comparative tests organised by these laboratories;
- (b) coordinate the activities of official laboratories designated in accordance with Article 36(1) with a view of harmonising and improving the methods of laboratory analysis, test or diagnosis and their use;
- (c) where appropriate, organise inter-laboratory comparative tests between official laboratories, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up;
- (d) ensure the dissemination to the competent authorities and official laboratories of information that the European Union reference laboratory supplies;
- (e) provide within the scope of their mission scientific and technical assistance to the competent authorities for the implementation of coordinated control plans adopted in accordance with Article 111;

Tuesday 15 April 2014

(f) where relevant, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;

(fa) assist actively in the diagnosis of outbreaks on national territory of animal, foodborne or zoonotic diseases by carrying out confirmatory diagnosis, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens, as specified for the national reference laboratories of the Union in point (h) of Article 92(2). [Am. 238]

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of responsibilities and tasks for national reference laboratories in addition to those provided in paragraph 1.

2a. This Article shall apply without prejudice to Article 32, second paragraph, of Regulation (EC) No 1829/2003 and the rules adopted under the fourth and fifth paragraphs of Article 32 of that Regulation, in addition to Annex II to Regulation (EC) No 1831/2003 and the rules adopted under the third and fourth paragraphs of Article 21 of that Regulation. [Am. 239]

Title IV

Administrative assistance and cooperation

Article 100

General rules

1. The competent authorities in the Member States concerned shall provide each other with administrative assistance in accordance with Articles 102 to 105, in order to ensure the correct application of the rules referred to in Article 1(2) in cases which have relevance in more than one Member State.

~~2. Administrative assistance shall include, where appropriate, participation by the competent authorities of a Member State in on the spot official controls that the competent authorities of another Member State perform. [Am. 240]~~

3. The provisions of this Title shall not prejudice national rules:

(a) applicable to the release of documents that are the object of, or related to, judicial proceedings;

(b) aimed at the protection of natural or legal persons' commercial interests.

4. All communications between competent authorities in accordance with Articles 102 to 105 shall be in writing.

~~5. In order to streamline and simplify communication exchanges, the Commission shall, by means of implementing acts, establish a standard format for:~~

~~(a) the requests for assistance provided for in Article 102(1);~~

~~(b) the communication of common and recurrent notifications and responses.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2). [Am. 241]~~

5a. Communications between competent authorities conducted in accordance with the provisions of this title shall be without prejudice to Commission Regulation (EU) No 16/2011⁽¹⁾ regarding communications through the Rapid Alert System for Food and Feed. [Am. 242]

⁽¹⁾ Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid Alert System for Food and Feed (OJ L 6, 11.1.2011, p. 7)

Tuesday 15 April 2014

Article 101

Liaison bodies

1. Each Member State shall designate one or more liaison bodies responsible for the exchange of communications between competent authorities in accordance with Articles 102 to 105.
2. The designation of liaison bodies shall not preclude direct contacts, exchange of information or cooperation between the staff of competent authorities in different Member States.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of minimum requirements that liaison bodies designated in accordance with paragraph 1 are required to comply with.
4. Member States shall communicate to the Commission and other Member States the details of their liaison bodies designated in accordance with paragraph 1, and any subsequent modification of those details.
5. The Commission shall publish and update on its website the list of liaison bodies communicated to it by the Member States in accordance with paragraph 4.
6. All requests for assistance pursuant to Article 102(1), and notifications and communications pursuant to Articles 103, 104 and 105 shall be transmitted by a liaison body to its correspondent in the Member State to which the request or the notification is addressed.
7. ~~The Commission shall, by means of implementing acts, establish the specifications of the technical tools and the procedures for communication between liaison bodies designated in accordance with paragraph 1.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2). [Am. 243]~~

Article 102

Assistance on request

1. Where the competent authorities in a Member State consider that, for the performance of official controls or for the effective follow-up to such controls in their territory, they require data or information from the competent authorities of another Member State, they shall issue a motivated request for administrative assistance to the competent authorities of that Member State. The requested competent authorities shall:
 - (a) acknowledge receipt of the request without delay;
 - (b) indicate within ~~ten~~ **15** days from the date of receipt of the request, the time necessary to provide an informed response to the request; **[Am. 244]**
 - (c) perform official controls or investigations necessary to provide the requesting competent authorities without delay with all necessary information and documents to enable them to take informed decisions and verify compliance with Union rules within their jurisdiction.
2. Documents may be transmitted in their original form or copies may be provided.
3. By agreement between the requesting competent authorities and the requested competent authorities, staff designated by the former may be present during the official controls and investigations referred to in point (c) of paragraph 1 performed by the requested competent authorities.

In such cases the staff of the requesting competent authorities:

- (a) shall at all times be able to produce written authority stating their identity and their official capacity;
- (b) shall have access to the same premises and documents as the staff of the requested competent authorities, through their intermediary, and for the sole purpose of the administrative enquiry being carried out;
- (c) may not, on their own initiative, exercise the powers of enquiry conferred on officials of the requested competent authorities.

Tuesday 15 April 2014

Article 103

Assistance without request

1. When the competent authorities in a Member State become aware of a non-compliance, and if such non-compliance may have implications for another Member State, they shall notify such information to the competent authorities of that other Member State without being requested to do so and without delay.
2. The competent authorities notified in accordance with paragraph 1:
 - (a) shall acknowledge receipt of the notification without delay;
 - (b) shall indicate within ~~ten~~ **15 working** days from the date of receipt of the notification: [Am. 245]
 - (i) what investigations they intend to carry out; or,
 - (ii) the reasons why they consider that no investigations are necessary;
 - (c) where investigations referred to in point (b) are considered necessary, they shall investigate the matter and inform the notifying competent authorities without delay of the results and, where appropriate, of any measures taken.

Article 104

Assistance in the event of non-compliance

1. Where, during official controls performed on animals or goods originating in another Member State, the competent authorities establish that such animals or goods do not comply with the rules referred to in Article 1(2) in such a way as to create a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment, or to constitute a serious infringement of those rules, they shall, without delay, notify the competent authorities of the Member State of dispatch and of any other concerned Member State in order to enable them to undertake appropriate investigations.

1a. The other concerned Member States referred to in paragraph 1 shall, in the case of infringements of Regulation (EC) No 1/2005 include:

- (a) *the Member State that granted the authorisation to the transporter;*
- (b) *where a deficiency in the means of transport is involved in the failure to observe the requirements of that Regulation, the Member State that granted the certificate of approval of the means of transport;*
- (c) *where the driver is involved in the failure to observe the requirements of that Regulation, the Member State that issued the driver's certificate of competence.* [Am. 246]

2. The notified competent authorities shall without delay:

- (a) acknowledge receipt of the notification;
- (b) indicate what investigations they intend to carry out;
- (c) investigate the matter, take all necessary measures and inform the notifying competent authorities of the nature of the investigations and official controls performed, of the decisions taken and of the reasons for such decisions;

(ca) inform all relevant, concerned stakeholders, as specified in national food safety contingency plans. [Am. 247]

3. If the notifying competent authorities have reason to believe that the investigations performed or the measures taken by the notified competent authorities do not adequately address the non-compliance established, they shall request the notified competent authorities to complement the official controls performed or the measures taken. In such cases:

- (a) the competent authorities from the two Member States shall seek an agreed approach with the aim of appropriately addressing the non-compliance, including through joint official controls and investigations performed in accordance with Article 102(3);

Tuesday 15 April 2014

(b) they shall inform the Commission without delay where they are not able to agree on appropriate measures.

4. When official controls performed on animals or goods originating in another Member State show repeated cases of non-compliance with the rules referred to in Article 1(2), the competent authorities of the Member State of destination shall inform the Commission and the competent authorities of the other Member States without delay.

Article 105

Assistance by third countries

1. When competent authorities receive information from a third country indicating non-compliance or a risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment, they shall, without delay:

- (a) notify such information to the competent authorities in other concerned Member States;
- (b) communicate such information to the Commission where it is or may be relevant at Union level.

2. Information obtained through official controls and investigations performed in accordance with this Regulation may be communicated to the third country referred to in paragraph 1, provided that:

- (a) the competent authorities which have provided the information consent to such communication;
- (b) the third country has undertaken to provide the assistance necessary to gather evidence of practices that are or appear to be non-compliant with Union rules or that pose a risk to humans, animals or plants or the environment;
- (c) relevant Union and national rules applicable to the communication of personal data to third countries are complied with.

Article 106

Coordinated assistance and follow-up by the Commission

1. The Commission shall coordinate without delay the measures and actions undertaken by competent authorities in accordance with this Title where:

- (a) information available to the Commission reports activities that are, or appear to be, non-compliant with the rules referred to in Article 1(2), and such activities have, or might have, ramifications in more than one Member State; or,
- (b) information available to the Commission indicates that the same, or similar, activities that are, or appear to be, non-compliant with the rules referred to in Article 1(2) might be taking place in more than one Member State; and,
- (c) the competent authorities in the Member States concerned are unable to agree on appropriate action to address the non-compliance with the rules referred to in Article 1(2).

2. In the cases referred to in paragraph 1 the Commission may:

- (a) in collaboration with the Member State concerned, send an inspection team to perform an on-the-spot official control;
- (b) request, by means of implementing acts, that the competent authorities in the Member State of dispatch and, where appropriate, in other Member States concerned, appropriately intensify official controls and report to it on the measures taken by them;
- (c) take any other appropriate measure in accordance with the rules referred to in Article 1(2).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 to establish rules for the rapid exchange of information in the cases referred to in paragraph 1.

Tuesday 15 April 2014

Title V

Planning and reporting

Article 107

Multi-annual national control plans (MANCP) and single authority for the MANCP

1. Member States shall ensure that official controls governed by this Regulation are performed by the competent authorities on the basis of a multi-annual national control plan, the preparation and implementation of which are coordinated across their territory.
2. Member States shall designate ~~a single~~ **the** authority **or authorities** responsible for: [Am. 248]
 - (a) the coordination of the preparation of the plan referred to in paragraph 1 across all competent authorities responsible for the official controls;
 - (b) ensuring that such plan is coherent and consistently implemented.

Article 108

Content of the multi-annual national control plans

1. Multi-annual national control plans shall be prepared so as to ensure that:
 - (a) official controls are planned in all the areas governed by the rules referred to in Article 1(2) and in accordance with the criteria laid down in Article 8 and in the rules provided for in Articles 15 to 24;
 - (b) there is efficient prioritisation of official controls and efficient allocation of control resources.
2. Multi-annual national control plans shall contain general information on the structure and organisation of the systems of official control in the Member State concerned, **for each of the sectors concerned** and shall contain at least information on the following: [Am. 249]
 - (a) the strategic objectives of the multi-annual national control plan and on how the prioritisation of official controls and allocation of resources reflect these objectives;
 - (b) the risk categorisation of the official controls;
 - (c) the designation of competent authorities and their tasks at central, regional and local level, and on resources available to those authorities;
 - (d) where appropriate, the delegation of tasks to delegated bodies;
 - (e) the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments;
 - (f) control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in those sectors;
 - (g) procedures and arrangements in place to ensure compliance with the obligations of the competent authorities provided for in Article 4(1);
 - (h) the training of staff of the competent authorities;
 - (i) the documented procedures provided for in Article 11(1);
 - (j) the organisation and operation of contingency plans in accordance with the rules referred to Article 1(2);
 - (k) the organisation of cooperation and mutual assistance between competent authorities in the Member States.

Tuesday 15 April 2014

Article 109

Preparation and implementation of multi-annual control plans

1. Member States shall ensure that the multi-annual national control plan provided for in Article 107(1) is made available to the public, with the exception of those parts of the plan the disclosure of which could undermine the effectiveness of official controls.

1a. The multi-annual national control plan may be prepared in consultation with relevant operators, with a view to ensuring a risk-based approach to official controls. [Am. 250]

2. The multi-annual national control plan shall be updated every time it is necessary to adjust it to changes to the rules referred to in Article 1(2), and shall be reviewed on a regular basis to take account at least of the following factors:

- (a) the emergence of new diseases, pests of plants or other risks to human or plant animal health, animal welfare or, ~~in the case of GMOs and plant protection products,~~ to the environment; **[Am. 251]**
- (b) significant changes to the structure, management or operation of the competent authorities in the Member State;
- (c) the results of Member States' official controls;
- (d) the results of Commission controls performed in the Member State in accordance with Article 115(1);
- (e) scientific findings;
- (f) the outcome of official controls performed by the competent authorities of third country in a Member State.

3. Member States shall provide the Commission with an up-to-date version of their multi-annual national control plan on request.

~~Article 110~~

~~Delegated powers for multi-annual national control plans~~

~~The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the multi-annual national control plans provided for in Article 107(1).~~

~~Those delegated acts shall lay down rules on:~~

- ~~(a) criteria for the risk categorisation of the operators' activities;~~
- ~~(b) priorities for official controls based on the criteria laid down in Article 8 and in the rules provided for in Articles 15 to 24;~~
- ~~(c) procedures to maximise the effectiveness of official controls;~~
- ~~(d) the main performance indicators to be applied by the competent authorities in assessing the multi-annual national control plan and its implementation. **[Am. 252]**~~

Article 111

Coordinated control plans and information and data collection

With a view to conducting Union-wide targeted assessment of the state of application of the rules referred to in Article 1(2) or establishing the prevalence of certain hazards across the Union, the Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning:

- (a) the **preparation**, organisation and the implementation of coordinated control plans of limited duration in one of the areas governed by the rules referred to in Article 1(2); **[Am. 253]**

Tuesday 15 April 2014

- (b) the organisation, on an ad hoc basis, of the collection of data and information in relation to the ~~application of a specific set of the rules referred to in Article 1(2) or regarding the prevalence of certain hazards;~~ [Am. 254]

(ba) the role of stakeholders in the development and implementation of the coordinated control plans. [Am. 255]

Article 112

Annual reports by the Member States

1. By 30 June every year, each Member State shall submit to the Commission a report setting out:
 - (a) any amendments made to its multi-annual national control plan to take account of the factors referred to in Article 109(2);
 - (b) the results of official controls performed in the previous year under its multi-annual national control plan;
 - (c) the type and number of cases of non-compliance with the rules referred to in Article 1(2) detected in the previous year by the competent authorities, **specified per sector, and with an adequate level of detail;** [Am. 256]
 - (d) the measures taken to ensure the effective operation of its multi-annual national control plan, including enforcement action and the results of such measures;

(da) the information on fees referred to in paragraph 2 of Article 83 on transparency. [Am. 257]

2. In order to ensure the uniform presentation of the annual reports provided for in paragraph 1, the Commission shall, by means of implementing acts, adopt and update as necessary standard model forms for the submission of the information and data referred to in paragraph 1.

Those implementing acts shall, whenever possible, allow the use of the standard model forms adopted by the Commission for the submission of other reports on official controls that the competent authorities are required to submit to the Commission in accordance with the rules referred to in Article 1(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 113

Annual reports by the Commission

1. The Commission shall, **by 31 December every second year after the entry into force of this Regulation,** make available to the public an annual report on the operation of official controls in the Member States, taking into account: [Am. 258]

- (a) the annual reports submitted by the Member States in accordance with Article 112, **which shall include the information on fees referred to in paragraph 2 of Article 83 on transparency;** [Am. 259]
- (b) the results of Commission controls performed in accordance with Article 115(1);
- (c) any other relevant information.

2. The annual report provided for in paragraph 1 ~~may, where appropriate,~~ **shall** include recommendations on possible improvements to official control systems in Member States and specific official controls in certain areas. [Am. 260]

Tuesday 15 April 2014

Article 114

Contingency plans for food and feed

1. For the application of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002, Member States shall draw up operational contingency plans for food and feed setting out measures to be applied without delay when food or feed is found to pose a serious risk to human or animal health either directly or through the environment.
2. The contingency plans for food and feed provided for in paragraph 1 shall specify:
 - (a) the competent authorities to be involved;
 - (b) the powers and responsibilities of the authorities referred to in point (a);
 - (c) channels and procedures for sharing information between competent authorities and other parties concerned as appropriate.
3. Member States shall review their contingency plans for food and feed regularly to take into account changes in the organisation of the competent authorities and experience gained from implementing the plan and simulation exercises.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning:
 - (a) rules for the establishment of the contingency plans provided for in paragraph 1 to the extent necessary to ensure the consistent and efficient use of the general plan for crisis management provided for in Article 55(1) of Regulation (EC) No 178/2002;
 - (b) the role of stakeholders in the establishment and operation of those contingency plans.

Title VI

Union activities

Chapter I

Commission controls

Article 115

Commission controls in Member States

1. Commission experts shall perform controls in each Member State to:
 - (a) verify the application of the rules referred to in Article 1(2) and those provided for in this Regulation;
 - (b) verify the functioning of national control systems and of the competent authorities which operate them;
 - (c) investigate and collect information:
 - (i) on official controls and enforcement practices;
 - (ii) on important or recurring problems with the application or enforcement of the rules referred to in Article 1(2);
 - (iii) in relation to emergency situations, emerging problems or new developments in the Member States.

Tuesday 15 April 2014

2. The controls provided for in paragraph 1 shall be organised in cooperation with the competent authorities of the Member States and be performed on a regular basis.
3. The controls provided for in paragraph 1 may include on the spot verifications. The Commission experts may accompany the staff of the competent authorities performing official controls.
4. Experts from the Member States may assist the Commission experts. National experts accompanying Commission experts shall be given the same rights of access as the Commission experts.

Article 116

Reports by the Commission on controls by its experts in Member States

1. The Commission shall:
 - (a) prepare a draft report on the findings of controls performed in accordance with Article 115(1);
 - (b) send to the Member State where those controls were performed a copy of the draft report provided for in point (a) for its comments;
 - (c) take the comments of the Member State referred to in point (b) into account in preparing the final report on the findings of the controls performed by its experts in the Member States as provided for in Article 115(1);
 - (d) make publicly available the final report referred to in point (c) and the comments of the Member State referred to in point (b).
2. Where appropriate, the Commission may recommend in its final reports provided for in paragraph 1 corrective or preventive action to be taken by the Member States to address the specific or systemic shortcomings identified by its experts during controls performed in accordance with Article 115(1).

Article 117

Programme of the Commission controls in Member States

1. The Commission shall, by means of implementing acts:
 - (a) establish an annual or multiannual control programme for the controls to be performed by its experts in the Member States as provided for in Article 115(1);
 - (b) by the end of each year, communicate to the Member States the annual control programme or any update to the multiannual control programme for the following year.
2. The Commission may, by means of implementing acts, amend its control programme to take account of developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated to the Member States **sufficiently well in advance**. [Am. 261]

Article 118

Obligations of the Member States as regards Commission controls

Member States shall:

- (a) take appropriate follow-up measures to remedy any specific or systemic shortcomings identified by the controls performed by the Commission experts in accordance to Article 115(1);
- (b) give all necessary assistance and provide all documentation and other technical support that Commission experts request to enable them to perform controls efficiently and effectively;
- (c) ensure that Commission experts have access to all premises or parts of premises, animals and goods, and to information, including computing systems, relevant for the execution of their duties.

Tuesday 15 April 2014

Article 119

Commission controls in third countries

1. Commission experts may perform controls in third countries in order to:
 - (a) verify the compliance or equivalence of third-country legislation and systems, including official certification and the issuance of official certificates, official labels, official marks and other official attestations, with the requirements laid down in the rules referred to in Article 1(2);
 - (b) verify the capacity of the third country control system to ensure that consignments of animals and goods exported to the Union comply with relevant requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto;
 - (c) collect information and data to elucidate the causes of recurring or emerging problems in relation to exports of animals and goods from a third country.
2. The controls provided for in paragraph 1 shall have particular regard to:
 - (a) the legislation of the third country;
 - (b) the organisation of the third country's competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;
 - (c) the training of staff in the performance of official controls;
 - (d) the resources including analytical, testing and diagnostic facilities available to competent authorities;
 - (e) the existence and operation of documented control procedures and control systems based on priorities;
 - (f) where applicable, the situation regarding animal health, zoonoses ~~and plant health~~, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases ~~and pests of plants~~; **[Am. 263]**
 - (g) the extent and operation of official controls performed on animals, plants and their products arriving from other third countries;
 - (h) the assurances which the third country can give regarding compliance with, or equivalence to, the requirements laid down in the rules referred to in Article 1(2).
3. In order to facilitate the efficiency and effectiveness of the controls provided for in paragraph 1, the Commission may, prior to performing such controls, request that the third country concerned provide:
 - (a) the information referred to in Article 124(1);
 - (b) where appropriate, the written records on the official controls it performs.
4. The Commission may appoint experts from Member States to assist its own experts during the controls provided for in paragraph 1.

Article 120

Frequency of Commission controls in third countries

The frequency of controls performed by the Commission in third countries shall be determined on the basis of:

- (a) a risk assessment of the animal and goods exported to the Union from them;
- (b) the rules referred to in Article 1(2);
- (c) the volume and nature of animals and goods entering the Union from the third country concerned;
- (d) the results of controls already performed by the Commission experts or by other inspection bodies;

Tuesday 15 April 2014

- (e) the results of official controls on animals and goods entering the Union from the third country and of any other official controls that competent authorities of Member States have performed;
- (f) information received from the European Food Safety Authority or similar bodies;
- (g) information received from internationally recognised bodies such as:
 - (i) the World Health Organisation;
 - (ii) the Codex Alimentarius Commission;
 - (iii) the World Organisation for Animal Health;
 - (iv) European and Mediterranean Plant Protection Organisation;
 - (v) the secretariat of the International Plant Protection Convention;
 - (vi) Organisation for Economic Co-operation and Development;
 - (vii) United Nations Economic Commission for Europe;
 - (viii) the secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Biodiversity;
- (h) evidence of emerging disease situations or other circumstances that might result in animals and goods entering the Union from a third country presenting health or environmental risks;
- (ha) the likelihood of fraudulent practices which might deceive consumer expectations regarding the nature, quality and composition of foods and goods; [Am. 264]**
- (i) the need to investigate or respond to emergency situations in individual third countries.

Article 121

Reports by the Commission on controls by its experts in third countries

The Commission shall report on the findings of each control performed in accordance with Articles 119 and 120.

Its report shall, where appropriate, contain recommendations.

The Commission shall make its reports publicly available.

Article 122

Programme of the Commission controls in third countries

The Commission shall communicate its programme of controls in third countries to Member States in advance and report on the results. The Commission may amend that programme to take account of developments in the areas governed by the rules referred to in Article 1(2). Any such amendment shall be communicated to the Member States.

Article 123

Third-country controls in Member States

1. Member States shall inform the Commission of:
 - (a) planned controls in their territory by the competent authorities of third countries;
 - (b) the intended schedule and scope of such controls.

Tuesday 15 April 2014

2. Commission experts may participate in the controls referred to in paragraph 1, at the request of either of the following:

- (a) the competent authorities of Member States where those controls are being performed;
- (b) the competent authorities of the third country performing those controls.

The participation by Commission experts and the final schedule and scope of the controls referred to in paragraph 1 shall be organised in close cooperation between the Commission and the competent authorities of the Member State where those controls are being performed.

3. The participation by Commission experts in the controls referred to in paragraph 1 shall serve in particular to:

- (a) provide advice on the rules referred to in Article 1(2);
- (b) provide information and data available at Union level that may be useful for the control performed by the competent authorities of the third country;
- (c) ensure uniformity with regard to controls performed by the competent authorities of third countries.

Chapter II

Conditions for the entry into the Union of animals and goods

Article 124

Information on third countries' control systems

1. The Commission shall request third countries intending to export animals and goods to the Union to provide the following accurate and up-to-date information on the general organisation and management of sanitary and phytosanitary control systems in their territory:

- (a) any sanitary or phytosanitary regulations adopted or proposed within their territory;
- (b) risk-assessment procedures and factors taken into consideration for the assessment of risks and for the determination of the appropriate level of sanitary or phytosanitary protection;
- (c) any control and inspection procedures and mechanisms, including, where relevant, on animals or goods arriving from other third countries;
- (d) official certification mechanisms;
- (e) where appropriate, any measures taken following recommendations provided for in the second paragraph of Article 121;
- (f) where relevant, results of official controls performed on animals and goods intended to be exported to the Union;
- (g) where relevant, information on changes made to the structure and functioning of control systems adopted to meet Union sanitary or phytosanitary requirements or recommendations provided for in the second paragraph of Article 121.

2. The request for information referred to in paragraph 1 shall be proportionate, taking account of the nature of the animals and goods to be exported to the Union and of the specific situation and structure of the third country.

Tuesday 15 April 2014

Article 125

Establishment of additional conditions for entry into the Union of animals and goods

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 139 concerning the conditions to be respected by animals and goods entering the Union from third countries where these are necessary to ensure that the animals and goods comply with the relevant requirements established by the rules referred to in Article 1(2), with the exception of points (d), (e), (g) and (h) of Article 1(2) and of Article 6 of Regulation (EC) No 853/2004, or with requirements recognised to be at least equivalent.
2. The conditions referred to in paragraph 1 shall identify animals and goods by referring to their codes from the Combined Nomenclature and may include:
 - (a) the requirement that certain animals and goods shall only enter the Union from a third country or region of a third country which appears on a list drawn up by the Commission for that purpose;
 - (b) the requirement that consignments of certain animals and goods from third countries be dispatched from and obtained or prepared in establishments which comply with the relevant requirements referred to in paragraph 1 or with requirements recognised to be at least equivalent;
 - (c) the requirement that consignments of certain animals and goods be accompanied by an official certificate, an official attestation, or by any other evidence that the consignments comply with the relevant requirements referred to in paragraph 1 or with requirements recognised to be at least equivalent;
 - (d) the obligation to provide the evidence referred to in point (c) in accordance with a specific format;
 - (e) any other requirement necessary to ensure that certain animals and goods ~~offer a level of protection of health and, as regards GMOs and plant protection products, of the environment, equivalent to that ensured by~~ **comply with** the requirements referred to in paragraph 1. [**Am. 266**]
3. Where, in case of risks arising from animals and goods entering the Union from third countries to human health, animal health or, as regards GMOs and plant protection products, to the environment, imperative grounds of urgency so require, the procedure provided for in Article 140 shall apply to delegated acts adopted pursuant to paragraph 1.
4. The Commission may, by means of implementing acts, lay down rules concerning the format and type of official certificates, official attestations or evidence required in accordance with the rules provided for in point (c) of paragraph (2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 126

Inclusion in the list of third countries referred to in point (a) of Article 125(2)

1. The inclusion of a third country or region thereof in the list referred to in point (a) of Article 125(2) shall be made in accordance with paragraphs 2 and 3 of this Article.
2. The Commission shall approve, by means of implementing acts, the request transmitted to it for that purpose by the third country concerned, accompanied by appropriate evidence and guarantees that the concerned animals and goods from that third country comply with the relevant requirements referred to in Article 125(1) or with requirements equivalent thereto. Those implementing acts shall be adopted and updated in accordance with the examination procedure referred to in Article 141(2).
3. The Commission shall decide on the request referred to in paragraph 2 taking into account, as appropriate:
 - (a) the third country's legislation in the sector concerned;
 - (b) the structure and organisation of the competent authorities of the third country and its control services, the powers available to them, the guarantees that can be provided with regard to the application and enforcement of the legislation of the third country applicable to the sector concerned, and the reliability of the official certification procedures;

Tuesday 15 April 2014

- (c) the performance by the competent authorities of the third country of adequate official controls and other activities to assess the presence of hazards for human, animal or plant health, for animal welfare or for the environment in relation to GMOs and plant protection products;
- (d) the regularity and rapidity of information supplied by the third country on the presence of hazards for human, animal or plant health, for animal welfare or for the environment in relation to GMOs and plant protection products;
- (e) the guarantees given by a third country that:
 - (i) conditions applied to the establishments from which animals or goods are exported to the Union comply with requirements that are equivalent to those referred to in Article 125(1);
 - (ii) a list of the establishments referred to in point (i) is drawn up and kept up to date;
 - (iii) the list of establishments referred to in point (i) and its updated versions are communicated to the Commission without delay;
 - (iv) the establishments referred to in point (i) are the subject of regular and effective controls by the competent authorities of the third country;
- (f) any other information or data on the capability of the third country to ensure that only animals or goods which offer the same or an equivalent level of protection as that afforded by the relevant requirements referred to in Article 125(1) enter the Union.

Article 127

Establishment of special measures regarding the entry into the Union of certain animals and goods

1. Where, in cases other than those referred to in Article 53 of Regulation (EC) No 178/2002, Article 249 of Regulation (EU) No .../... (*) and in Articles 27(1), 29(1), 40(2), 41(2), 47(1), 49(2) and 50(2) of Regulation (EU) No .../... (**), there is evidence that the entry into the Union of certain animals or goods originating from a third country, a region thereof or a group of third countries, may pose a risk to human, ~~or animal or plant health or, as regards GMOs and plant protection products,~~ to the environment, or where there is evidence that widespread serious non-compliance with the rules referred to in Article 1(2) might be taking place, the Commission shall adopt, by means of ~~implementing~~ **delegated acts in accordance with Article 139**, the measures necessary to contain such risk or put an end to the identified non-compliance. ~~These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2). [Am. 267]~~
2. The measures referred to in paragraph 1 shall identify animals and goods by referring to their codes from the Combined Nomenclature and may include:
 - (a) the prohibition of entry into the Union of the animals and goods referred to in paragraph 1 originating or dispatched from the concerned third countries or regions thereof;
 - (b) the requirement that the animals and goods referred to in paragraph 1 originating or dispatched from certain third countries or regions thereof be subject, prior to dispatch, to specific treatment or controls;
 - (c) the requirement that the animals and goods referred to in paragraph 1 originating or dispatched from certain third countries or regions thereof be subject, upon entry into the Union, to specific treatment or controls;
 - (d) the requirement that consignments of the animals and goods referred to in paragraph 1 originating or dispatched from certain third countries or regions thereof, be accompanied by an official certificate, an official attestation, or by any other evidence that the consignment complies with requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent;

(*) Number of the Regulation on animal health.

(**) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

- (e) the requirement that the evidence referred to in point (d) be provided in accordance with a specific format;
 - (f) other measures necessary to contain the risk.
3. When adopting the measures referred to in paragraph 2, account shall be taken of:
- (a) the information collected in accordance with Article 124;
 - (b) any other information that the third countries concerned have provided;
 - (c) where necessary, the results of Commission controls provided for in Article 119(1).
4. On duly justified imperative grounds of urgency relating to human health and animal health or, as regards GMOs and plant protection products, to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 141(3).

Article 128

Equivalence

1. In the areas governed by the rules referred to in Article 1(2), with the exclusion of points (d), (e), (g) and (h) of Article 1(2), the Commission may, by means of implementing acts, recognise that measures applied in a third country, or regions thereof, are equivalent to the requirements laid down in those rules, on the basis of:

- (a) a thorough examination of information and data provided by the third country concerned pursuant to Article 124(1);
- (b) where appropriate, the satisfactory outcome of a control performed in accordance with Article 119(1);

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

2. The implementing acts referred to in paragraph 1 shall set out the modalities governing the entry of animals and goods into the Union from the third country concerned, or regions thereof, and may include:

- (a) the nature and content of the official certificates or attestations that must accompany the animals or goods;
- (b) specific requirements applicable to the entry into the Union of the animals or goods and the official controls to be performed at entry into the Union;
- (c) where necessary, procedures for drawing up and amending lists of regions or establishments in the third country concerned from which the entry of animals and goods into the Union is permitted.

3. The Commission shall, by means of implementing acts, repeal without delay the implementing acts provided for in paragraph 1 where any of the conditions for the recognition of equivalence cease to be fulfilled.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Article 128a

Supporting developing countries

1. With a view to ensuring that developing countries can comply with this Regulation, measures may be taken, and may be implemented for as long as they continue to have a demonstrable impact, to support the following activities:

- **compliance with the conditions governing the entry into the Union of animals and goods;**
- **drafting of guidelines on the organisation of official controls on products to be exported to the Union;**
- **sending of European Union or Member State experts to developing countries to assist with the organisation of official controls;**

Tuesday 15 April 2014

— *involvement of control staff from developing countries in training programmes or courses.*

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 setting out provisions covering the forms of support for developing countries referred to in paragraph 1. [Am. 268]

Chapter III

Training of staff of the competent authorities

Article 129

Training and exchange of staff of the competent authorities

1. The Commission ~~may~~ **shall** organise training activities for the staff of the competent authorities and, where appropriate, for staff of other authorities of the Member States involved in investigations of possible violations of the provisions of this Regulation and of the rules referred to in Article 1(2). **[Am. 269]**

The Commission ~~may~~ **shall** organise those activities in cooperation with Member States. **[Am. 270]**

2. The training activities referred to in paragraph 1 shall facilitate the development of a harmonised approach to official controls and other official activities in Member States. They shall include, as appropriate, training on:

- (a) this Regulation and the rules referred to in Article 1(2);
- (b) control methods and techniques relevant for the official controls and for the other official activities of the competent authorities;
- (c) production, processing and marketing methods and techniques.

3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.

4. Competent authorities shall ensure that the knowledge acquired through the training activities referred to in paragraph 1 is disseminated as necessary and appropriately used in the staff training activities referred to in Article 4(2) and (3).

Training activities aimed at disseminating such knowledge shall be included in the training programmes referred to in Article 4(2).

5. The Commission may organise in cooperation with the Member States programmes for the exchange of staff of the competent authorities performing official controls or other official activities between two or more Member States.

Such exchange may take place through the temporary secondment of staff of the competent authorities from one Member State to the other or through the exchange of such staff between the relevant competent authorities.

6. The Commission shall, by means of implementing acts, lay down rules for the organisation of the training activities referred to in paragraph 1 and of the programmes referred to in paragraph 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Tuesday 15 April 2014

Chapter IV

Information management systems

Article 130

Information management system for official controls (IMSOC)

1. The Commission shall set up and manage a computerised information management system for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls are **automatically forwarded from databases in the Member States and** managed and handled **and automatically exchanged** (‘the IMSOC’), **taking into account existing national systems.** [Am. 271]

1a. When forwarding electronic certificates or other electronic documents, the Commission and Member States shall use standard international programming languages, message structures and transmission protocols and safe transmission procedures. [Am. 272]

2. The IMSOC shall:

- (a) integrate fully and provide the necessary updates to the TRACES system as established by Decision 2003/24/EC;
- (b) integrate fully and provide the necessary updates to existing computerised systems managed by the Commission and used for the rapid exchange of data, information and documents in relation to risks to human, animal health and welfare, and plant health, as established by Article 50 of Regulation (EC) No 178/2002, Article 20 of Regulation (EU) .../... (*) and Article 97 of Regulation (EU) .../... (**);
- (c) provide appropriate linkages between the TRACES system and the systems referred to in point (b) to allow, as necessary, the efficient exchange and update of data between those systems and between the TRACES system and those systems.

2a. When exchanging electronic data, such as electronic certificates, the Commission and the competent authorities of the Member States shall use internationally standardised language, message structure and exchange protocols. [Am. 273]

Article 131

General functionalities of the IMSOC

The IMSOC shall:

- (a) allow for the computerised handling and exchange of information, data and documents necessary for the performance of official controls, resulting from the performance of official controls or the recording of the performance or outcome of official controls in all cases where the rules referred to in Article 1(2) and the delegated acts provided for in Articles 15 to 24 provide for the exchange among competent authorities, between the competent authorities and the Commission, and where appropriate with other authorities and the operators, of such information, data and documents;
- (b) provide a mechanism for the exchange of data and information in accordance with Title IV;
- (c) provide a tool to collect and manage the reports on official controls provided by the Member States to the Commission;
- (d) allow for the production, handling and transmission, including in electronic form, of the journey log referred to in Article 5(4) of Regulation (EC) No 1/2005, of the records obtained by the navigation system referred to in Article 6(9) of Regulation (EC) No 1/2005, of official certificates and of the common health entry document referred to in Article 54 of this Regulation.

(*) Number of the Regulation on animal health.

(**) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

Article 132

Use of the IMSOC in case of animals and goods subject to specific official controls

1. In case of animals or goods whose movements within the Union or placing on the market are subject to specific requirements or procedures established by the rules referred to in Article 1(2), the IMSOC shall enable the competent authorities at the place of dispatch and other competent authorities responsible for performing official controls on those animals or goods to exchange in real time data, information and documents concerning animals or goods being moved from one Member State to another and on official controls performed.

The first subparagraph shall not apply to goods subject to the rules referred to in Article 1(2)(g) and (h).

However, the Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning when and to what extent the first subparagraph shall apply to the goods referred to in the second subparagraph.

2. In case of exported animals and goods for which Union rules apply in relation to the issuance of the export certificate, the IMSOC shall enable the competent authorities of the place of dispatch and other competent authorities responsible for performing official controls to exchange in real time data, information and documents concerning such animals and goods and the result of controls performed on those animals and goods.

3. In case of animals or goods subject to the official controls referred to in Title II, Chapter V, Sections I and II, the IMSOC shall:

- (a) enable the competent authorities at the border control posts and other competent authorities responsible for performing official controls on those animals or goods to exchange in real time data, information and documents concerning those animals and goods and on controls performed on those animals or goods;
- (b) enable the competent authorities at the border control posts to share and exchange relevant data, information and documents with customs authorities and other authorities responsible for performing controls on animals or goods entering the Union from third countries, and with operators involved in entry procedures, in accordance with the rules adopted pursuant to Articles 14(4) and 73(2) and with other relevant Union rules;
- (c) support and operate the procedures referred to in point (a) of Article 52(2) and in Article 63(6).

Article 133

Empowerment for the adoption of rules for the functioning of the IMSOC

The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the establishment of:

- (a) the technical specifications and the specific rules for the functioning of the IMSOC and of its components;
- (b) contingency arrangements to be applied in case of unavailability of any of the functionalities of the IMSOC;
- (c) the cases where and the conditions under which concerned third countries and international organisations may be granted partial access to the functionalities of the IMSOC and the modalities of such access;
- (d) the cases where and the conditions under which exemptions from the use of the TRACES system can be granted to occasional users;
- (e) the rules concerning an electronic system under which electronic certificates issued by the competent authorities of third countries shall be accepted by the competent authorities.

Tuesday 15 April 2014

Title VII

Enforcement action

Chapter I

Action by the competent authorities and penalties

Article 134

General obligations of the competent authorities as regards enforcement action

1. When acting in accordance with this Chapter, the competent authorities shall give priority to action to be taken to eliminate or contain risks to human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, to the environment. ***Given the increasing frequency of fraud in the food area, more emphasis shall be put on tackling practices which mislead consumers as to the nature or the quality of the food they purchase and consume. [Am. 336]***
2. In case of suspicion of non-compliance, the competent authorities shall perform an investigation in order to confirm or to eliminate that suspicion.
3. Where necessary for its purposes, the investigation referred to in paragraph 2 shall include:
 - (a) the performance of intensified official controls on animals, goods and operators for an appropriate period, ***in keeping with the nature of the risk; [Am. 274]***
 - (b) the official detention of animals and goods and of any unauthorised substances or products as appropriate.

Article 135

Investigations and measures in case of established non-compliance

1. Where the non-compliance is established, the competent authorities shall:
 - (a) perform any further investigation necessary to determine the origin and extent of the non-compliance and to establish the operator's responsibilities;
 - (b) take appropriate measures to ensure that the operator remedies the non-compliance and ~~prevents~~ ***establishes systems to prevent*** further occurrences of it. **[Am. 275]**

When deciding which measures to take, the competent authorities shall take account of the nature of the non-compliance and the operator's past record with regard to compliance.

2. When acting in accordance with paragraph 1, competent authorities shall, as appropriate:
 - (a) order or perform treatments on animals;
 - (aa) ***where the outcome of the official controls on journey logs provided for in point (i) of paragraph (b) of Article 18(1) is not satisfactory, require the organiser to change the arrangements for the intended long journey so that it complies with Regulation (EC) No 1/2005; [Am. 276]***
 - (b) order the unloading, transfer to another means of transport, holding ~~and~~ ***in suitable accommodation with appropriate*** care of animals, quarantine periods, the postponement of the slaughter of animals, ***that veterinary assistance must be sought if necessary; [Am. 277]***
 - (c) order treatments on goods, the alteration of labels or corrective information to be provided to consumers;
 - (d) restrict or prohibit the placing on the market, the movement, the entry into the Union or the export of animals and goods, prohibit their return to the Member State of dispatch or order their return to the Member State of dispatch;
 - (e) order that the operator increases the frequency of own controls;

Tuesday 15 April 2014

- (ea) **require business operators carrying out the killing of animals or any related operations falling within the scope of Regulation (EC) No 1099/2009 to amend their standard operating procedures and, in particular, slow down or stop production; [Am. 278]**
 - (f) order that certain activities of the operator concerned be subject to increased or systematic official controls;
 - (g) order the recall, withdrawal, removal and destruction of goods, authorising, where appropriate, the use of the goods for purposes other than those for which they were originally intended;
 - (h) order the isolation or closure, for an appropriate period of time, of all or part of the business of the operator concerned, or its establishments, holdings or other premises;
 - (i) order the cessation for an appropriate period of time of all or part of the activities of the operator concerned and, where relevant, of the internet sites it operates or employs;
 - (j) order the suspension or withdrawal of the approval of the establishment, plant, holding or means of transport concerned, or of the authorisation of a transporter **or of the certificate of competence of the driver; [Am. 279]**
 - (k) order the slaughter or killing of animals provided that this is the most appropriate measure to safeguard human health and animal health and welfare;
 - (l) take any other measure the competent authorities deem appropriate to ensure compliance with the rules referred to in Article 1(2).
3. The competent authorities shall provide the operator concerned, or its representative, with:
- (a) written notification of their decision concerning the action or measure to be taken in accordance with paragraphs 1 and 2, together with the reasons for that decision; and,
 - (b) information on rights of appeal against such decisions and on the applicable procedure and time limits.
4. All expenditure incurred pursuant to this Article shall be borne by the responsible operators.

Article 136

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and take all measures necessary to ensure that they are applied. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those rules to the Commission by the date referred to in the second subparagraph of Article 162(1) and shall notify it without delay of any subsequent amendment affecting them.

Irrespective of the financial advantage sought, the severity of the penalties should also reflect the degree of risk of damage to consumers' health. [Am. 280]

2. Member States shall ensure that financial penalties applicable to intentional violations of this Regulation and of the rules referred to in Article 1(2) **are set** at least ~~offset~~ **double** the economic advantage sought through the violation. **[Am. 281]**

3. Member States shall ensure in particular that penalties are provided for in the following cases:

- (a) where operators fail to cooperate during official controls or other official activities;
 - (b) false or misleading official certification **and declarations; [Am. 282]**
 - (c) fraudulent production or use of official certificates, official labels, official marks and other official attestations;
- (ca) where consumers' health is damaged. [Am. 283]**

Tuesday 15 April 2014

Article 136a**Reporting of breaches**

- 1. Member States shall ensure that competent authorities establish effective and reliable mechanisms to encourage reporting of potential or actual breaches of this Regulation and of national measures related to this Regulation to competent authorities.**
- 2. The mechanisms referred to in paragraph 1 shall include at least:**
 - (a) specific procedures for the receipt of reports on breaches and their follow-up;**
 - (b) appropriate protection for employees of institutions who report breaches committed within the institution against retaliation, discrimination or other types of unfair treatment at a minimum;**
 - (c) protection of personal data concerning both the person who reports the breaches and the natural person who is allegedly responsible for a breach, in accordance with Directive 95/46/EC;**
 - (d) clear rules that ensure that confidentiality is guaranteed in all cases in relation to the person who reports the breaches committed within the institution, unless disclosure is required by national law in the context of further investigations or subsequent judicial proceedings.**
- 3. Member States shall require institutions to have in place appropriate procedures for their employees to report breaches internally through a specific, independent and autonomous channel. Such a channel may also be provided through arrangements provided for by social partners. The same protection as referred to in points (b), (c) and (d) of paragraph 2 shall apply. [Am. 284]**

Chapter II

Union enforcement measures

Article 137

Serious failure in a Member State's control system

- 1. Where the Commission has evidence of a serious failure in a Member State's control systems and such failure may constitute a possible and widespread risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, to the environment, or result in a widespread infringement of the rules referred to in Article 1(2), it shall, by means of implementing acts, adopt one or more of the following measures, to be applied until the failure in the control system is eliminated:**
 - (a) the prohibition to make available on the market or to transport, move or otherwise handle certain animals or goods concerned by the failure in the official control system;**
 - (b) special conditions for the activities, animals or goods referred to in point (a);**
 - (c) the suspension of the operation of official controls in border control posts or other control points concerned by the failure in the official control system or the withdrawal of such border control posts or other control points;**
 - (d) other appropriate temporary measures necessary to contain that risk until the failure in the control system is eliminated.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(2).

Tuesday 15 April 2014

2. The measures referred to in paragraph 1 shall be adopted only after the Member State concerned has failed to correct the situation upon request and within the time limit set by the Commission.

3. On duly justified imperative grounds of urgency relating to human and animal health or, as regards GMOs and plant protection products, to the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 141(3).

Title VIII

Common provisions

Chapter I

Procedural provisions

Article 138

Amendment of Annexes and references to European standards

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning amendments to Annexes II and III to this Regulation, in order to take into account changes to the rules referred to in Article 1(2), technical progress and scientific developments.

2. In order to keep up-to-date the references to the European standards referred to in point (b)(iv) of Article 26, point (e) of Article 36(4) and point (a) of Article 91(3), the Commission shall be empowered to adopt delegated acts amending those references in the event that CEN amends them.

Article 139

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Article 15(2), Article 17, Article 23(1), Article 23(2), Article 24a, Article 25(3), Article 40, Article 43(4), Article 45(3), Article 46, Article 49, Article 51(1), Article 52(1) and (2), Article 56(2), Article 60(3), Article 62(2), Article 69(3), Article 75(1) and (2), Article 97(2), Article 98(6), Article 99(2), Article 101(3), Article 106(3), Article 111, Article 114(4), Article 125(1), Article 127(1), Article 128a(2), the third subparagraph of Article 132(1), Article 133, Article 138(1) and (2), Article 143(2), Article 144(3) and Article 153(3) shall be conferred **on the Commission** for ~~an indeterminate~~ a period of ~~time~~ **5 years** from ... (*). **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of identical duration, unless the European Parliament or Council opposes such an extension not later than 3 months before the end of each period.** [Am. 285]

2a. For the period during which these delegated powers are exercised, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. [Am. 286]

(*) Date of entry into force of this amending Act.

Tuesday 15 April 2014

3. The delegation of powers referred to in Article 15(2), Article 17, Article 23(1), Article 23(2), Article 24a, Article 25(3), Article 40, Article 43(4), Article 45(3), Article 46, Article 49, Article 51(1), Article 52(1) and (2), Article 56(2), Article 60(3), Article 62(2), Article 69(3), Article 75(1) and (2), Article 97(2), Article 98(6), Article 99(2), Article 101(3), Article 106(3), Article 111, Article 114(4), Article 125(1), Article 127(1), Article 128a(2), the third subparagraph of Article 132(1), Article 133, Article 138(1) and (2), Article 143(2), Article 144(3) and Article 153(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 15(2), Article 17, Article 23(1), Article 23(2), Article 24a, Article 25(3), Article 40, Article 43(4), Article 45(3), Article 46, Article 49, Article 51(1), Article 52(1) and (2), Article 56(2), Article 60(3), Article 62(2), Article 69(3), Article 75(1) and (2), Article 97(2), Article 98(6), Article 99(2), Article 101(3), Article 106(3), Article 111, Article 114(4) and 125(1), 127(1), 128a(2), the third subparagraph of Article 132(1), Article 133, Article 138(1) and (2), Article 143(2), Article 144(3) and Article 153(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Article 140

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 139(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 141

Committee

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That Committee shall be a Committee within the meaning of Regulation (EU) No 182/2011. ***This shall apply with the exception of cases covered by Article 23, which requires the Commission to be assisted by committees set up under Regulation (EC) No 834/2007, Regulation (EU) No 1151/2012 regarding DOP, protected geographical indications ('PGI') and traditional speciality guaranteed ('TSG') food product designations, Regulation (EC) No 1234/2007 regarding DOP and PGI wine designations and Regulation (EC) No 110/2008 of the European Parliament and of the Council⁽¹⁾ regarding the geographical indications of spirit drinks.*** [Am. 287]

⁽¹⁾ Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

Tuesday 15 April 2014

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Chapter II Transitional and final provisions

Article 142

Repeals

1. Regulation (EC) No 882/2004, Directives 89/608/EEC and 96/93/EC and Decision 92/438/EEC are repealed as from ... (*).

However, Articles 14 to 17 and 26 to 29 of Regulation (EC) No 882/2004 shall continue to apply until ... (**).

The designation of each of the European Union reference laboratories referred to in Annex VII to Regulation (EC) No 882/2004 shall continue to apply until the designation, in each of the areas concerned, of a European Union reference laboratory pursuant to Article 91(2) of this Regulation. [Am. 288]

1a. The designation of each of the European Union reference laboratories referred to in Annex VII to Regulation (EC) No 882/2004 shall continue to apply until such time as, in each of the areas concerned, a European Union reference laboratory is designated in accordance with Article 91(2) of this Regulation, without prejudice to Article 91(3a) thereof. [Am. 289]

2. ~~Regulation (EC) No 854/2004 and~~ Directives 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC and 97/78/EC are repealed as from ... (***) **[Am. 290]**

3. References to the repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex IV.

Article 143

Transitional measures related to the repeals of Directives 91/496/EEC and 97/78/EC

1. The relevant provisions of Directives 91/496/EEC and 97/78/EC which govern matters referred to in Article 45(2), Article 46, points (b), (c) and (d) of Article 49, Article 52(1) and (2), point (a) of Article 56(1) of this Regulation shall continue to apply until the date to be determined in the delegated act adopted in accordance with paragraph 2.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the date on which the provisions referred to in paragraph 1 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 45(2), Article 46, points (b), (c) and (d) of Article 49, Article 52(1) and (2) and point (a) of Article 56(1) of this Regulation.

(*) Date of entry into force of this Regulation + 1 year.

(**) Date of entry into force of this Regulation + 3 years.

(***) Date of entry into force of this Regulation + 3 years.

Tuesday 15 April 2014

Article 144

Transitional measures related to the repeal of Directive 96/23/EC

1. Competent authorities shall continue to perform the official controls necessary to detect the presence of the substances and groups of residues listed in Annex I to Directive 96/23/EC, in accordance to Annexes II, III and IV to that Directive until the date to be determined in the delegated act adopted in accordance with paragraph 3.
2. Article 29(1) and (2) of Directive 96/23/EC shall continue to apply until the date to be determined in the delegated act adopted in accordance with paragraph 3.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the date on which the competent authorities shall cease to perform official controls in accordance with paragraph 1, and on which Article 29(1) and (2) of Directive 96/23/EC shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Articles 16 and 111 of this Regulation.

Article 145

Amendments to Directive 98/58/EC

Directive 98/58/EC is amended as follows:

(a) Article 2 is amended as follows:

- (i) point 3 is deleted;
- (ii) the following second subparagraph is added:

‘The definition of “competent authorities” laid down in point (5) of Article 2 of Regulation (EU) No .../.... (*) shall also apply.’;

(b) Article 6 is amended as follows:

- (i) paragraph 1 is deleted;
- (ii) paragraph 2 is replaced by the following:

‘2. Member States shall submit to the Commission by 30 June each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.’;

(c) point (a) of paragraph 3 is deleted;

(d) Article 7 is deleted.

Article 146

Amendments to Directive 1999/74/EC

Directive 1999/74/EC is amended as follows:

(a) Article 8 is amended as follows:

- (i) paragraph 1 is deleted;
- (ii) paragraph 2 is replaced by the following:

‘Member States shall submit to the Commission by 30 June each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of these reports to the Member States.’;

(*) Number of this Regulation.

Tuesday 15 April 2014

(iii) point (a) of paragraph 3 is deleted;

(b) Article 9 is deleted.

Article 147

Amendments to Regulation (EC) No 999/2001

Regulation (EC) No 999/2001 is amended as follows:

(a) Articles 19 and 21 are deleted;

(b) In Annex X, Chapters A and B are deleted.

Article 148

~~Amendments to Regulation (EC) No 1829/2003~~

~~Regulation (EC) No 1829/2003 is amended as follows:~~

~~(a) Article 32 is amended as follows:~~

~~(i) the first and second subparagraphs are deleted~~

~~(ii) the third subparagraph is replaced by the following:~~

~~'Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the tasks of the European Union reference laboratory and the national reference laboratories designated in accordance with Articles 91(1) and 98(1) of Regulation (EU) No XXX/XXXX [number of this Regulation] for that area.'~~

~~(iii) in the fifth subparagraph the words 'and the annex' shall be deleted.~~

~~(iv) in the sixth subparagraph the words 'and adapting the Annex' shall be deleted.~~

~~(b) the Annex is deleted. [Am. 291]~~

Article 149

~~Amendments to Regulation (EC) No 1831/2003~~

~~Regulation (EC) No 1831/2003 is amended as follows:~~

~~(a) in Article 7, paragraph 3(f) is replaced by the following~~

~~'a written statement that three samples of the feed additive have been sent by the applicant directly to the European Union reference laboratory referred to in Article 21.'~~

~~(b) Article 21 is amended as follows:~~

~~(i) the first, third and fourth paragraphs are deleted;~~

~~(ii) paragraph 2 is replaced by the following:~~

~~'Applicants for the authorisation of additives shall contribute to supporting the cost of the tasks of the European Union reference laboratory and the national reference laboratories designated in accordance with Articles 91(1) and 98(1) of Regulation (EU) No XXX/XXXX [number of this Regulation] for that area.'~~

~~(c) Annex II is deleted. [Am. 292]~~

Article 150

Amendments to Regulation (EC) No 1/2005

Regulation (EC) No 1/2005 is amended as follows:

(a) Article 2 is amended as follows:

(i) points (d), (f), (i) and (p) are deleted;

Tuesday 15 April 2014

(ii) the following second subparagraph is added:

'The definitions of "competent authorities", "border control post", "official veterinarian" and "exit point" laid down in points (5), (29), (32), and (36) of Article 2 of Regulation (EU) No .../.... (+) (*) shall also apply.

(*) OJ L ..., ..., p. ...;

(b) Articles 14 to 16, Article 21, Article 22(2), Articles 23 and 24 and Article 26 ~~are deleted~~ **shall continue to apply until the legislative proposals referred to in Article 18 are established; [Am. 293]**

(c) Article 27 is amended as follows:

(i) paragraph 1 is deleted;

(ii) paragraph 2 is replaced by the following:

'2. Member States shall submit to the Commission by 30 June each year an annual report for the previous year on the inspections carried by the competent authority to verify compliance with the requirements of this Regulation. The report shall be accompanied by an analysis of the major deficiencies detected and an action plan to address them.';

(d) Article 28 is deleted.

Article 151

Amendments to Regulation (EC) No 396/2005 and related transitional measures

1. Regulation (EC) No 396/2005 is amended as follows:

(a) Articles 26 and 27, Article 28(1) and (2) and Article 30 are deleted;

(b) the introductory phrase of Article 31(1) is replaced by the following:

'1. Member States shall submit the following information concerning the previous calendar year to the Commission, the Authority and the other Member States by 30 June each year:'.

2. Article 26, Article 27(1) and Article 30 of Regulation (EC) No 396/2005 shall continue to apply until the date **of the application of the corresponding rules** to be determined in the delegated act adopted in accordance with paragraph 3 **established pursuant to the legislative proposals referred to in Article 16 of this Regulation. [Am. 294]**

3. ~~The Commission shall be empowered to adopt delegated acts in accordance to Article 139 concerning the date on which Articles 26, 27(1) and 30 referred to in paragraph 2 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated acts provided for in Article 16 of this Regulation. [Am. 295]~~

Article 152

Amendments to Directive 2007/43/EC

Directive 2007/43/EC is amended as follows:

(a) Article 2 is amended as follows:

(i) in paragraph 1, points (c) and (d) are deleted;

(+) Number of this Regulation.

Tuesday 15 April 2014

(ii) the following paragraph 3 is added:

‘3. The definitions of “competent authorities” and of “official veterinarian” laid down in points (5) and (32) of Article 2 of Regulation (EU) No .../.... (+) (*) shall also apply.

_____ (*) OJ L ..., ..., p. ...;

(b) Article 7 is amended as follows:

(i) paragraph 1 is deleted;

(ii) paragraph 2 is replaced by the following:

‘2. Member States shall submit to the Commission by 30 June each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.’

Article 153

Amendments to Regulation (EC) No 834/2007 and related transitional measures

1. Regulation (EC) No 834/2007 is amended as follows:

(a) Article 2 is amended as follows:

(i) point (n) is replaced by the following:

‘(n) “competent authorities” means competent authorities as defined in point (5) of Article 2 of Regulation (EU) No .../.... (+) (*).

_____ (*) OJ L ..., ..., p. ...;

(ii) point (o) is deleted;

(iii) point (p) is replaced by the following:

‘(p) “control body” means a delegated body as defined in point (38) of Article 2 of Regulation (EU) No .../.... (+);

(b) in point (a) of Article 24(1), ‘Article 27(10)’ is replaced by ‘Articles 3(3) and 25(4) of Regulation (EU) No .../.... (+);

(c) Article 27 is amended as follows:

(i) paragraph 1 is replaced by the following:

‘1. Official controls to verify compliance with this Regulation shall be performed in accordance with Regulation (EC) No 882/2004.’;

(ii) paragraphs ~~2 3 to 6 and 8~~ to 14 are deleted; [Am. 296]

(+) Number of this Regulation.

(+) Number of this Regulation.

(+) Number of this Regulation.

(+) Number of this Regulation.

Tuesday 15 April 2014

(d) in Article 29(1), 'Article 27(4)' is replaced by 'Articles 3(3) and 25(4) of Regulation (EU) No .../....(+);

(e) in Article 30, paragraph 2 is deleted.

2. ~~Articles Paragraphs 3 to 14 of Article 27 and paragraph 2 of Article 30(2)~~ of Regulation (EC) No 834/2007 shall continue to apply until the date to be determined in the delegated act to be adopted in accordance with paragraph 3. **[Ams. 297 and 298]**

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 139 concerning the date on which the provisions referred to in paragraph 2 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated acts provided for in Article 23(2) of this Regulation.

Article 154

Amendments to Directive 2008/119/EC

Directive 2008/119/EC is amended as follows:

(a) Article 2 is amended as follows:

(i) point 2 is deleted;

(ii) the following second subparagraph is added:

'The definition of "competent authorities" laid down in point (5) of Article 2 of Regulation (EU) No .../.... (+) (*) shall also apply.

(*) OJ L ..., ..., p. ...;

(b) Article 7 is amended as follows:

(i) paragraphs 1 and 2 are deleted;

(ii) paragraph 3 is replaced by the following:

'3. Member States shall submit to the Commission by 30 June each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.;

(c) Article 9 is deleted.

Article 155

Amendments to Directive 2008/120/EC

Directive 2008/120/EC is amended as follows:

(a) Article 2 is amended as follows:

(i) point 10 is deleted;

(+) Number of this Regulation.

(+) Number of this Regulation.

Tuesday 15 April 2014

(ii) the following second subparagraph is added:

‘The definition of “competent authorities” laid down in point (5) of Article 2 of Regulation (EU) No .../.... (+) (*) shall also apply.

(*) OJ L ..., ..., p. ...;

(b) Article 8 is amended as follows:

(i) paragraphs 1 and 2 are deleted;

(ii) paragraph 3 is replaced by the following:

‘Member States shall submit to the Commission by 30 June each year an annual report for the previous year on the inspections carried out by the competent authority to check compliance with the requirements of this Directive. The report shall be accompanied by an analysis of the most serious findings of non-compliance and a national action plan to prevent or decrease their occurrence for the forthcoming years. The Commission shall submit summaries of those reports to the Member States.’;

(c) Article 10 is deleted.

Article 156

Amendments to Regulation (EC) No 1099/2009

Regulation (EC) No 1099/2009 is amended as follows:

(a) Article 2 is amended as follows:

(i) point (q) is deleted;

(ii) the following second subparagraph is added:

‘In addition to the definitions referred to in the first subparagraph, the definition of “competent authorities” laid down in point (5) of Article 2 of Regulation (EU) No .../.... (+) (*) shall also apply.

(*) OJ L ..., ..., p. ...;

(b) Article 22 is deleted.

Article 157

Amendments to Regulation (EC) No 1069/2009

Regulation (EC) No 1069/2009 is amended as follows:

(a) Article 3 is amended as follows:

(i) points 10 and 15 are deleted;

(ii) the following second subparagraph is added:

‘The definition of “competent authorities” and “transit” laid down in points (5) and (50) of Article 2 of Regulation (EU) No .../.... (+) (*) shall also apply.

(*) OJ L ..., ..., p. ...;

(+) Number of this Regulation.
 (+) Number of this Regulation.
 (+) Number of this Regulation.

Tuesday 15 April 2014

(b) Articles 45, 49 and 50 are deleted.

Article 158

Amendments to Regulation (EC) No 1107/2009

Article 68 of Regulation (EC) No 1107/2009 is amended as follows:

(a) the first paragraph is replaced by the following:

‘Member States shall finalise and submit to the Commission by 30 June each year a report on the scope and the results of the official controls performed in order to verify compliance with this Regulation.’;

(b) the second and third paragraphs are deleted.

Article 159

Amendments to Directive 2009/128/EC and related transitional measures

1. Directive 2009/128/EC is amended as follows:

(a) in Article 8, paragraph 1, the second subparagraph of paragraph 2 and paragraphs 3, 4, 6 and 7 are deleted;

(b) Annex II is deleted.

2. Paragraph 1, the second subparagraph of paragraph 2 and paragraphs 3, 4 and 6 of Article 8 and Annex II of Directive 2009/128/EC shall continue to apply until the date ~~to be determined in the delegated act~~ **of the application of the corresponding rules to be adopted in accordance with paragraph 3 established pursuant to the legislative proposals referred to in Article 22 of this Regulation.** [Am. 299]

~~3. The Commission shall be empowered to adopt delegated acts in accordance to Article 139 concerning the date on which the provisions referred to in paragraph 2 shall no longer apply. That date shall be the date of the application of the corresponding rules to be established pursuant to the delegated acts provided for in Article 22 of this Regulation.~~ [Am. 300]

Article 160

Amendments to Regulation (EU) No 1151/2012

Regulation (EU) No 1151/2012 is amended as follows:

(a) Article 36 is amended as follows:

(i) the heading is replaced by the following: ‘Content of official controls’;

(ii) paragraphs 1 and 2 are deleted;

(iii) in paragraph 3, the introductory phrase is replaced by the following:

‘3. official controls performed in accordance with Regulation (EU) No .../... (+) (*) shall cover:

(*) OJ L ..., ..., p. ...’;

(b) Article 37 is amended as follows:

(i) in paragraph 1, the first subparagraph is replaced by the following:

‘1. In respect of protected designations of origin, protected geographical indications and traditional specialities guaranteed that designate products originating within the Union, verification of compliance with the product specification, before placing the product on the market, shall be carried out by:

(a) the competent authorities designated in accordance with Article 3 of Regulation (EU) No .../... (+); or,

(+) Number of this Regulation.

(+) Number of this Regulation.

Tuesday 15 April 2014

- (b) delegated bodies within the meaning of point 38 of Article 2 of Regulation (EU) No .../....(+).;
 - (ii) in paragraph 3, the first subparagraph is deleted;
 - (iii) in paragraph 4, the words 'paragraphs 1 and 2' are replaced by the words: 'paragraph 2';
- (c) Articles 38 and 39 are deleted.

Article 161

Amendments to Regulation (EU) No .../2013 (+)

Regulation (EU) No .../2013 (+) is amended as follows:

(a) Article 29 is amended as follows:

(i) the heading is replaced by the following:

'European Union reference laboratories and centres';

(ii) paragraph 1 is replaced by the following:

'1. To cover the costs they incur to implement the work programmes approved by the Commission, grants may be awarded to:

(a) the European Union reference laboratories referred to in Article 91 of Regulation (EU) No .../.... (+) (*);

~~(b) the European Union reference centres for plant reproductive material referred to in Article 93 of that Regulation; [Am. 301]~~

(c) the European Union reference centres for animal welfare referred to in Article 95 of that Regulation;

(ca) the European Union reference centres for the authenticity and integrity of the agri-food chain.[Am. 302]

(*) OJ L ..., ..., p. ...;

(iii) in paragraph 2, point (a) is replaced by the following:

'(a) costs of personnel, regardless its status, directly involved in activities of the laboratories or centres which are carried out in their capacity of Union reference laboratory or centre;';

(b) the following Article 29a is added:

'Article 29a

Accreditation of national reference laboratories for plant health

1. Grants may be awarded to the national reference laboratories referred to in Article 98 of Regulation (EU) No .../.... (+) for costs incurred for obtaining accreditation according to the standard EN ISO/IEC 17025 for the use of methods of laboratory analysis, test and diagnosis to verify compliance with the rules on protective measures against pests of plants.

(+) Number of this Regulation.

(+) Number of the Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

(+) Number of the Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

(+) Number of this Regulation.

(+) Number of this Regulation.

Tuesday 15 April 2014

2. **The grants referred to in paragraph 1** may be awarded to a single national reference laboratory in each Member State for each European Union reference laboratory for plant health, up to three years after the designation of that European Union reference laboratory. [Am. 303]

Article 162

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Unless otherwise provided for in paragraphs 2 to 5, it shall apply from ... (+).

No later than one year after entry into force of this Regulation, the Commission shall provide a comprehensive guidance document, to assist operators and national authorities to effectively implement this Regulation. [Am. 304]

1a. No later than five years after the entry into force of this Regulation, the Commission shall submit a report to the European Parliament and the Council to present the experience gained from the application of this Regulation and consider in particular the reduction of administrative burden on private sector and the efficiency and effectiveness of controls carried out by competent authorities. [Am. 305]

2. In the area covered by the rules referred to in point (g) of Article 1(2), this Regulation, shall apply from ... (+), with the following exceptions:

(a) Articles 91 and 92 and Articles 97 to 99 shall apply in accordance with paragraph 1;

(b) Article 33(1), (2), (3) and (4), point (e) of Article 36(4) and Article 36(5) shall apply from ... (+).

~~3. In the area covered by the rules referred to in point (h) of Article 1(2), this Regulation, shall apply from [date of application of the Regulation on the production and making available on the market of plant reproductive material], with the following exceptions:~~

~~(a) Articles 93, 94 and 97 shall apply in accordance with paragraph 1;~~

~~(b) Article 33(1), (2) (3) and (4) shall apply from [date of entry into force of this Regulation + 5 years].~~ [Am. 306]

4. Article 15(1), Article 18(1), Articles 45 to 62 and Articles 76 to 84, ~~point (b) of Article 150, point~~ **points (b) and (c)** (i) of Article 152, point (b)(i) of Article 154, **and** point (b)(i) of Article 155 ~~and point (b) of Article 156~~ shall apply from ... (+). **Point (b) of Article 150 and point (b) of Article 156 shall not apply until the delegated acts that replace them are in force.** [Am. 307]

5. Article 161 shall apply from ... (+).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the European Parliament

The President

For the Council

The President

-
- (+) Date of entry into force of this Regulation + 1 year.
 (+) Date of application of the Regulation on protective measures against pests of plants.
 (+) Date of entry into force of this Regulation + 5 years.
 (+) Date of entry into force this Regulation + 3 years.
 (+) Date of entry into force of this Regulation.

Tuesday 15 April 2014

ANNEX I

TERRITORIES REFERRED TO IN POINT 45 OF ARTICLE 2

1. The territory of the Kingdom of Belgium
2. The territory of the Republic of Bulgaria
3. The territory of the Czech Republic
4. The territory of the Kingdom of Denmark with the exception of the Faroe Islands and Greenland
5. The territory of the Federal Republic of Germany
6. The territory of the Republic of Estonia
7. The territory of Ireland
8. The territory of the Hellenic Republic
9. The territory of the Kingdom of Spain with the exception of Ceuta and Melilla
10. The territory of the French Republic
11. The territory of the Italian Republic
12. The territory of the Republic of Cyprus
13. The territory of the Republic of Latvia
14. The territory of the Republic of Lithuania
15. The territory of the Grand Duchy of Luxembourg
16. The territory of Hungary
17. The territory of the Republic of Malta
18. The territory of the Kingdom of the Netherlands in Europe
19. The territory of the Republic of Austria
20. The territory of the Republic of Poland
21. The territory of the Portuguese Republic
22. The territory of Romania
23. The territory of the Republic of Slovenia
24. The territory of the Slovak Republic
25. The territory of the Republic of Finland
26. The territory of the Kingdom of Sweden
27. The territory of the United Kingdom of Great Britain and Northern Ireland

For the purpose of the official controls performed by the competent authorities to verify the compliance with the rules referred to in point (g) of Article 1(2) and other official activities carried out in relation to point (g) of Article 1(2), references to third countries shall be read as references to third countries and to the territories listed in Annex I of Regulation (EU) No .../... (*), and references to the Union territory shall be read as references to the Union territory without the territories listed in that Annex.

(*) Number of the Regulation on protective measures against pests of plants.

Tuesday 15 April 2014

ANNEX II

TRAINING OF STAFF OF THE COMPETENT AUTHORITIES

CHAPTER I: SUBJECT MATTER FOR THE TRAINING OF STAFF PERFORMING OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES

1. Different control methods and techniques, such as, inspection, verification, screening, targeted screening, sampling, and laboratory analysis, diagnosis and testing
2. Control procedures
3. The rules referred to in Article 1(2)
4. Assessment of non-compliance with the rules referred to in Article 1(2)
5. The hazards in the production, processing and distribution of animals and goods
- 5a. *The risks posed by antimicrobial resistance to human and animal health* [Am. 309]**
6. The different stages of production, processing and distribution, and the possible risks to human health, and where appropriate to the health of animals and plants, to the welfare of animals, **and** to the environment, ~~and to the identity and quality of plant reproductive material~~ [Am. 310]
7. The evaluation of the application of HACCP procedures and of good agricultural practices
8. Management systems such as quality assurance programmes that the operators manage and their assessment in so far as these are relevant for the requirements set out in the rules referred to in Article 1(2)
9. Official certification systems
10. Contingency arrangements for emergencies, including communication between Member States and the Commission
11. Legal proceedings and implications of official controls
12. Examination of written, documentary material and other records, including those related to inter-laboratory comparative testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with the rules referred to in Article 1(2); this may include financial and commercial aspects
13. Control procedures and requirements for entry into the Union of animals and goods arriving from third countries.
14. Any other area necessary to ensure that official controls are performed in accordance with this Regulation.

CHAPTER II: SUBJECT AREAS FOR CONTROL PROCEDURES

1. The organisation of the competent authorities and the relationship between central competent authorities and authorities to which they have conferred tasks to perform official controls or other official activities
2. The relationship between competent authorities and delegated bodies or natural persons to which they have delegated tasks related to official controls or other official activities
3. A statement on the objectives to be achieved
4. Tasks, responsibilities and duties of staff
5. Sampling procedures, control methods and techniques, including laboratory analysis, test and diagnosis, interpretation of results and consequent decisions

Tuesday 15 April 2014

6. Screening and targeted screening programmes
 7. Mutual assistance in the event that official controls require more than one Member State to take action
 8. Action to be taken following official controls
 9. Cooperation with other services and departments that may have relevant responsibilities or with operators
 10. Verification of the appropriateness of methods of sampling and of laboratory analysis, test and diagnosis
 11. Any other activity or information required for the effective functioning of the official controls.
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Tuesday 15 April 2014

ANNEX IIa

OFFICIAL AUXILIARIES

1. *The competent authority may appoint as official auxiliaries only persons who have undergone training and passed a test in accordance with the following requirements.*
2. *The competent authority must make arrangements for such tests. To be eligible for these tests, candidates must prove that they have received:*
 - (a) *at least 500 hours of theoretical training and at least 400 hours of practical training, covering the areas specified in paragraph 5; and*
 - (b) *such additional training as is required to enable official auxiliaries to undertake their duties competently.*
3. *The practical training referred to in point (a) of paragraph 2 is to take place in slaughterhouses and cutting plants, under the supervision of an official veterinarian, and on holdings and in other relevant establishments.*
4. *Training and tests are to concern principally red meat or poultry meat. However, persons who undergo training for one of the two categories and passed the test, need only undergo abridged training to pass the test for the other category. Training and test should cover wild game, farmed game and lagomorphs, where appropriate.*
5. *Training for official auxiliaries is to cover, and tests are to confirm knowledge of, the following subjects:*
 - (a) *in relation to holdings:*
 - (i) *theoretical part:*
 - *familiarity with the farming industry organisation, production methods, international trade, etc.,*
 - *good livestock husbandry practices,*
 - *basic knowledge of diseases, in particular zoonoses-viruses, bacteria, parasites, etc.,*
 - *monitoring for disease, use of medicines and vaccines, residue testing,*
 - *hygiene and health inspection,*
 - *animal welfare on the farm and during transport,*
 - *environmental requirements — in buildings, on farms and in general,*
 - *relevant laws, regulations and administrative provisions,*
 - *consumer concerns and quality control;*
 - (ii) *practical part:*
 - *visits to holdings of different types and using different rearing methods,*
 - *visits to production establishments,*
 - *observation of the loading and unloading of animals,*
 - *laboratory demonstrations,*
 - *veterinary checks,*
 - *documentation;*

Tuesday 15 April 2014

(b) in relation to slaughterhouses and cutting plants:

(i) theoretical part:

- *familiarity with the meat industry organisation, production methods, international trade and slaughter and cutting technology,*
- *basic knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene of work,*
- *HACCP and the audit of HACCP-based procedures,*
- *animal welfare on unloading after transport and at the slaughterhouse,*
- *basic knowledge of the anatomy and physiology of slaughtered animals,*
- *basic knowledge of the pathology of slaughtered animals,*
- *basic knowledge of the pathological anatomy of slaughtered animals,*
- *relevant knowledge concerning TSEs and other important zoonoses and zoonotic agents,*
- *knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,*
- *basic knowledge of microbiology,*
- *ante-mortem inspection,*
- *examination for trichinosis,*
- *post-mortem inspection,*
- *administrative tasks,*
- *knowledge of the relevant laws, regulations and administrative provisions,*
- *sampling procedure,*
- *fraud aspects;*

(ii) practical part:

- *animal identification,*
- *age checks,*
- *inspection and assessment of slaughtered animals,*
- *post-mortem inspection in a slaughterhouse,*
- *examination for trichinosis,*
- *identification of animal species by examination of typical parts of the animal,*
- *identifying and commenting on parts of slaughtered animals in which changes have occurred,*
- *hygiene control, including the audit of the good hygiene practices and the HACCP-based procedures,*

Tuesday 15 April 2014

- recording the results of ante-mortem inspection,
 - sampling,
 - traceability of meat,
 - documentation.
6. Official auxiliaries are to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official auxiliary is, wherever possible, to undertake annual continuing education activities.
 7. Persons already appointed as official auxiliaries must have adequate knowledge of the subjects mentioned in paragraph 5. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.
 8. However, when official auxiliaries carry out only sampling and analysis in connection with examinations for trichinosis, the competent authority need only ensure that they receive training appropriate to these tasks. [Am. 311]
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Tuesday 15 April 2014

ANNEX III

CHARACTERISATION OF METHODS OF ANALYSIS

1. Methods of analysis and measurement results should be characterised by the following criteria:
 - (a) accuracy (trueness and precision);
 - (b) applicability (matrix and concentration range);
 - (c) limit of detection;
 - (d) limit of quantification;
 - (e) precision;
 - (f) repeatability;
 - (g) reproducibility;
 - (h) recovery;
 - (i) selectivity;
 - (j) sensitivity;
 - (k) linearity;
 - (l) measurement uncertainty;
 - (m) other criteria that may be selected as required.
 2. The precision values referred to in point(e) of paragraph 1 shall either be obtained from a collaborative trial which has been conducted in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725 'Accuracy (trueness and precision) of measurement methods and results') or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and reproducibility values shall be expressed in an internationally recognised form (e.g. the 95 % confidence intervals as defined by ISO 5725 'Accuracy (trueness and precision) of measurement methods and results'). The results from the collaborative trial shall be published or freely available.
 3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.
 4. In situations where methods of analysis can only be validated within a single laboratory, then they should be validated in accordance with internationally accepted scientific protocols or guidelines, or where performance criteria for analytical methods have been established, be based on criteria compliance tests.
 5. Methods of analysis adopted under this Regulation should be edited in the standard layout for methods of analysis recommended by the ISO.
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Tuesday 15 April 2014

ANNEX IV

CORRELATION TABLE REFERRED TO IN ARTICLE 142(3)

1. Regulation (EC) No 882/2004

Regulation (EC) No 882/2004	This Regulation
Article 1(1) first subparagraph	Article 1(1)
Article 1(1) second subparagraph	Article 1(2)
Article 1(2)	Article 1(4)
Article 1(3)	—
Article 1(4)	—
Article 2	Article 2
Article 3(1)	Article 8(1)
Article 3(2)	Article 8(4)
Article 3(3)	Article 9
Article 3(4)	Article 8(6)
Article 3(5)	Article 8(6)
Article 3(6)	Article 8(7)
Article 3(7)	—
Article 4(1)	Article 3(1)
Article 4(2)	Article 4(1)(a), (c), (d), (e), (f), (g) and (i)
Article 4(3)	Article 3(2)
Article 4(4)	Article 4(1)(b)
Article 4(5)	Article 4(4)
Article 4(6)	Article 5(1)
Article 4(7)	Article 5(3)
Article 5(1) first subparagraph	Article 25(1)
Article 5(1) second subparagraph	Article 25(3)
Article 5(1) third subparagraph	Article 25(2) first subparagraph
Article 5(2)(a), (b), (c) and (f)	Article 26
Article 5(2)(d)	—
Article 5(2)(e)	Article 28
Article 5(3)	Article 29
Article 5(4)	—

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Article 6	Article 4(2) and (3)
Article 7(1), first subparagraph	Article 10(1), first subparagraph
Article 7(1), second subparagraph, point (a)	Article 10(1), second subparagraph
Article 7(1), second subparagraph, point (b)	—
Article 7(2), first sentence	Article 7(1)
Article 7(2), second sentence	—
Article 7(2), third sentence	—
Article 7(3)	Article 7(2), and (3)
Article 8(1)	Article 11(1)
Article 8(2)	Article 4(1)(h)
Article 8(3)(a)	Article 11(2)
Article 8(3)(b)	Article 11(3)
Article 8(4)	—
Article 9(1)	Article 12(1) first subparagraph
Article 9(2)	Article 12(1) second subparagraph
Article 9(3)	Article 11(2)
Article 10	Article 13
Article 11(1)	Article 33(1) and (2)
Article 11(2)	—
Article 11(3)	Article 33(5)
Article 11(4)	Article 33(7)
Article 11(5)	Article 34(1) first subparagraph and (2)
Article 11(6)	Article 34(1)(b)(i)
Article 11(7)	Article 33(6)
Article 12(1)	Article 36(1)
Article 12(2)	Article 36(4)(e)
Article 12(3)	Article 36(5)(c)
Article 12(4)	Article 38(2)
Article 13	Article 114

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Article 14(1)	—
Article 14(2)	Article 43(3)
Article 14(3)	—
Article 15(1)	Article 42(1) first sentence
Article 15(2)	Article 42(2) and (4)
Article 15(3)	Article 42(2) and (4)
Article 15(4)	—
Article 15(5)	Article 45(1)(d), 45(2)(b) and 52(3), first sentence
Article 16(1)	Article 43(1)
Article 16(2)	Article 42(1) second sentence
Article 16(3) first sentence	Article 43(2)
Article 16(3) second sentence	Article 33(6)
Article 17(1) first indent	Article 57(1)
Article 17(1) second indent	Article 54(1),(2)(a), (3) and Article 56(1)
Article 17(2)	—
Article 18	Article 63(1), (2) and (3)
Article 19(1)	Article 64(1) and (3)
Article 19(2)a	Article 65
Article 19(2)b	Article 64(5)
Article 19(3)	Article 64(4)
Article 19(4)	Article 6
Article 20	Article 69
Article 21(1)	Article 70(1)
Article 21(2)	Article 67
Article 21(3)	Article 64(1)
Article 21(4)	Article 64(4)
Article 22	Article 84(d)
Article 23(1)	Article 71(1)
Article 23(2)	Article 71(2) and 72

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Article 23(3)	Article 71(3)
Article 23(4)	Article 71(2)
Article 23(5)	Article 71(4)(a)
Article 23(6)	Article 71(2)(c) and (4)(b)
Article 23(7)	Article 72
Article 23(8)	Article 72
Article 24(1)	Article 73(1)
Article 24(2)	Article 55
Article 24(3)	Article 44
Article 24(4)	Article 74
Article 25(1)	—
Article 25(2)(a)	—
Article 25(2)(b)	Article 75(1)(c)
Article 25(2)(c)	Article 75(1)(f)
Article 25(2)(d)	Article 46(c) and (d), and 75(1)(e) and (k)
Article 25(2)(e)	—
Article 25(2)(f)	Article 68
Article 25(2)(g)	Article 75(1)(h)
Article 25(2)(h)	Article 44(2)(b)
Article 26	Article 76(1)
Article 27(1)	Article 76(2)
Article 27(2)	Article 77
Article 27(3)	—
Article 27(4)	Article 79(1)
Article 27(5)	—
Article 27(6)	—
Article 27(7)	—
Article 27(8)	Article 81(2)
Article 27(9)	Article 82(1)
Article 27(10)	—
Article 27(11)	Article 81(1)
Article 27(12) first sentence	Article 83

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Article 27(12) second sentence	—
Article 28	Article 84
Article 29	—
Article 30(1) point (a)	Article 86
Article 30(1) point (b)	Article 89 point (a)
Article 30(1), point (c)	Article 87(2)
Article 30(1) point (d)	Article 89 points (b) and (f)
Article 30(1) point (e)	Article 89 point (c)
Article 30(1) point (f)	Article 89 point (d)
Article 30(1) point (g)	Article 89 point (e)
Article 30(2)(a)	Article 88(1)(e)
Article 30(2)(b)	Article 88(1)(c)
Article 30(3)	—
Article 31	—
Article 32(1)(a)	Article 92(2)(a)
Article 32(1)(b)	Article 92(2)(b)
Article 32(1)(c)	Article 92(2)(c)
Article 32(1)(d)	Article 92(2)(d)
Article 32(1)(e)	Article 92(2)(e)
Article 32(1)(f)	Article 92(2)(g)
Article 32(2)(a)	Article 92(2)(a), (b) and (c)
Article 32(2)(b)	Article 92(2)(h)
Article 32(2)(c)	Article 92(2)(d)
Article 32(2)(d)	Article 92(2)(g)
Article 32(2)(e)	Article 92(2)(d)
Article 32(3)	Article 91(3)(a)
Article 32(4)(a)	Article 91(3)(c)
Article 32(4)(b)	Article 91(3)(d)
Article 32(4)(c)	Article 91(3)(d)
Article 32(4)(d)	Article 7
Article 32(4)(e)	Article 91(3)(e)
Article 32(4)(f)	Article 92(2)(j)(iii)
Article 32(4)(g)	Article 91(3)(e)

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Article 32(4)(h)	Article 91(3)(f)
Article 32(5)	Article 97(1)
Article 32(6)	Article 97(2)
Article 32(7)	—
Article 32(8) first sentence	Article 97(3)
Article 32(8) second sentence	Article 97(4)
Article 32(9)	—
Article 33(1)	Article 98(1)
Article 33(2)	Article 99(1)
Article 33(3)	Article 98(2)
Article 33(4)	Article 98(4)
Article 33(5)	Article 98(5)
Article 33(6)	Article 99(2)
Article 33(7)	—
Article 34(1)	Article 100(1)
Article 34(2)	Article 100(1) and (2)
Article 34(3)	Article 100(3)
Article 35(1)	Article 101(1)
Article 35(2)	Article 101(4)
Article 35(3)	Article 101(2)
Article 35(4)	—
Article 36(1)	Article 102(1)(c)
Article 36(2) first sentence	—
Article 36(2) second sentence	Article 102(2)
Article 36(3) first subparagraph	Article 102(3) first sentence
Article 36(3) second subparagraph	—
Article 36(3) third subparagraph, first sentence	Article 102(3)(c)
Article 36(3) third subparagraph, second sentence	Article 102(3)(b)
Article 36(4)	Article 102(3)(a)
Article 37(1)	Article 103(1)
Article 37(2)	Article 103(2)

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Article 38(1)	Article 104(1)
Article 38(2)	Article 104(2)(c)
Article 38(3)	Article 104(3)
Article 39(1)	Article 105(1)
Article 39(2)	Article 105(2)
Article 40(1)	Article 106(1)
Article 40(2)	—
Article 40(3)	Article 106(2)
Article 40(4)	—
Article 41	Article 107(1)
Article 42(1)(a)	—
Article 42(1)(b)	Article 109(2)
Article 42(1)(c)	Article 109(3)
Article 42(2)	Article 108(2)
Article 42(3)	Article 109(2)
Article 43(1) first sentence	Article 110, first subparagraph
Article 43(1) second sentence	Article 110, second subparagraph
Article 43(1)(a)	—
Article 43(1)(b)	Article 110(a) and (b)
Article 43(1)(c)	Article 110(b) and (c)
Article 43(1)(d) to (j)	—
Article 43(1)(k)	Article 110(d)
Article 43(2)	—
Article 44(1)	Article 112(1)
Article 44(2)	—
Article 44(3)	Article 112(1)
Article 44(4), first subparagraph, first sentence	Article 113(1)
Article 44(4) first subparagraph, second sentence	Article 113(2)
Article 44(5)	—
Article 44(6)	Article 113(1)

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Article 45(1)	Article 115(1)(2) and (4)
Article 45(2)	—
Article 45(3)	Article 116
Article 45(4)	Article 117
Article 45(5)	Article 118
Article 45(6)	—
Article 46(1) first sentence	Article 119(1)
Article 46(1) second sentence	Article 119(4)
Article 46(1) third sentence	Article 119(2)
Article 46(2)	Article 119(3)
Article 46(3)	Article 120
Article 46(4)	—
Article 46(5)	—
Article 46(6)	Article 121
Article 46(7)	Article 122
Article 47(1)	Article 124(1)(a) to (e)
Article 47(2)	Article 124(2)
Article 47(3)	Article 124(1)(f) and (g)
Article 47(4)	—
Article 47(5)	—
Article 48(1)	Article 125(1)
Article 48(2)	Article 125(2)
Article 48(3)	Article 126(1) and (2)
Article 48(4)	Article 126(3)
Article 48(5) first sentence	Article 126(3)(f)
Article 48(5) second and third sentence	—
Article 49	Article 128
Article 50	—
Article 51(1)	Article 129(1) and (2)
Article 51(2)	Article 129(3)
Article 51(3)	—

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Article 52	Article 123
Article 53	Article 111
Article 54(1)	Article 135(1)
Article 54(2)	Article 135(2)
Article 54(3)	Article 135(3)
Article 54(4)	Article 103(1)
Article 54(5)	Article 84(1) (a) and(c) and Article 135(4)
Article 55(1)	Article 136(1)
Article 55(2)	Article 136(1)
Article 56(1)	Article 137(1)
Article 56(2)(a)	—
Article 56(2)(b)	Article 137(2)
Articles 57 to 61	—
Article 62	Article 141
Article 63(1)	—
Article 63(2)	Article 23
Article 64 first subparagraph	Article 138(1)
Article 64 point (1)	Article 138(1)
Article 64 point (2)	Article 138(2)
Article 65	—
Article 66	—
Article 67	
Annex I	Annex I
Annex II	Annex II
Annex III	Annex III
Annex IV	—
Annex V	—
Annex VI	Article 78 and 79(2)

Tuesday 15 April 2014

Regulation (EC) No 882/2004	This Regulation
Annex VII	—
Annex VIII	—
2. Directive 96/23/EC	
Directive 96/23/EC	This Regulation
Article 1	—
Article 2(a)	Article 16
Article 2(b)	—
Article 2(c)	Article 16
Article 2(d)	Article 2(5)
Article 2(e)	Article 16
Article 2(f)	Article 36(1)
Article 2(g)	—
Article 2(h)	Article 16
Article 2(i)	—
Article 3	Articles 8(1) and (2), 16, 107(1) and 111
Article 4(1)	Article 3(1)
Article 4(2)	Articles 3(2)(a), 107(2) and 112
Article 4(3)	—
Article 5	Articles 109(2) and (3), 112(1)(a) and 108(2)
Article 6	Articles 16(a) and (b)
Article 7	Article 108(2)
Article 8(1)	—
Article 8(2)	—
Article 8(3), (4) and (5)	Articles 10, 112 and 113
Article 9(A)	—
Article 9(B)	—
Article 10	Article 14

Tuesday 15 April 2014

Directive 96/23/EC	This Regulation
Article 11(1) and (2)	Articles 8(2) and 9
Article 11(3)	Articles 16(c), 134 and 135
Article 12 first paragraph	Article 8(4)
Article 12 second paragraph	Article 14
Article 13	Articles 16(c), 134 and 135
Article 14(1)	Articles 98 and 99
Article 14(2)	Article 91
Article 15(1) first subparagraph	Article 16(a) and (b)
Article 15(1) second subparagraph	Article 33(7)
Article 15(1) third subparagraph	—
Article 15(2) first subparagraph	Article 33(7)
Article 15(2) second subparagraph	Article 34(3)
Article 15(3) first, second and third subparagraphs	Articles 16(c) and 135
Article 15(3) fourth subparagraph	Title II Chapter V Section III
Article 16(1)	Articles 103(1), 106(1) and 135
Article 16(2) and (3)	Articles 16(c) and 135
Article 17	Articles 16(c) and 135
Article 18	Articles 16(c) and 135
Article 19	Article 135(4)
Article 20(1)	Title IV
Article 20(2) first subparagraph	Article 104(1) and (2)
Article 20(2) second subparagraph	Article 104(3)
Article 20(2) third and fourth subparagraphs	Article 106(1)(d)
Article 20(2) fifth and sixth subparagraphs	Article 106(2)
Article 21	Articles 115, 116 and 118
Article 22	Article 134
Article 23	Articles 16(c) and 135

Tuesday 15 April 2014

Directive 96/23/EC	This Regulation
Article 24(1) and (2)	Articles 15(2)(d), 16(c), 134 and 135
Article 24(3)	Articles 15(2)(d), 16(c) and 135
Article 25	Articles 16(c) and 135(2)
Article 26	Article 6
Article 27	Article 136
Article 28	Article 136
Article 29(1) and (2)	Articles 124, 125, 126 and 128
Article 29(3)	Title II Chapter V Section II
Article 29(4)	Article 112(1)
Article 30(1) and (2)	Title II Chapter V Section III
Article 30(3)	Article 128(3)
Article 31	Title II Chapter VI
Article 33	Article 141
Article 34	Article 16(a) and (b)
Article 35	—
Article 36	—
Article 37	—
Article 38	—
Article 39	—
Annex I	Article 16(a) and (b)
Annex II	Article 16(a) and (b)
Annex III	Article 16(a) and (b)
Annex IV	Article 16(a) and (b)
3. Directives 89/662/EEC and 90/425/EEC	
Directive 89/662/EEC	This Regulation
Article 1	—

Tuesday 15 April 2014

Directive 89/662/EEC	This Regulation
Article 2(1), (2) and (3)	—
Article 2(4)	Article 2(5)
Article 2(5)	Article 2(32)
Article 3(1) first and second subparagraphs	—
Article 3(1) third subparagraph	Article 8(1)
Article 3(1) fourth subparagraph	Article 134(2) and (3) and Article 135
Article 3(2)	—
Article 3(3)	—
Article 4(1) first sentence	Article 8(1), 9, 134 and 135
Article 4(1) first indent	Article 8(6)(a)
Article 4(1) second indent	—
Article 4(2)	Article 136
Article 5(1)(a) first subparagraph	Article 8
Article 5(1)(a) second subparagraph	Article 134(2) and (3)
Article 5(1)(b)	—
Article 5(2)	—
Article 5(3)(a), (b) and (d)	—
Article 5(3)(c)	Article 8(7)
Article 5(4) and (5)	—
Article 6(1)	Article 47
Article 6(2)	—
Article 7(1)	Title IV and Article 135
Article 7(2)	—
Article 8(1)	Title IV
Article 8(2)	Articles 6 and 135(3)
Article 8(3)	Article 135(4)
Article 9	—
Article 10	Article 3(1)
Article 11	Articles 9, 13 and 14
Article 12	—

Tuesday 15 April 2014

Directive 89/662/EEC	This Regulation
Article 13	—
Article 14	—
Article 15	—
Article 16(1)	Article 112(1)
Article 16(2)	—
Article 16(3)	Article 112(2)
Article 17	Article 141
Article 18	Article 141
Article 19	—
Article 20	—
Article 22	—
Article 23	—
Annex A	—
Annex B	—
Directive 90/425/EEC	This Regulation
Article 1	—
Article 2(1) to (5)	—
Article 2(6)	Article 2(5)
Article 2(7)	Article 2(32)
Article 3(1) and (2)	—
Article 3(3)	Articles 8, 134(2) and (3) and 135
Article 3(4)	—
Article 4(1)	Article 8
Article 4(2)	—
Article 4(3)	Article 136
Article 5(1)(a) first subparagraph	Article 8
Article 5(1)(a) second subparagraph	Article 134(2) and (3)
Article 5(1)(b)(i) first subparagraph	—

Tuesday 15 April 2014

Directive 90/425/EEC	This Regulation
Article 5(1)(b)(i) second subparagraph	Article 8
Article 5(1)(b)(ii), (iii) and (iv)	—
Article 5(2)(a) first subparagraph	Article 8(7)
Article 5(2)(a) second and third subparagraphs	—
Article 5(2)b	—
Article 5(3)	—
Article 6	—
Article 7(1)	Article 47
Article 7(2)	—
Article 8(1)	Title IV and Article 135
Article 8(2)	—
Article 9(1)	Title IV
Article 9(2)	Articles 6 and 135(3)
Article 9(3)	Article 135(4)
Article 9(4)	—
Article 10	—
Article 11	Article 3(1)
Article 12	—
Article 13	Articles 9, 13 and 14
Article 14	—
Article 15	—
Article 16	—
Article 17	Article 141
Article 18	Article 141
Article 19	Article 141
Article 20	Articles 130, 131, 132 and 133
Article 21	—

Tuesday 15 April 2014

Directive 90/425/EEC	This Regulation
Article 22(1)	Article 112(1)
Article 22(2)	—
Article 22(3)	Article 112(2)
Article 23	—
Article 24	—
Article 26	—
Article 27	—
Annex A	—
Annex B	—
Annex C	—

4. Directives 97/78/EC and 91/496/EEC

Directive 97/78/EC	This Regulation
Article 1	—
Article 2	Article 2
Article 2(2)(a)	Article 2(17)
Article 2(2)(b)	Article 2(46)
Article 2(2)(c)	Article 2(47)
Article 2(2)(d)	Article 2(48)
Article 2(2)(e)	—
Article 2(2)(f)	Article 2(27)
Article 2(2)(g)	Article 2(29)
Article 2(2)(h)	—
Article 2(2)(i)	—
Article 2(2)(j)	—
Article 2(2)(k)	Article 2(5)
Article 3(1) and (2)	Article 45(1)
Article 3(3)	Article 14 and 54(1), (2)(a) and (3)
Article 3(4)	Article 55
Article 3(5)	Article 45(2) and (3) and Article 56

Tuesday 15 April 2014

Directive 97/78/EC	This Regulation
Article 4(1)	Article 47(4)
Article 4(2)	—
Article 4(3) and (4)	Article 47(1), (2) and (3) and Article 50
Article 4(5)	Article 50
Article 5(1)	Article 54(2)(b) and(4)
Article 5(2)	Article 56(2)
Article 5(3)	Article 48(2) and (3)
Article 5(4)	Article 56
Article 6(1)(a), first paragraph	Article 62(1)
Article 6(1)(a) second paragraph	Article 62(2)
Article 6(1)(b)	—
Article 6(2)	Article 57 and 60
Article 6(3)	Article 61
Article 6(4)	Article 58(1) and 61(3)
Article 6(5)	—
Article 6(6)	Article 58(2), 60(3), 61(5), 62(2), 62(4)
Article 7(1)	Article 48(1)
Article 7(2)	Article 47(1), (2) and (3) and Article 50
Article 7(3)	Article 55
Article 7(4)	Article 48(2), 53 and 54(4)
Article 7(5)	—
Article 7(6)	Article 50 and 56
Article 8(1)	—
Article 8(2)	Article 75(1)(b)
Article 8(3),(4), (5), (6), (7)	Article 75(2)
Article 9	Article 49(b) and (c)
Article 10(1), (2), (4)	Article 52(2)
Article 10(3)	—
Article 11	Article 49(d)
Article 12	Articles 46(h) and 75(1)(k)

Tuesday 15 April 2014

Directive 97/78/EC	This Regulation
Article 13	Article 75(1)(c)
Article 14	—
Article 15	Article 75(1)(h)
Article 16(1)(a)	Article 46(d)
Article 16(1)(b)	Article 46(e)
Article 16(1)(c)	Article 46(c)
Article 16(1)(d)	Article 46(g)
Article 16(1)(e)	Article 46(a)
Article 16(1)(f)	Article 46(b)
Article 16(2)	—
Article 16(3)	—
Article 16(4)	Article 75(1)(c) and (f)
Article 17(1)	Article 64(5)
Article 17(2)	Article 64(1), (2) and (3)
Article 17(2)(a)	Article 64(3)(b), 67 and Article 70
Article 17(2)(a) first indent	—
Article 17(2)(a) second indent	Article 66(1)(a)
Article 17(2)(b)	Article 67
Article 17(3)	Article 63(4), (5) and (6)
Article 17(4)	—
Article 17(5)	Articles 64(3), 67, 84(1)(d)
Article 17(6)	—
Article 17(7)	Article 63(6), 68 and 70(3)
Article 18	Article 62(2)
Article 19(1)	Article 75(1)(g)
Article 19(2)	Article 75(1)(a)
Article 19(3)	Article 62(3)(a) and 62(4)
Article 20(1)	Article 63
Article 20(2)	—
Article 22(1)	—
Article 22(2)	Article 65

Tuesday 15 April 2014

Directive 97/78/EC	This Regulation
Article 22(3)	—
Article 22(4)	—
Article 22(5)	—
Article 22(6)	—
Article 22(7)	—
Article 24	Article 63(4), (5) and (6)
Article 24(3)	Articles 71 and 128
Article 25(1)	Articles 100-106
Article 25(2)	Article 6
Article 25(3)	—
Article 26	Article 129(5) and (6)
Article 27	Article 4(2) and (3) and 129(1) and (6)
Article 28	—
Article 29	—
Article 30	—
Article 31	—
Article 32	—
Article 33	—
Article 34	—
Article 35	—
Article 36	—
Annex I	Annex I
Annex II	Article 62
Annex III	Article 50
Directive 91/496/EEC	This Regulation
Article 1	—
Article 2(1)	—
Article 2(2)a	Article 2(46)

Tuesday 15 April 2014

Directive 91/496/EEC	This Regulation
Article 2(2)b	Article 2(47)
Article 2(2)c	Article 2(48)
Article 2(2)d	—
Article 2(2)e	Article 2(27)
Article 2(2)f	Article 2(29)
Article 3(1)(a)	Articles 54(1) and (2)(a), 56(1)(b)
Article 3(1)(b)	Article 45(1), 64(2)
Article 3(1)(c)(i)	Articles 54(2)(b), 54(4), and 55
Article 3(1)(c)(ii)	Article 77(1)(d)
Article 3(1)(d)	Article 55
Article 3(2)	—
Article 4(1)	Articles 47(1), 47(2) and 50
Article 4(2)	Articles 47(1), 47(3), 47(4) and 50
Article 4(3)	Article 49c
Article 4(4)	Article 77(1)(d)
Article 4(5)	Article 4(2) and (3), 49(c) and 50
Article 5	Articles 53, 54(2)(b), 54(4), 55, 56(1)(a), and 64(1).
Article 6(1)	—
Article 6(2)(a)	Article 62(1) and (2)
Article 6(2)(b)	Article 62(1)
Article 6(2)(c)	Article 57
Article 6(2)(d)	Article 62(3)(a) and (4)
Article 6(3)	Article 58
Article 6(3)(a)	Article 58(1)(b)
Article 6(3)(b)	Article 58(1)(c)
Article 6(3)(c)	Articles 57(2) and 62(3)
Article 6(3)(d)	Article 58(1)(d)
Article 6(3)(e)	Articles 57(2) and 62(3)
Article 6(3)(f)	Articles 57(2) and 62(3)
Article 6(3)(g)	Article 58(1)(e)

Tuesday 15 April 2014

Directive 91/496/EEC	This Regulation
Article 6(4)	Article 57 and 58(1)
Article 6(5)	Article 58(2)
Article 7(1) first indent	Article 48(2)
Article 7(1) second indent	Articles 54(2)(b), 54(4) and 56
Article 7(1) third indent	Article 48(1)
Article 7(2)	Article 56
Article 7(3)	—
Article 8	Article 51(1)(b)
Article 9	Article 49(d)
Article 10	Article 64(2)
Article 11(1)	Article 63
Article 11(2)	—
Article 12 (1)	Articles 64, 66 and 67
Article 12(2)	Articles 64(3), 67, 84(1)(d)
Article 12(3)	Articles 68, 69(3) and 70(3)
Article 12(4)	—
Article 12(5)	—
Article 13	Article 62(2)
Article 14	—
Article 15	Article 77(1)(d)
Article 16	Articles 52
Article 17	Article 6
Article 17a	—
Article 18(1)	—
Article 18(2)	Article 65
Article 18(3)	—
Article 18(4)	—
Article 18(5)	—

Tuesday 15 April 2014

Directive 91/496/EEC	This Regulation
Article 18(6)	—
Article 18(7)	—
Article 18(8)	—
Article 19	Article 115 and 116
Article 20	Articles 100 to 106
Article 21	Article 129 (5) and (6)
Article 22	—
Article 23	—
Article 24	—
Article 25	—
Article 26	—
Article 27	—
Article 28	—
Article 29	—
Article 30	—
Article 31	—
Annex A	Article 62
Annex B	Article 64(2)

5. Directive 96/93/EC

Directive 96/93/EC	This Regulation
Article 1	—
Article 2(1)	Article 2(22)
Article 2(2)	Article 2
Article 3(1)	Article 87(2)(b)
Article 3(2)	Article 87(3)(a) and (b)
Article 3(3)	Article 88(1)(a)
Article 3(4)	Article 87(3)(b)

Tuesday 15 April 2014

Directive 96/93/EC	This Regulation
Article 3(5)	Article 89
Article 4(1)	Articles 87(2)(a) and 88(2)
Article 4(2)	Article 88(1)(b)
Article 4(3)	Article 88(1)(d)
Article 5	Article 88(2)
Article 6	Article 128
Article 7	Article 141
Article 8	—
Article 9	—
Article 10	—

6. Directive 89/608/EEC

Directive 89/608/EEC	This Regulation
Article 1	—
Article 2	—
Article 3	Title IV
Article 4	Title IV
Article 5	Title IV
Article 6	Title IV
Article 7	Title IV
Article 8	Title IV
Article 9	Title IV
Article 10	Article 7 and Title IV
Article 11	—
Article 12	Title IV
Article 13	—
Article 14	—

Tuesday 15 April 2014

Directive 89/608/EEC	This Regulation
Article 15	Article 7 and Title IV
Article 16	—
Article 17	—
Article 18	—
Article 19	—
Article 20	—
7. Decision 92/438/EEC	
Decision 92/438/EEC	This Regulation
Article 1	Articles 130 to 133
Article 2	—
Article 3	Articles 130 to 133
Article 4	Articles 130 to 133
Article 5	Articles 130 to 133
Article 6	Article 62(3)(f)
Article 7	—
Article 8	—
Article 9	—
Article 10	—
Article 11	—
Article 12	—
Article 13	—
Article 14	—
Article 15	—
Annex I	Articles 130 to 133
Annex II	Articles 130 to 133
Annex III	Articles 130 to 133

Tuesday 15 April 2014

P7_TA(2014)0381

Animal health *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on Animal Health (COM(2013)0260 — C7-0124/2013 — 2013/0136(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/60)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0260),
 - having regard to Article 294(2) and Articles 43(2) and 114(3) and point (b) of Article 168(4) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0124/2013),
 - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Austrian Federal Council, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 10 December 2013 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to Rules 55 and 37 of its Rules of Procedure,
 - having regard to the report of the Committee on Agriculture and Rural Development and the opinions of the Committee on the Environment, Public Health and Food Safety and the Committee on Fisheries (A7-0129/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0136**Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on ~~Animal Health~~ *the prevention and control of animal diseases which are transmissible among animals or to humans* [Am. 1]**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114(3) and Article 168(4)(b) thereof,

⁽¹⁾ Not yet published in the Official Journal.

Tuesday 15 April 2014

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) The impact of transmissible animal diseases and the measures necessary to control these diseases can be devastating for individual animals, animal populations, animal keepers and the economy **and can have a major influence on public health and food safety**. [Am. 2]
- (2) As recent experiences have demonstrated, transmissible animal diseases may also have a significant impact on public health **and food safety**, as for example in the case of avian influenza and salmonella. [Am. 3]
- (3) In addition, adverse interactive effects can be observed with regard to biodiversity, climate change and other environmental aspects. Climate change may influence the emergence of new diseases, the prevalence of existing diseases and the geographic distribution of disease agents and vectors, including those affecting wildlife.
- (3a) **Proper control of infectious animal diseases, including zoonotic diseases, is a prerequisite for a functioning single market for trade in live animals, animal products and food**. [Am. 4]
- (4) In order to ensure high standards of animal and public health in the Union, the rational development of the agriculture and aquaculture sectors and to increase productivity, animal health rules should be laid down at Union level. These rules are necessary, inter alia, to contribute to the completion of the internal market, and to avoid the spread of infectious diseases.
- (4a) **Article 13 of the Treaty on the Functioning of the European Union (TFEU) recognises that animals are sentient beings. Union legislation on animal welfare requires animal owners, animal keepers and competent authorities to respect animal welfare requirements guaranteeing their humane treatment and avoiding them unnecessary pain and suffering. Such rules are based on scientific evidence and may improve animal health**. [Am. 5]
- (5) The current Union animal health legislation consists of a series of linked and interrelated basic acts that lay down rules on animal health applying to intra-Union trade, entry into the Union of animals and products, disease eradication, veterinary controls, notification of diseases and financial support in relation to different animal species, but an overarching legal framework, providing harmonised principles across the sector is missing.
- (5a) **With a view to making the provisions of Union animal health legislation as clear as possible, and thus ensuring that they are fully and correctly implemented, a criterion and principle for organising the delegated and implemented acts adopted pursuant to this Regulation needs to be laid down**. [Am. 6]

⁽¹⁾ Not yet published in the Official Journal.

⁽²⁾ Position of the European Parliament of 15 April 2014.

Tuesday 15 April 2014

- (6) The Animal Health Strategy for the Union (2007– 2013) proposes that ‘Prevention is better than cure’ and was adopted by the Commission in its Communication of 19 September 2007 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. It aims to ~~put~~ **promote animal health through putting** greater focus on preventive measures, disease surveillance, disease control and research, in order to reduce the incidence of animal diseases and minimise the impact of outbreaks when they do occur. It proposes the adoption of a ‘single and simplified regulatory framework for animal health’ seeking convergence to international standards while ensuring a firm commitment to high standards of animal health. [Am. 7]
- (7) The aim of this Regulation is to implement the commitments and visions provided for in that Animal Health Strategy, including the ‘One health’ principle, and to consolidate the legal framework for a common Union animal health policy through a single, simplified, and flexible regulatory framework for animal health.
- (7a) **The Commission Communication on the new Animal Health Strategy for the European Union stresses that a joint approach should be taken to prevention and biosecurity measures, given that contagious disease agents can spread easily from one farm to another.** [Am. 8]
- (8) Animals may suffer from a broad range of infectious or non-infectious diseases. Many diseases can be treated, have an impact only on the individual animal concerned or do not spread to other animals or to humans. On the other hand, transmissible diseases may have a broader impact on animal or public health with effects felt on a population level. The animal health rules laid down in this Regulation should only be limited to those latter diseases.
- (9) In laying down those animal health rules, it is essential that considerations are given to the link between animal health and public health, the environment, food and feed safety, ~~animal welfare~~, food security, economic, social ~~and cultural aspects~~, **cultural aspects and especially animal welfare, given the interdependency of animal welfare and animal health** [Am. 9].
- (10) Council Decision 94/800/EC ⁽¹⁾ approved on behalf of the then European Community, with regard to that portion of those matters which falls within its competence the Agreement establishing the World Trade Organization (WTO), and also the Agreements set out in Annexes 1, 2 and 3 to that Agreement which include the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement regulates the use of measures necessary to protect human, animal or plant life or health so that they do not arbitrarily or unjustifiably discriminate between WTO members. If international standards exist, they are required to be used as a basis. However, the members have the right to set their own relevant standards provided that such standards are based on scientific evidence.
- (11) As regards animal health the SPS Agreement refers to the standards of the World Organisation for Animal Health (OIE) as regards animal health conditions for international trade. In order to reduce the risk of trade disruption, EU measures on animal health should aim for an appropriate level of convergence with OIE standards.
- (12) In specific circumstances where a significant animal or public health risk exists but scientific uncertainty persists, Article 5(7) of the SPS Agreement which has been interpreted for the Union in the Communication from the Commission of 2 February 2000 on the precautionary principle allows a Member of that agreement to adopt provisional measures on the basis of available pertinent information. In such circumstances, the WTO Member is required to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.
- (13) The risk assessment, on the basis of which the measures under this Regulation are taken, should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Due account should also be taken of the opinions of the European Food Safety Authority established by Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽²⁾.

⁽¹⁾ Council Decision 94/800/EC, of 22 December 1994, concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ L 336, 23.12.1994, p. 1).

⁽²⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Tuesday 15 April 2014

- (14) Regulation (EC) No 1069/2009 of the European Parliament and the Council⁽¹⁾ lays down both public and animal health rules for certain animal by-products and derived products in order to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain. In order to avoid any overlap of Union legislation, this Regulation should therefore only apply to animal by-products and derived products where specific rules are not laid down in Regulation (EC) No 1069/2009, and where an animal health risk is involved. For instance, Regulation (EC) No 1069/2009 does not regulate how to handle animal by-products and derived products in the context of disease control measures, and so these issues are duly covered by this Regulation.
- (15) In addition, specific rules on transmissible animal diseases including those transmissible to humans ('zoonoses') are already laid down in Regulation (EC) No 999/2001 of the European Parliament⁽²⁾, Directive 2003/99/EC of the European Parliament and of the Council⁽³⁾ and Regulation (EC) No 2160/2003 of the European Parliament and of the Council⁽⁴⁾, and specific rules on communicable diseases in humans in Decision No 2119/98/EC of the European Parliament and of the Council⁽⁵⁾. Those acts should remain in force following the adoption of this Regulation. Accordingly, in order to avoid any overlap of Union legislation, this Regulation should only apply to zoonoses to the extent that specific rules are not already laid down in those other Union acts.
- (16) Diseases occurring in wild animal populations may have a detrimental effect on the agriculture and aquaculture sectors, on public health, the environment and biodiversity. It is therefore appropriate that the scope of this Regulation should, in such cases, cover wild animals, both as potential victims of those diseases and as their vectors.
- (17) Animal diseases are not only transmitted through direct contact between animals or between animals and humans. They are also carried further afield through water and air systems, vectors such as insects, or the semen, ova and embryos used in artificial insemination, ovum donation or embryo transfer. Disease agents may also be contained in food and other products of animal origin such as leather, fur, feathers, horn and any other material derived from the body of an animal. Moreover various other objects such as transport vehicles, equipment, fodder and hay and straw may diffuse disease agents. Therefore, effective animal health rules need to cover all paths of infection and material involved therein.
- (18) Animal diseases may have detrimental effects on the distribution of animal species in the wild, and thus affect biodiversity. Microorganisms causing animal diseases can therefore fall within the definition of invasive alien species of the United Nations Convention on Biological Diversity. The measures provided for in this Regulation also take account of biodiversity and thus this Regulation should cover animal species and disease agents, including those defined as invasive animal species, which play a role in the transmission of, or are affected by, diseases covered by this Regulation.

⁽¹⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

⁽²⁾ Regulation (EC) No 999/2001 of the European Parliament and of the Council, of 22 May 2001, laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

⁽³⁾ Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).

⁽⁴⁾ Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

⁽⁵⁾ Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1).

Tuesday 15 April 2014

- (19) In Union legislation adopted prior to this Regulation separate animal health rules are laid down for terrestrial and aquatic animals. Council Directive 2006/88/EC ⁽¹⁾ lays down specific rules for aquatic animals. Yet in most cases, the main principles for good animal health governance **and good animal husbandry** are applicable to both groups of animal species. Accordingly, the scope of this Regulation should cover both terrestrial and aquatic animals and aligns those animal health rules where applicable. However, for certain aspects, in particular the registration and approval of establishments and the traceability and movements of animals within the Union, this Regulation adheres to the approach adopted in the past, which was to lay down different sets of animal health rules for terrestrial and aquatic animals due to their different environments and accordingly different requirements to safeguard health. [Am. 10]
- (20) Union legislation adopted prior to this Regulation and in particular Council Directive 92/65/EEC ⁽²⁾ also lays down basic animal health rules for other animal species not regulated in other Union acts, such as reptiles, amphibians, marine mammals, and others which are not aquatic or terrestrial animals as defined in this Regulation. Usually, such species do not represent a significant health risk for humans or other animals and therefore only a few animal health rules, if any, apply. In order to avoid unnecessary administrative burdens and costs, this Regulation should adhere to the approach adopted in the past, namely to provide the legal framework for detailed animal health rules for movements of such animals and their products to be laid down if the risks involved so require.
- (21) The keeping of pet animals, including ornamental aquatic animals in households and non-commercial ornamental aquaria, both indoors and outdoors, generally represents a lower health risk compared to other ways of keeping or moving animals on a broader scale, such as those common in agriculture. Therefore, it is not appropriate that the general requirements concerning registration, record keeping and movements within the Union apply to such animals, as this would represent an unjustified administrative burden and cost. Registration and record keeping requirements should therefore not apply to pet keepers. In addition, specific rules should be laid down for non-commercial movements of pet animals within the Union.
- (22) Some defined groups of animals, for which special animal health rules exist in this Regulation, need to be listed as species in an Annex, due to the broad scope of the group. This is the case for the group of hooved mammals classified as ungulates. This list may need to be changed in the future due to reasons of changed taxonomy, scientific development or technical updates justified by science. Similarly, the list of species of pet animals may need to be adjusted due to developments in society, or changed habits of keeping pet animals, in particular where these animals transmit diseases. Therefore, in order to take account of such changes, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the lists of pet animals and ungulates set out in Annexes I and II to this Regulation.
- (23) Not all transmissible animal diseases can or should be prevented and controlled through regulatory measures, for example, if the disease is too widespread, diagnostic tools are not available, or if the private sector can take measures to control the disease by itself. Regulatory measures to prevent and control transmissible animal diseases may have important economic consequences for the relevant sectors and disrupt trade. It is therefore essential that such measures are only applied when proportionate and necessary, such as when a disease presents or is suspected to present a significant risk to animal or public health.
- (24) Furthermore, the preventive and control measures for each transmissible animal disease should be 'tailor-made' in order to address its unique epidemiological profile and its consequences. The preventive and control rules applying to each of them should therefore be disease specific, **and strict attention should be paid to different regional conditions**. [Am. 11]

⁽¹⁾ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

⁽²⁾ Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

Tuesday 15 April 2014

- (25) For transmissible animal diseases a disease condition is usually associated with clinical or pathological manifestation of the infection. However, for the purpose of this Regulation, which aims to control the spread of and eradicate certain transmissible animal diseases, the disease definition should be wider in order to include other carriers of the disease agent.
- (26) Some transmissible animal diseases do not easily spread to other animals or to humans and thus do not cause economic or biodiversity damage on a wide scale. Therefore, they do not represent a serious threat to animal or public health in the Union and can thus, if desired, be addressed by national rules.
- (27) For transmissible animal diseases that are not subject to measures laid down at Union level, but which are of some economic importance for the private sector at a local level, the latter should, with the assistance of the competent authorities of the Member States, take actions to prevent or control such diseases, for instance through self-regulatory measures or the development of codes of practice.
- (28) In contrast to the transmissible animal diseases described in recitals 26 and 27, highly transmissible animal diseases may easily spread across borders and, if they are also a zoonosis, they may also have an impact on public health and food safety. Hence highly transmissible animal diseases and zoonoses should be covered by this Regulation.
- (29) Action No. 5 of the Communication from the Commission to the European Parliament and the Council — Action plan against the rising threats from Antimicrobial Resistance emphasises the preventive role of this Regulation and the consequent expected reduction of the use of antibiotics in animals. Resistance of microorganisms to antimicrobials to which they were previously responsive is increasing. This resistance complicates the treatment of infectious diseases in humans and animals. As a result, microorganisms that have developed resistance to antimicrobials should be treated as if they were transmissible diseases, and thus covered by the scope of this Regulation.
- (30) New hazards associated with certain diseases or species may develop in particular due to changes in the environment, the climate, animal husbandry, farming traditions but also through social changes **and changes in economic and trade relations inside and outside the Union. Unless they are totally eradicated, diseases currently confined to limited geographical areas could spread and cause economic damage over wider areas. Furthermore, scientific progress may also lead to new knowledge and increased awareness concerning existing diseases. Furthermore At the same time**, diseases and species that are important today may be marginalised in the future. Therefore the scope of this Regulation should be broad and the rules laid down should be focused on diseases with high public relevance. The OIE has, with the support of the European Commission, developed a system of disease prioritisation and categorisation, by producing a study on the 'Listing and categorisation of priority animal diseases, including those transmissible to humans' and a tool for such an exercise. This Regulation should introduce such an approach in Union legislation. [Am. 12]
- (31) ~~In order to ensure uniform conditions for the implementation of this Regulation in relation to transmissible animal diseases at Union level, it is necessary to establish a harmonised list of transmissible animal diseases ('listed diseases'): Thus implementing powers to lay down such a list should be conferred on the Commission,~~ **which should be set out in a table in an Annex attached to this Regulation. The power to adopt acts amending or supplementing such a list should be delegated to the Commission in accordance with Article 290 TFEU.** [Am. 13]
- (32) Emerging diseases with the potential to cause serious public or animal health risks and impacts on health, the economy or the environment may appear in the future. Following the assessment of such diseases and after adopting temporary emergency measures, when relevant, a quick reaction and insertion of such diseases in the list of listed diseases may be necessary. Therefore the power to adopt acts in accordance with the urgency procedure should be delegated to the Commission in these duly justified cases of risks to public or animal health.

Tuesday 15 April 2014

- (33) Listed diseases will require different management approaches. Some highly contagious diseases which are currently not present in the Union require stringent measures to immediately eradicate them as soon as they occur. For other diseases that might already be present in parts of the Union, compulsory or voluntary eradication is required. In both cases, it is appropriate to put in place restrictions on movements of animals and products, such as a prohibition of movements to and from affected areas, or simply testing prior to dispatch. In other instances it might be appropriate only to implement surveillance of the disease's distribution, without taking further measures. This would be the case, in particular, in the event of an emerging disease for which there is limited information.
- (34) Criteria should be laid down to ensure that all relevant aspects are considered when determining which transmissible animal diseases should be listed for the purposes of this Regulation and to determine the applicability of disease prevention and control rules of the Regulation to the different listed diseases to ensure coherence and consistency. In order to ensure that technical and scientific progress and developments of relevant international standards are taken into account, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission with respect to the possible amendments of those criteria.
- (35) The prevention and control rules of this Regulation for a specific transmissible animal disease should apply to species of animals which can transmit the disease in question, by being susceptible to it or by acting as its vector. ~~In order to ensure uniform conditions for the implementation of this Regulation,~~ It is **thus** necessary to establish a harmonised list of species to which the measures for specific listed diseases should apply at Union level ('listed species') and ~~thus implementing powers to lay down such a list should be conferred on the Commission~~ **which should be set out in a table in an Annex to this Regulation. The power to adopt acts amending or supplementing such a list should be delegated to the Commission in accordance with Article 290 TFEU.** [Am. 14]
- (36) Based on the importance and the level of impact of a listed disease, its distribution, prevalence and incidence in the Union, **the risk of spreading** and the availability of disease prevention and control measures in respect of that listed disease, a different category of specific disease prevention and control rules provided for in this Regulation should apply coherently and consistently to each listed disease. [Am. 15]
- (37) ~~In order to ensure uniform conditions for the implementation of this Regulation in relation to the disease prevention and control measures applicable to listed diseases,~~ It is necessary to determine, **and lay down in a list**, the application of the rules, provided for in this Regulation, to listed diseases at Union level. ~~Thus implementing powers to lay down which listed diseases are to be subject to which rules, should be conferred on the Commission.~~ **Such a list should be kept and updated in a table in an Annex to this Regulation. The power to adopt acts amending or supplementing such a list should be delegated to the Commission in accordance with Article 290 TFEU.** [Am. 16]
- (38) Operators, animal professionals and pet keepers working with animals are in the best position to observe and ensure the health of the animals and products under their responsibility. They should therefore hold primary responsibility for carrying out measures for the prevention and control of the spread of diseases among animals and products under their responsibility, **and should work individually and collectively to improve animal health practices** [Am. 17].
- (39) Biosecurity is one of the key prevention tools at the disposal of operators, and others working with animals to prevent the introduction, development and spread of transmissible animal diseases to, from and within an animal population. The role of biosecurity is also recognised in the Impact Assessment for the adoption of the EU Animal Health Law and possible impacts are specifically assessed. In order to ensure that the biosecurity measures applied by operators, animal professionals and pet keepers are sufficiently flexible, that they are adjusted to suit the type of production and the species or categories of animals involved and that they take account of the local circumstances and technical developments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission with respect to supplementary and more detailed biosecurity requirements.

Tuesday 15 April 2014

- (40) Biocidal products, such as disinfectants for veterinary hygiene or food and feed areas, insecticides, repellents or rodenticides play an important role in biosecurity strategies, both at farm level as well as during animal transport. They should therefore be considered a part of biosecurity.
- (41) Knowledge of animal health, including of disease symptoms, consequences of diseases and possible means of prevention including biosecurity, treatment and control is a prerequisite for efficient animal health management and essential in ensuring the early detection of animal diseases. Operators and other animal professionals should therefore acquire such knowledge as appropriate. That knowledge may be acquired by different means, for example formal education, but also through the Farm Advisory System existing in the agricultural sector or by informal training to which national and European farmer organisations and other organisations may be valuable contributors. Those alternative means of acquiring such knowledge should also be recognised by this Regulation. **The same may also be said of pet keepers, while bearing in mind their different position and level of responsibility.** [Am. 18]
- (42) Veterinarians and aquatic animal health professionals play a crucial role in all aspects of animal health management, and general rules concerning their roles and responsibilities should be laid down in this Regulation.
- (43) Veterinarians have the education and the professional qualifications which ensure that they have acquired the knowledge, skills and competencies necessary, inter alia, to diagnose diseases and treat animals. In addition, in some Member States for historical reasons, or due to the lack of veterinarians dealing with aquatic diseases, there exists a specialised profession called 'aquatic animal health professionals'. These professionals are traditionally not veterinarians but they practice aquatic animal medicine. This Regulation should therefore respect the decision of those Member States who recognise that profession. In those cases, aquatic animal health professionals should have the same responsibilities and obligations as veterinarians concerning their specific area of work. This approach is in line with the Aquatic Animal Health Code of the OIE.
- (44) In order to ensure that the veterinarians and aquatic animal health professionals who undertake activities that fall within the scope of this Regulation are adequately qualified and receive appropriate training, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect to their qualification and training.
- (45) Member States and in particular the competent authority thereof responsible for animal health are amongst the key actors in the prevention and control of transmissible animal diseases. The competent authority for animal health plays an important role in relation to surveillance, eradication, disease control measures, contingency planning, raising disease awareness, and in the facilitation of animal movements and in international trade by the issuing of animal health certificates. To be able to perform their duties under this Regulation, Member States depend on having access to adequate financial, infrastructural and personnel resources throughout their territories, including laboratory capacity and scientific and other relevant know-how.
- (46) The competent authority cannot always perform all the activities required to be carried out by it under this Regulation due to the limited resources. For that reason it is necessary to provide a legal basis for the delegation of the performance of those activities to veterinarians **and other qualified professionals. For the same reason, it is of utmost importance that those veterinarians and professionals have no conflicts of interest.** In order to ensure that the necessary conditions are laid down for the general application of disease prevention and control measures across the Union, the power to adopt acts in accordance with Article 290 ~~of the Treaty on the Functioning of the European Union~~ TFEU should be delegated to the Commission in respect to the delegation of the performance of those activities to veterinarians and their appropriate training. [Am. 19]
- (47) Optimal animal health management can only be achieved in cooperation with animal keepers, operators, **veterinarians, animal health professionals**, other stakeholders and trading partners. To secure their support it is necessary to organise decision making procedures and the application of the measures provided for in this Regulation in a clear and transparent manner. Therefore the competent authority should take appropriate steps to keep the public informed, especially when there are reasonable grounds to suspect that animals or products may present a risk for animal or public health, **food safety or the environment** and when a case is of public interest. [Am. 20]

Tuesday 15 April 2014

- (48) To avoid the release of disease agents from laboratories, institutes and other facilities handling disease agents it is vital that they take appropriate biosecurity, biosafety and bio-containment measures. This Regulation should therefore provide for safety measures to be observed while handling or transporting such disease agents, vaccines and other biological products. This obligation should also apply to any legal or natural person, who is involved in such an activity. In order to ensure that safety standards are respected when handling highly contagious biological agents, vaccines and other biological products, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the safety measures in those laboratories, institutes and facilities and for movements of disease agents.
- (49) Early detection and a clear chain of disease notification and reporting are crucial for effective disease control. In order to achieve an efficient and quick response any suspicion or confirmation of an outbreak of certain listed diseases should be immediately notified to the competent authority **veterinarians or aquatic animal health professionals. At the same time, a professional approach to notification and reporting must be ensured, in order to avoid unnecessary health scares.** Those notification obligations should **therefore** be applicable to ~~any natural and legal person in order to ensure that no disease outbreaks remain unnoticed~~ **all operators, animal professionals and pet keepers.** [Am. 21]
- (50) Veterinarians are key actors in the investigation of diseases and a key link between operators and the competent authority. Therefore, they should be notified by the operator in cases of abnormal mortalities, other serious disease problems or significantly decreased production rates with an undetermined cause.
- (51) In order to ensure the effective and efficient notification and to clarify different circumstances related to abnormal mortalities and other serious disease signs, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of criteria to determine when relevant circumstances for the notification occur and the rules for further investigation, where this is relevant.
- (52) For certain listed diseases it is vital that the Commission and the other Member States are immediately notified about diseases. Such Union notification will enable neighbouring or other affected Member States to take precautionary measures when so warranted. In order to ensure uniform conditions for the implementation of such Union notification, implementing powers shall be conferred on the Commission.
- (53) On the other hand, for some diseases immediate notification and action are not necessary. In those cases the gathering of information and reporting in relation to the occurrence of those diseases is essential to control the disease situation and where necessary to take disease prevention and control measures. This reporting requirement may also apply to diseases which are subject to Union notification but where additional information is needed for the implementation of effective disease prevention and control measures. In order to ensure that the correct information and data, which are necessary to prevent the spread or to control each particular disease, are collected in the right timeframe, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the matters to be reported.
- (54) A key purpose of disease notification and reporting is to generate reliable, transparent and accessible epidemiological data. A computerised information system for the effective collection and management of surveillance data should be established at Union level for listed diseases and, when relevant, for emerging diseases or antimicrobial resistant pathogens. That system should promote optimal data availability, facilitation of data exchange, and reduction of administrative burden for the competent authorities of the Member States by merging disease notification and reporting within the Union and at international level into one process (that is the WAHIS/WAHID database of the OIE). Consistency with the exchange of information in accordance with Directive 2003/99/EC should also be ensured.

Tuesday 15 April 2014

- (55) In order to ensure uniform conditions for the implementation of the Union disease notification and reporting rules, implementing powers should be conferred on the Commission to establish a list of diseases which are subject to Union notification and Union reporting rules provided for in this Regulation and to establish the necessary procedures, formats, data and information exchanges regarding disease notification and reporting.
- (56) Surveillance is a key element of disease control policy. It should provide for the early detection of transmissible animal diseases and efficient notification, thereby enabling the sector and the competent authority to implement, where feasible, timely disease prevention and control measures, and the eradication of a disease. Furthermore, it should supply information on the animal health status of each Member State and the Union, thereby substantiating disease freedom and facilitating trade with third countries.
- (57) Operators observe their animals on a regular basis and are best positioned to detect abnormal mortalities or other serious disease symptoms. Operators are therefore the cornerstone of any surveillance and essential for the surveillance undertaken by the competent authority. ***In the context of this Regulation and with respect to wild animals, the role of hunters should also be recognised as instrumental in monitoring diseases due to their experience and knowledge of the diseases affecting wild animals. Similarly hunting associations and holder of hunting rights could also supplement the work of operators in monitoring wild animals.*** [Am. 22]
- (58) To ensure close collaboration and exchange of information between operators and veterinarians or aquatic animal health professionals and to supplement the surveillance undertaken by operators, establishments should, as appropriate for the type of production and other relevant factors, be subject to animal health visits. In order to ensure a proportionate level of surveillance to the risks involved in different types of establishments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the criteria and the content of such animal health visits in different types of establishments.
- (59) It is essential that the competent authority has in place a system of surveillance for the listed diseases which are subject to surveillance. This should also apply to emerging diseases, where the potential health risks of that disease should be assessed and epidemiological data collected for that assessment. To ensure the best use of resources information should be collected, shared and used in the most effective and efficient manner possible.
- (60) The surveillance methodology, frequency and intensity should be adapted to each specific disease and take into account the specific purpose of the surveillance, the animal health status in the region concerned and any additional surveillance conducted by operators.
- (61) In some cases, and depending on the epidemiological profile of a disease and relevant risk factors, a structured surveillance programme may need to be put in place. In that case it is appropriate that Member States develop epidemiologically based surveillance programmes. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission concerning the surveillance design, the criteria for official confirmation of outbreaks and the case definitions of those diseases and requirements for surveillance programmes in relation to their contents, information to be included and the period of application.
- (62) To promote coordination between the Member States and ensure that those surveillance programmes are consistent with Union objectives, they should be submitted to the Commission and other Member States for information. Furthermore, the Member State implementing the surveillance programme should also submit regular reports on the results of that surveillance programme to the Commission. In order to ensure uniform conditions for the implementation of surveillance programmes, implementing powers should be conferred on the Commission to establish a list of diseases subject to surveillance programmes and to set up harmonised procedures, formats, data and information exchange.

Tuesday 15 April 2014

- (63) Member States that are not free or are not known to be free from listed diseases which are subject to eradication measures as provided for in this Regulation, should be required to establish compulsory eradication programmes to eradicate those diseases where the eradication is compulsory in the Union, ~~or have the possibility to establish voluntary eradication programmes, to eradicate those diseases where the eradication is envisaged in the Union, but is not compulsory. To ensure uniform conditions of general application throughout the Union, it is necessary to lay down harmonised requirements for such compulsory or voluntary eradication programmes. In order to ensure effective disease eradication, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the objectives of disease control strategies, disease control measures under the compulsory or voluntary eradication programmes and requirements of such programmes. [Am. 23]~~
- (63a) *On the other hand, there are some diseases which are of Union concern but for which it is not necessary to require Member States to eradicate the disease. Member States have the possibility to establish voluntary eradication programmes for such diseases, if they decide that eradication is important for them. Such voluntary eradication programmes would be recognised at the Union level. This programme would entail implementing certain relevant disease control measures. It may also enable the Member State, subject to approval by the Commission, to require certain guarantees when receiving animals from other Member States or from third countries, such as additional testing for the disease and assurances about those test results in a movement certificate. Their programme may also be eligible for a Union financial contribution, if the disease is listed in Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ⁽¹⁾ and they submit an application for funding. [Am. 24]*
- (63b) *To ensure uniform conditions of general application throughout the Union, it is necessary to lay down harmonised requirements for such compulsory or voluntary eradication programmes. In order to ensure effective disease eradication, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the objectives of disease control strategies, disease control measures under the compulsory or voluntary eradication programmes and requirements of such programmes. [Am. 25]*
- (64) In order to ensure uniform conditions for the implementation of disease eradication programmes, implementing powers should be conferred on the Commission to lay down the procedures for the submission of such programmes, performance indicators, and reporting.
- (65) Furthermore, Member States should have the possibility of declaring the whole of their territories, zones or compartments thereof free of one or more of listed diseases, which are subject to rules on compulsory or voluntary eradication programmes, in order to be protected against the introduction of such listed diseases from other parts of the Union or from third countries or territories. A clear harmonised procedure, including the necessary criteria for disease-free status, should be established for that purpose. In order to ensure uniform conditions for the implementation of the recognition of disease-free status within the Union it is necessary that such a disease-free status is officially approved and thus implementing powers to approve such status should be conferred on the Commission.
- (66) The OIE has introduced the concept of compartmentalisation in the framework of the Terrestrial and Aquatic Animal Health Codes (the OIE Codes). In Union legislation adopted prior to this Regulation, that concept is only recognised for particular animal species and diseases, specified in specific Union legislation, namely for avian influenza and aquatic animal diseases. This Regulation should establish the possibility of using the compartment system for other animal species and diseases. In order to lay down the detailed conditions for the recognition, rules for approval and the requirements for compartments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission.
- (67) Member States should make their disease-free territory, zones and compartments thereof publicly known for the purpose of informing trading partners and facilitating trade.

⁽¹⁾ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Tuesday 15 April 2014

- (68) In order to lay down the detailed conditions for the recognition of disease-free status, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the criteria for obtaining such status, the evidence needed to substantiate freedom from disease, special disease prevention and control measures, restrictions, information to be provided, derogations, and conditions for the maintenance, suspension, withdrawal or restoration of disease-free status.
- (69) In order to ensure uniform conditions for the implementation of procedures to obtain disease free status, implementing powers should be conferred on the Commission to establish the listed diseases which may be subject to compartmentalisation and lay down detailed rules on formats for the submission of applications and information exchange.
- (70) The presence of an entirely non-immune population of animals, susceptible to certain listed diseases, requires permanent disease awareness and preparedness. Contingency plans have proved to be a crucial tool for the successful control of disease emergencies in the past. In order to ensure this effective and efficient tool for the control of disease emergencies, which is flexible to adjust to the emergency situations, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the detailed requirements and conditions for contingency plans.
- (71) Past animal health crises have shown the benefits of having specific, detailed and rapid management procedures for disease emergencies. Those organisational procedures should ensure a rapid and effective response and improve coordination of efforts of all involved parties, and in particular the competent authorities and the stakeholders.
- (72) To ensure the applicability of contingency plans in real emergency situations, it is essential to practise and test that the systems are working. For that purpose the competent authorities of the Member States should carry out simulation exercises, in cooperation with the competent authorities of the neighbouring Member States and third countries and territories, where feasible and relevant.
- (73) In order to ensure uniform conditions for the implementation of contingency plans and simulation exercises, implementing powers should be conferred on the Commission to lay down rules for the practical implementation of those plans and exercises.
- (74) Veterinary medicinal products such as vaccines, hyper immune sera and antimicrobials play an important role in the prevention and control of transmissible animal diseases. The Impact Assessment for the adoption of the EU Animal Health Law highlights in particular the importance of vaccines as a tool in the prevention, control and eradication of animal diseases.
- (75) However, control strategies for some transmissible animal diseases require prohibition or restriction of the use of certain veterinary medicinal products, as their use would hamper the effectiveness of those strategies. For example, hyper immune sera or antimicrobial agents may mask the expression of a disease, make the detection of a disease agent impossible or render a swift and differential diagnosis difficult and thus endanger the correct detection of disease, **thereby significantly putting at risk public and animal health.** [Am. 26]
- (76) However, those control strategies may substantially vary between different listed diseases. Thus this Regulation should provide for rules on the use of veterinary medicinal products for the prevention and control of ~~listed~~ **certain** diseases and for harmonised criteria for consideration when determining whether or not to use and how to use vaccines, hyper-immune sera and antimicrobials. In order to ensure a flexible approach and to address the specificities of different listed diseases and the availability of the effective treatments, the power to adopt acts in accordance with Article 290 ~~of the Treaty on the Functioning of the European Union~~ **TFEU** should be delegated to the Commission in respect of the restrictions, prohibitions or obligations to use certain veterinary medicinal products in the framework of the control of certain ~~listed~~ diseases. In the case of urgency and in order to address emerging risks with possible devastating implications for animal or public health, economy, society or environment, it should be possible for these measures to be adopted by the urgency procedure. [Am. 27]

Tuesday 15 April 2014

- (77) Following the conclusions of the Expert opinion on vaccine and/or diagnostic banks for major animal diseases ⁽¹⁾ it should also be made possible for the Union and the Member States to establish reserves of antigens, vaccines and diagnostic reagents for listed diseases that represent a serious threat for animal or public health. The establishment of a Union antigen, vaccine and diagnostic reagent bank would promote the Union's animal health objectives by enabling a quick and effective response when its resources are required and represents an efficient use of limited resources.
- (78) In order to ensure such a quick and effective response, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, in respect of the establishment and the management of such banks, and safety standards and requirements for the operation of those. However, this Regulation should not provide for the rules on the financing of the disease preventive and control measures, including vaccination.
- (79) Criteria for priority access to the Union antigen, vaccine and diagnostic reagent banks' resources should be established in order to ensure their effective distribution in emergencies. **Similarly, for those Member States which have not set up national antigen, vaccine and diagnostic reagent banks or which find that stocks are limited in the Union banks, criteria for access to the resources of other Member States should be established.** [Am. 28]
- (80) For reasons of security in relation to bio-terrorism and agro-terrorism, certain detailed information concerning the Union antigen, vaccine and diagnostic reagent banks should be treated as classified information and its publication should be prohibited.
- (81) In order to ensure uniform conditions for the management of the Union antigen, vaccine and diagnostic reagent banks, implementing powers should be conferred on the Commission to lay down detailed rules concerning which biological products are to be included in those banks and for which diseases, and detailed rules on the supply, quantities, storage, delivery, procedural and technical requirements for vaccines, antigens and diagnostic reagents and the frequency and content of submissions of information to the Commission.
- (82) In the event of an outbreak of a listed disease considered to represent a high risk to animal or public health in the Union, it is necessary to take immediate disease control measures to eradicate that listed disease in order to protect animal and public health and the relevant sectors.
- (83) Operators, animal professionals and pet keepers should have the primary responsibility for controlling and preventing the spread of transmissible animal diseases. They should take immediate action in case of suspicion or confirmation of highly contagious diseases.
- (84) The competent authority should be responsible for initiating the first investigations to confirm or rule out an outbreak of a highly contagious listed disease, considered to represent a high risk to animal or public health in the Union.
- (85) The competent authority should put in place preliminary disease control measures to prevent the possible spread of the listed disease and undertake an epidemiological enquiry.
- (85a) According to Directive 2003/99/EC, Member States is to transmit a report to the Commission every year on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance. Similarly, as part of the control**

⁽¹⁾ Doc SANCO/7070/2010.

Tuesday 15 April 2014

plans and control programme provided for in Regulation (EU) No xxxx/xxxx (official controls Regulation) ⁽¹⁾ (*) and in Regulation (EC) No 2160/2003, Member States should take strategic measures to monitor, prevent and control other infectious animal diseases, including those not listed in the Annex to this Regulation. These measures should include a strategy for good animal husbandry and responsible use of veterinary medicines. [Am. 29]

- (86) As soon as a listed disease is confirmed the competent authority should take the necessary disease control measures, if necessary including the establishment of restricted zones, to eradicate and prevent the further spread of that disease.
- (86a) **Disease control measures that become necessary in the event of a disease outbreak may adversely affect biodiversity and the conservation of farm animal genetic resources. In keeping with the Convention on Biological Diversity and the EU Biodiversity Strategy, the competent authority should take account of the impact on biodiversity and farm animal genetic resources when determining the application of disease control measures. [Am. 30]**
- (87) The occurrence of a listed disease in wild animals may pose a risk to public health and the health of kept animals, **or vice versa**. Special rules should therefore be laid down for disease control and eradication measures in wild animals, **or**, where needed, **in kept animals**. [Am. 31]
- (88) For listed diseases, which are not highly contagious, and which are subject to compulsory eradication, the disease control measures should be implemented to prevent the spread of those listed diseases, in particular to non-infected areas. However, those measures may be more limited or different comparing to those applicable for the most dangerous listed diseases. This Regulation should therefore provide for special rules for those diseases. Member States that have a voluntary eradication programme in place, should also implement such disease control measures. However, the level and intensity of disease control measures should be proportionate and take into account the characteristics of the listed disease in question, its distribution and its significance for the Member State **or region** concerned by it and the Union as a whole. [Am. 32]
- (89) In order to ensure the effective application of the disease control measures provided for in this Regulation by operators, pet keepers and the competent authorities and taking into account the specificities of the disease control measures for particular listed diseases and the risk factors involved, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, in respect of the detailed disease control measures in the event of suspicion or confirmation of a listed disease in establishments, other locations and restricted zones.
- (90) In order to provide for the possibility for special disease control measures to be adopted by the Commission on a temporary basis in the event that the disease control measures laid down in this Regulation are not sufficient or appropriate to address that risk, implementing powers should be conferred on the Commission concerning the laying down of special disease control measures for a limited period of time.
- (91) The registration of certain transporters and establishments keeping terrestrial animals or handling germinal products or transporting them is necessary to allow the competent authorities to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases.
- (92) Where a certain type of establishment keeping terrestrial animals or handling or storing germinal products poses a particular animal health risk, it should be subject to approval by the competent authority.

⁽¹⁾ Regulation (EU) xxxx/xxxx of the European Parliament and of the Council of xxxx on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 1/2005, (EC) No 396/2005, (EC) No 834/2007, (EC) No 1099/2009, (EC) No 1069/2009, (EC) No 1107/2009, Regulations (EU) No 1151/2012 and (EU) No 652/2014 as well as Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation) (EE L ...).

(*) Date and reference number of 2013/0140(COD).

Tuesday 15 April 2014

- (93) To avoid unjustified administrative burdens and costs, particularly to small and medium size enterprises (SMEs), flexibility should be given to the Member States to adapt the system of registration and approval to local and regional conditions and production patterns.
- (94) In the interest of reducing administrative burdens, registration and approvals should, where possible, be integrated into a registration or approval system which Member State may already have established for other purposes.
- (95) Operators have first-hand knowledge of the animals under their care. They should therefore maintain up-to-date records of information which are relevant for assessing the animal health status, for traceability and for an epidemiological enquiry in the event of the occurrence of a listed disease. Those records should be easily accessible to the competent authority.
- (96) In order to ensure the public availability of up-to-date information concerning the registered establishments and transporters and approved establishments the competent authority should establish and keep a register of such establishments and transporters. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, in respect of the information to be contained in the register of establishments and transporters and the record keeping requirements, as regards the information to be recorded, derogations from the record keeping requirements and the specific additional requirements for germinal products.
- (97) In order to ensure uniform conditions for the implementation of the requirements laid down in this regulation on the registration and approval of establishments and on the record keeping and registers, implementing powers should be conferred to the Commission to lay down rules concerning the information obligations, exemptions and other rules, the formats and operational specifications of the registers and records.
- (98) Efficient traceability is a key element of disease control policy. Identification and registration requirements specific for the different species of kept terrestrial animals and germinal products should be in place in order to facilitate the effective application of the disease prevention and control rules provided for in this regulation. In addition, it is important to provide for the possibility of establishing an identification and registration system for species for which such arrangements do not exist at present, or when changing circumstances and risks so warrant.
- (99) In order to ensure the smooth operation of the identification and registration system and ensure traceability, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, in respect of the obligations concerning databases, designation of the competent authority, detailed identification and registration requirements for different animal species and documents.
- (100) It is appropriate to reduce administrative burdens and costs and provide for flexibility of the system in circumstances where the traceability requirements can be achieved by means other than those set out in this Regulation. The Commission should therefore be empowered to adopt delegated acts in accordance with Article 290 TFEU concerning the derogations from the identification and registration requirements.
- (101) In order to ensure uniform conditions for the implementation of the identification and registration system and traceability, implementing powers should be conferred on the Commission to lay down rules concerning the technical specifications for databases, means of identification, documents and formats, the deadlines, and criteria for derogations from such systems.
- (102) An important tool for preventing the introduction and spread of a transmissible animal disease is the use of restrictions on movements of animals and products that may transmit that disease. However, restricting the movement of animals and products may have a severe economic impact and interfere with the operation of the internal market. Such restrictions should therefore only be applied where necessary and proportionate to the risks involved. This approach is in line with the principles laid down in the SPS Agreement and the OIE international standards.
- (103) The general requirements laid down in this Regulation should apply to all animal movements, such as the prohibition of movement of animals from an establishment where there are abnormal mortalities or other disease symptoms with an undetermined cause or disease prevention requirements during transport.

Tuesday 15 April 2014

- (104) The legal framework, currently laid down in Union legislation for the movement of terrestrial animals lays down harmonised rules primarily for the movement of terrestrial animals and products between Member States, while leaving it up to the Member States to determine the necessary movement requirements within their territory. A comparison of the current situation with an option where rules for movements within Member States would also be harmonised at Union level, was extensively elaborated in the Impact Assessment on the EU Animal Health Law. It has been concluded that the current approach should be maintained, as complete harmonisation of all movements would be very complex and the benefits in terms of the facilitation of movements between Member States do not outweigh the negative impact this could have on the ability to control diseases.
- (105) For animals that are moved between Member States a set of basic animal health requirements apply. In particular, animals may not be moved from establishments with abnormal mortalities or signs of disease of unknown cause. However, mortalities, even if abnormal, which are linked to scientific procedures authorised under Directive 2010/63/EU of the European Parliament and of the Council ⁽¹⁾ and which are not of infectious origin related to listed diseases, should not be a reason to prevent the movements of animals intended for scientific purposes. **Nonetheless, these mortalities should be registered by the competent authority. [Am. 33]**
- (106) However, this Regulation should provide for flexibility to facilitate the movement of species and categories of terrestrial animals, which represent a low risk for spreading listed diseases between Member States. In addition, further possibilities for derogations should be provided for in cases where Member States or operators successfully put in place alternative risk mitigating measures such as high levels of biosecurity and effective surveillance systems.
- (107) Ungulates and poultry are groups of animal species of high economic significance and are subject to specific movement requirements under Union legislation adopted prior to this Regulation, namely Council Directive 64/432/EEC ⁽²⁾, Council Directive 91/68/EEC ⁽³⁾, Council Directive 2009/156/EC ⁽⁴⁾, Council Directive 2009/158/EC ⁽⁵⁾ and partially Directive 92/65/EEC. The main rules for the movement of those species should be laid down in this Regulation. The detailed requirements which largely depend on the diseases that may be transmitted by different species or categories of animals should be regulated in subsequent Commission acts, taking into account the specificities of the diseases, species and categories of animals in question.
- (108) As **movements and** assembly operations for ungulates and poultry represent a particularly high disease risk, it is appropriate to lay down specific rules in this Regulation to protect the health of the animals involved and prevent the spread of transmissible animal diseases. **[Am. 34]**
- (109) Depending on the listed diseases and listed species, it is necessary to lay down specific animal health requirements for certain animal species other than kept ungulates and poultry. Rules for these species were also laid down in the legal framework applicable prior to this Regulation and in particular in Directive 92/65/EEC. That Directive lays down specific movement rules for animal species including bees, bumble bees, apes, dogs and cats etc. and this Regulation should therefore provide a legal basis for the adoption of delegated and implementing acts laying down specific movement rules for those animal species.
- (110) Confined establishments, usually used for the keeping of laboratory animals or zoo animals, normally involve a high level of biosecurity, a favourable and well controlled health status and are subject to fewer movements or movements solely within the closed circuits of those establishments. The status of confined establishments, for

⁽¹⁾ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

⁽²⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 121, 29.7.1964, p. 1977).

⁽³⁾ Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19).

⁽⁴⁾ Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae (OJ L 192, 23.7.2010, p. 1).

⁽⁵⁾ Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (OJ L 343, 22.12.2009, p. 74).

Tuesday 15 April 2014

which the operators may apply for on a voluntary basis, was first introduced in Directive 92/65/EEC, where rules and requirements for approval and movement requirements for approved bodies, institutes and centres are laid down. That system enables those establishments to exchange animals amongst themselves with fewer movement requirements and at the same time providing health guarantees within the circuit of confined establishments. Therefore it has been broadly accepted by the operators, and used as a voluntary option. It is therefore appropriate to preserve the concept of confined establishments and also to lay down rules for movement between those establishments in this Regulation.

- (111) For scientific purposes, such as research or diagnostic purposes, and in particular those authorised in accordance with Directive 2010/63/EU, it may be necessary to move animals which do not comply with the general animal health requirements laid down in this Regulation and represent a higher animal health risk. Those kinds of movements should not be prohibited or unduly restricted by the provisions of this Regulation, as this could impede otherwise authorised research activities and delay scientific progress. Nonetheless, it is essential that rules are laid down in this Regulation to ensure that movements of those animals take place in a safe manner **and are registered by the competent authority.** [Am. 35]
- (112) Movement patterns of circus animals, animals kept in zoos, animals intended for exhibition and certain other animals often deviate from the movement patterns of other kept species. Specific consideration should be taken in adapting Union rules on movement to such animals, taking into account specific risks and alternative risk mitigation measures.
- (113) In order to ensure that the objectives of recitals 102 to 112 of this Regulation are achieved, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, concerning the disease preventive measures in transport, specific rules for movement of certain animal species and special circumstances, such as assembly operations or rejected consignments, and special requirements or derogations for other types of movements, such as movement for scientific purposes.
- (114) In order to ensure the possibility for special rules for movements, where the movement rules are not sufficient or appropriate to limit the spread of a certain disease, implementing powers should be conferred on the Commission to lay down special movement rules for a limited period of time.
- (115) Kept terrestrial animals that are moved between Member States should comply with the requirements for such movements. In the case of species presenting a health risk and of greater economic importance, they should be accompanied by an animal health certificate issued by the competent authority.
- (116) To the extent technically, practically and financially feasible, technological developments should be availed of to reduce the administrative burdens on operators and the competent authority in relation to certification and notification by using information technology to replace the paper documentation and facilitate notification procedures and using them as far as possible for multiple purposes.
- (117) In cases where an animal health certificate issued by the competent authority is not required, an operator who moves animals to another Member State should issue a self-declaration document which confirms that the animals meet the movement requirements laid down in this Regulation.
- (118) In order to ensure the achievement of the objectives referred to in recitals 115, 116 and 117 of this Regulation the powers to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, concerning rules on the content, information obligations, and derogations from the animal health certification requirements, specific certification rules and the obligations of official veterinarians to conduct appropriate checks before the signing the animal health certificate.
- (119) Notification of movements of animals and germinal products between Member States and in some cases within the national territories of Member States is essential to ensure traceability of animals and those germinal products, where these movements may be linked to a risk of spreading transmissible animal diseases. Therefore, such movements should be notified and registered. The IMSOC system provided for in Article 130(1) of Regulation (EU) No xxxx/xxxx (*) (Official controls Regulation) should be used for that purpose.

(*) Reference number of 2013/0140(COD).

Tuesday 15 April 2014

- (120) In order to ensure uniform conditions for the implementation of the rules laid down in this Regulation on animal health certification and movement notification, implementing powers should be conferred on the Commission to lay down rules concerning the model animal health certificates, self-declaration documents, formats and deadlines for movement notification for both terrestrial and aquatic animals, germinal products and where also relevant, products of animal origin.
- (121) The specific nature of movements of pet animals represents an animal health risk which deviates significantly from that of other kept animals. ~~Specific rules for~~ Such movements should therefore **continue to be laid down in this Regulation. In order to** **governed by the provisions already adopted. This will** ensure that pet animals do not pose a significant risk for the spread of transmissible animal diseases. The power to adopt ~~acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the detailed rules for movements of those animals. In order to ensure uniform conditions for the implementation of the animal health requirements laid down in this Regulation concerning the movements of pet animals, implementing powers should be conferred on the Commission to lay down~~ rules concerning the disease prevention and control measures to be taken for such movements **should be conferred on the Commission in accordance with Article 290 TFEU, without prejudice to the provisions of Regulation (EU) No 576/2013 of the European Parliament and of the Council** ⁽¹⁾. [Am. 36]
- (122) Wild animals may for various reasons represent an animal and public health risk, for example, if they are moved into an establishment or from one environment to another environment. Appropriate preventive measures for movement of those animals may need to be taken to avoid the spread of transmissible animal diseases. In order to ensure that wild animals do not pose a significant risk for the spread of transmissible animal diseases the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, concerning the additional requirements for movements of wild terrestrial animals.
- (123) Germinal products can represent a similar risk of spreading transmissible animal diseases to live animals. In addition, there are specificities in their production, which are related to high health demands for breeding animals and which call for stricter or particular animal health requirements concerning the donor animals. In order to ensure safe movements of germinal products, their expected high health standard and to take into account some specific uses, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, concerning the detailed requirements for movement of germinal products of certain animal species, special requirements, such as for example their movement for scientific purposes, and derogations from the animal health certification obligation.
- (124) Products of animal origin can represent a risk for the spreading of transmissible animal diseases. Food safety requirements for products of animal origin laid down in Union legislation ensure good hygiene practices and reduce the animal health risks of such products. However, for certain cases specific animal health measures, such as disease control and emergency measures should be laid down in this Regulation to ensure that products of animal origin do not spread animal diseases. In order to ensure safe movements of products of animal origin in these particular cases, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, concerning detailed rules for movements of products of animal origin in relation to disease control measures taken, the obligations for animal health certification and derogations from those rules, where the risk involved with such movements, and the risk mitigating measures in place, permit so.
- (125) When Member States take national measures concerning movements of animals and germinal products or decide to take national measures to limit the impact of transmissible animal diseases other than listed diseases within their territory, those national measures ~~should not~~ **may only** interfere with the rules on the internal market laid down in Union legislation **when this is scientifically justified on the grounds of controlling infectious disease and is proportionate in relation to the risk**. Therefore, it is appropriate to set the framework for such national measures and ensure that they remain within the limits permitted under Union law. [Am. 37]

⁽¹⁾ Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

Tuesday 15 April 2014

- (126) The registration and approval of aquaculture establishments is necessary to allow the competent authorities to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases. Directive 2006/88/EC requires all establishments which move aquatic animals to be authorised. That system of authorisation should be maintained under this Regulation, notwithstanding that fact that in some official Union languages, different terms are used for this system of authorisation in this Regulation as compared to Directive 2006/88/EC.
- (127) The slaughter and processing of aquaculture animals which are subject to disease control measures may spread transmissible animal disease, for example as a result of effluents containing pathogens being discharged from processing establishments. It is therefore necessary to approve processing establishments which fulfil the risk mitigation measures to undertake such slaughter and processing. Therefore, this Regulation should provide for the approval of disease control aquatic food establishments.
- (128) In order to ensure the public availability of up-to-date information concerning registered and approved establishments the competent authority should establish and keep such a register. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, concerning the information to be included in register of aquaculture establishments and the record keeping requirements for aquaculture establishments and transporters.
- (129) In order to ensure uniform conditions for the implementation of the rules laid down in this Regulation for the registration and approval of aquaculture establishments and disease control aquatic food establishments, record keeping and registers of establishments, implementing powers should be conferred on the Commission to lay down rules concerning the information obligations, derogations and other implementing rules, and the format and operational specifications of the registers and records.
- (130) As it is not feasible in most cases to individually identify aquatic animals, the keeping of records at aquaculture establishments, disease control aquatic food establishments and by transporters is an essential tool in ensuring the traceability of aquatic animals. Records are also valuable for the surveillance of the health situation of establishments.
- (131) Similarly to terrestrial animals, it is necessary to lay down harmonised rules on the movement of aquatic animals, including rules on animal health certification and movement notification.
- (132) Directive 2006/88/EC lays down rules for movements of aquatic animals, which apply equally to movements within and between Member States. The key determining factor for movement rules for aquatic animals is the health status as regards the listed diseases of the Member State, zones and compartments of destination.
- (133) The same system should also be provided for in this Regulation. However, to encourage Member States to enhance the health status of their aquatic populations, some adjustments and added flexibility should be introduced.
- (134) In order to ensure movement control for aquatic animals, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, concerning the disease preventive measures applicable to transport, specific rules for movements of certain categories of aquatic animals for different purposes, specific requirements or derogations for certain types of movements, such as movement for scientific purposes and additional requirements for movement of wild aquatic animals.
- (135) In order to ensure the possibility of temporary derogations and specific requirements for movements of aquatic animals, where the movement rules laid down in this Regulation are not sufficient or appropriate to limit the spread of a certain listed disease, implementing powers should be conferred on the Commission for laying down special movement rules or derogations for a limited period of time.

Tuesday 15 April 2014

- (136) Union aquaculture production is extremely diverse as regards species and production systems and this diversification is rapidly increasing. This may warrant that national measures concerning diseases other than those that are regarded as listed diseases in accordance with this Regulation are taken at Member State level. However, such national measures should be justified, necessary and proportionate to the goals to be achieved. Furthermore, they should not affect movements between Member States unless it is necessary in order to prevent the introduction of or to control the spread of disease. National measures affecting trade between Member States should be approved and regularly reviewed at Union level.
- (137) Currently, listed diseases concern animal species other than those defined as terrestrial and aquatic by this Regulation, such as reptiles, amphibians, insects and others only to a very limited extent. It is therefore not appropriate to require that all the provisions of this Regulation apply to those animals. However, if a disease which concerns species other than terrestrial and aquatic should become listed, the relevant animal health requirements of this Regulation should apply to those species to ensure that adequate and proportionate disease prevention and control measures may be taken.
- (138) In order to ensure the possibility of laying down movement rules for those animals that are not defined as terrestrial and aquatic animals by this Regulation, and germinal products and products of animal origin from them, when a risk so warrants, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, concerning the registration and approval of establishments, record keeping and registers, identification and registration and traceability movement requirements, animal health certification and self-declaration and movement notification obligations for animals, germinal products and products of animal origin of those species.
- (139) When necessary to ensure uniform conditions for the implementation of the animal health requirements for those other animal species and germinal products and products of animal origin from them, implementing powers should be conferred on the Commission to lay down detailed rules concerning those requirements.
- (140) To prevent the introduction of listed diseases and emerging diseases into the Union, it is necessary to have in place efficient rules on the entry into the Union of animals, germinal products and products of animal origin that may transmit such diseases.
- (141) The requirements for entry of animals and products into the Union should mirror the requirements for movements of animal and products of the same category, species and intended use within the Union.
- (142) To ensure that animals, germinal products and products of animal origin from third countries or territories comply with the animal health requirements that provide guarantees that are equivalent to those provided for in Union legislation, it is essential that they are subject to appropriate controls by the competent authority of the third countries or territories exporting to the Union. Where relevant, the health status of a third country or territory of origin should be verified prior to accepting the entry of such animals, germinal products and products of animal origin. Consequently, only third countries and territories which can demonstrate that they meet the animal health standards for entry of the animals and products into the Union should be eligible to export them to the Union and be listed for that purpose.
- (143) For some species and categories of animals, germinal products and products of animal origin the Union lists of third countries and territories from which entry into the Union is permitted have not been established in Union acts adopted prior to the date of adoption of this Regulation. In those cases and pending the adoption of rules pursuant to Regulation, Member States should be permitted to determine from which countries and territories those animals, germinal products and products of animal origin may be permitted to enter their territory. In so determining, Member States should take into account the criteria laid down in this Regulation for the Union lists of third countries and territories.

Tuesday 15 April 2014

- (144) To ensure that the animal health requirements for the entry into the Union provided for in this Regulation are complied with and are in line with the principles of the OIE Animal Health Codes, all animals, germinal products and products of animal origin entering the Union should be accompanied by an animal health certificate issued by the competent authority of the third country or territory of origin confirming that all the animal health requirements for entry into the Union are complied with. However, deviation from this rule for commodities which pose a low animal health risk should be permitted.
- (145) Animal health certificates may stand on their own, but certification is often required in Union legislation for other purposes, for example to certify that public health or animal welfare requirements of animals or products have been complied with. This has to be taken into account. In order to minimise administrative burdens and costs those animal health certificates should also be permitted to include information required under other Union food and feed safety legislation.
- (146) Diseases may be spread by means other than animals, germinal products, products of animal origin and animal by-products and derived products. For instance, vehicles, transport containers, hay, straw, plant products, materials that may have been in contact with infected animals and equipment may also spread disease. Where necessary, measures should be taken to prevent these routes of disease transmission by those means.
- (147) In order to ensure the appropriate level of detail for the requirements for entry into the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, to supplement and amend the criteria for the listing of third countries and territories, criteria for the suspension or withdrawal from that list, supplementing the rules for the approval of establishments in third countries and territories and derogations, animal health requirements for the entry into the Union of consignments from third countries and territories, contents of animal health certificates, and the animal health requirements for disease agents, other materials, means of transport and equipment, which may transmit animal diseases.
- (148) In order to ensure uniform conditions for the implementation of the animal health requirements for the entry into the Union of consignments of animals, germinal products and products of animal origin, implementing powers should be conferred on the Commission to lay down rules on, inter alia the list of third countries and territories from which the entry into the Union of animals, germinal products and products of animal origin is allowed and model animal health certificates.
- (149) Past experience has shown that when an outbreak of a serious disease occurs in Member States or in third countries or territories from which animals or products enter the Union, disease prevention and control measures have to be taken immediately to limit its introduction and spread. Such an emergency may involve listed diseases, emerging diseases or other animal health hazards. In that context, it should be made clear which sets of disease prevention and control measures laid down in this Regulation may be used in the event of the occurrence of a listed or emerging disease or hazard. In all these cases it is essential that measures can be taken at very short notice and without any delay. As such measures would restrict movement within or into the Union they should be implemented at Union level whenever possible.
- (150) In order to ensure an effective and quick reaction to emerging risks, implementing powers should be conferred on the Commission to lay down emergency measures.
- (151) The Commission should adopt immediately applicable implementing acts in duly justified cases relating to inter alia the listing of diseases and species, the listed diseases that are to be subject to the sets of disease prevention and control rules, the stocking, supply, storage, delivery and other procedures of Union antigen, vaccine and diagnostic reagent banks, the laying down of special disease control measures and derogations for a limited period of time, the special movement rules for terrestrial and aquatic animals for a limited period of time, the emergency measures, and the listing of third countries and territories for entry into the Union.

Tuesday 15 April 2014

- (152) This Regulation lays down general and specific rules for the prevention and control of transmissible animal diseases and ensures a harmonised approach to animal health across the Union. In some areas, such as general responsibilities for animal health, notification, surveillance, registration and approval or traceability, the Member States should be allowed or encouraged to apply additional or more stringent national measures. However, such national measures should be permitted only if they do not compromise the animal health objectives of this Regulation, and if they are not in contradiction with the rules laid down therein and provided that they do not hinder movements of animals and products between Member States, unless it is necessary in order to prevent the introduction of or to control the spread of disease.
- (153) The national measures referred to in recital 152 should be subject to a simplified notification procedure in order to reduce the administrative burden. Experience has shown that the general notification procedure laid down in Directive 98/34/EC of the European Parliament and of the Council⁽¹⁾, has been an important tool for guiding and improving the quality of national technical regulations — in terms of increased transparency, readability and effectiveness, in non-harmonised or partly harmonised areas. It is therefore appropriate that this general notification procedure laid down in Directive 98/34/EC applies.
- (154) Currently, Union rules on animal health are laid down in the following acts of the European Parliament and of the Council and in subsequent Commission acts adopted pursuant to them:
- Council Directive 64/432/EEC,
 - Council Directive 77/391/EEC⁽²⁾,
 - Council Directive 78/52/EEC⁽³⁾,
 - Council Directive 80/1095/EEC⁽⁴⁾,
 - Council Directive 82/894/EEC⁽⁵⁾,
 - Council Directive 88/407/EEC⁽⁶⁾,
 - Council Directive 89/556/EEC⁽⁷⁾,
 - Council Directive 90/429/EEC⁽⁸⁾,
 - Council Directive 91/68/EEC,
 - Council Decision 91/666/EEC⁽⁹⁾,
 - Council Directive 92/35/EEC⁽¹⁰⁾,

⁽¹⁾ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

⁽²⁾ Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle (OJ L 145, 13.6.1977, p. 44).

⁽³⁾ Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle (OJ L 15, 19.1.1978, p. 34).

⁽⁴⁾ Council Directive 80/1095/EEC of 11 November 1980 laying down conditions designed to render and keep the territory of the Community free from classical swine fever (OJ L 325, 1.12.1980, p. 1).

⁽⁵⁾ Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58).

⁽⁶⁾ Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species (OJ L 194, 22.7.1988, p. 10).

⁽⁷⁾ Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p. 1).

⁽⁸⁾ Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ L 224, 18.8.1990, p. 62).

⁽⁹⁾ Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines (OJ L 368, 31.12.1991, p. 21).

⁽¹⁰⁾ Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness (OJ L 157, 10.6.1992, p. 19).

Tuesday 15 April 2014

- Council Directive 92/65/EEC,
- Council Directive 92/66/EEC ⁽¹⁾,
- Council Directive 92/118/EEC ⁽²⁾,
- Council Directive 92/119/EEC ⁽³⁾,
- Council Decision 95/410/EC ⁽⁴⁾,
- Council Directive 2000/75/EC ⁽⁵⁾,
- Council Decision 2000/258/EC ⁽⁶⁾,
- ~~Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 ⁽⁷⁾, [Am. 38]~~
- Council Directive 2001/89/EC ⁽⁸⁾,
- Council Directive 2002/60/EC ⁽⁹⁾,
- Council Directive 2002/99/EC ⁽¹⁰⁾,
- Council Directive 2003/85/EC ⁽¹¹⁾,

⁽¹⁾ Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease (OJ L 260, 5.9.1992, p. 1).

⁽²⁾ Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (OJ L 62, 15.3.1993, p. 49).

⁽³⁾ Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease (OJ L 62, 15.3.1993, p. 69).

⁽⁴⁾ Council Decision 95/410/EC of 22 June 1995 laying down the rules for the microbiological testing by sampling in the establishment of origin of poultry for slaughter intended for Finland and Sweden (OJ L 243, 11.10.1995, p. 25).

⁽⁵⁾ Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (OJ L 327, 22.12.2000, p. 74).

⁽⁶⁾ Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines (OJ L 79, 30.3.2000, p. 40).

⁽⁷⁾ ~~OJ L 204, 11.8.2000, p. 1.~~

⁽⁸⁾ Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (OJ L 316, 1.12.2001, p. 5).

⁽⁹⁾ Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (OJ L 192, 20.7.2002, p. 27).

⁽¹⁰⁾ Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

⁽¹¹⁾ Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1).

Tuesday 15 April 2014

- ~~Regulation (EU) No XXX/XXXX of the European Parliament and of the Council of ... on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 ⁽¹⁾, [Am. 39]~~
- Council Regulation (EC) No 21/2004 ⁽²⁾,
- Council Directive 2004/68/EC ⁽³⁾,
- Council Directive 2005/94/EC ⁽⁴⁾,
- Council Directive 2006/88/EC,
- Council Directive 2008/71/EC ⁽⁵⁾,
- Council Directive 2009/156/EC,
- Council Directive 2009/158/EC.

- (155) The rules laid down in the legislative acts referred to in recital 154 are to be replaced by this Regulation and by subsequent Commission acts to be adopted pursuant to this Regulation. Accordingly, those legislative acts should be repealed. However, to ensure legal clarity and avoid a legal vacuum, the repeal should only take effect when the relevant delegated and implementing acts are adopted pursuant to this Regulation. It is therefore necessary to provide the Commission with the empowerment to determine the dates when the repeal of those legislative acts should take effect.
- (156) The following Council acts in the area of animal health are obsolete and should be expressly repealed in the interests of clarity of Union legislation: Council Decision 78/642/EEC ⁽⁶⁾; Council Directive 79/110/EEC ⁽⁷⁾; Council Directive 81/6/EEC ⁽⁸⁾; Council Decision 89/455/EEC ⁽⁹⁾; Council Directive 90/423/EEC ⁽¹⁰⁾ and Council Decision 90/678/EEC ⁽¹¹⁾.
- (157) The requirements of this Regulation should not apply until all the delegated and implementing acts to be adopted by the Commission pursuant to this Regulation, have applied. It is appropriate to provide for at least 36 months to elapse between the date of entry into force of this Regulation and the date of application of the new rules, to allow the operators affected sufficient time to adapt.

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Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC (OJ L 5, 9.1.2004, p. 8).

⁽³⁾

Council directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC (OJ L 139, 30.4.2004, p. 321).

⁽⁴⁾

Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).

⁽⁵⁾

Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (OJ L 213, 8.8.2008, p. 31).

⁽⁶⁾

Council Decision 78/642/EEC of 25 July 1978 on health protection measures in respect of the Republic of Botswana (OJ L 213, 3.8.1978, p. 15).

⁽⁷⁾

Council Directive 79/110/EEC of 24 January 1979 authorizing the Italian Republic to postpone the notification and implementation of its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle (OJ L 29, 3.2.1979, p. 24).

⁽⁸⁾

Council Directive 81/6/EEC of 1 January 1981 authorizing the Hellenic Republic to communicate and to implement its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle (OJ L 14, 16.1.1981, p. 22).

⁽⁹⁾

Council Decision 89/455/EEC of 24 July 1989 introducing Community measures to set up pilot projects for the control of rabies with a view to its eradication or prevention (OJ L 223, 2.8.1989, p. 19).

⁽¹⁰⁾

Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries (OJ L 224, 18.8.1990, p. 13).

⁽¹¹⁾

Council Decision 90/678/EEC of 13 December 1990 recognizing certain parts of the territory of the Community as being either officially swine fever free or swine fever free (OJ L 373, 31.12.1990, p. 29).

Tuesday 15 April 2014

- (158) In order to ensure legal certainty as regards the application of rules for identification and registration of animals, disease control measures for certain zoonoses ~~and non-commercial movements of pet animals~~, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union **TFEU** should be delegated to the Commission in respect of the date on which ~~Regulations (EC) No 1760/2000, (EU) No XXX/XXX [Ex 998/2003] and (EC) No 21/2004 and Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC, and 2005/94/EC and 2008/71/EC~~ cease to apply. **[Am. 40]**
- (159) The implementing powers provided for in this Regulation should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (160) It is of particular importance that the Commission carry out appropriate consultations **with stakeholders** during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. **[Am. 41]**
- (161) This Regulation should not create a disproportionate administrative burden or economic impact for small and medium sized enterprises. Under this Regulation, based on consultation with stakeholders, the special situation of small and medium sized enterprises has been taken into account. A potential universal derogation from the requirements of this Regulation for such enterprises has not been considered, in view of the public policy objectives to protect animal health and public health. However, a number of derogations for such enterprises should be provided for in relation to the different requirements of this Regulation, taking into account the risks involved.
- (162) The objectives of this Regulation, namely to lay down animal health rules for animals, germinal products, products of animal origin, animal by-products and derived products to the extent that they are not covered by specific rules in other Union legislation and other material that can be involved in the spread of transmissible animal diseases, cannot be achieved sufficiently by the Member States, but can rather be more efficiently achieved at Union level through a common and coordinated legal framework for animal health. This Regulation is therefore in line with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

PART I

GENERAL RULES

Chapter 1

Subject matter, scope and definitions

Article 1

Subject matter

1. This Regulation lays down:

(a) rules for the prevention and control of animal diseases, which are transmissible to animals or to humans.;

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Tuesday 15 April 2014

(b) instruments and mechanisms to facilitate progress towards the declaration of disease free zones and territories;

(c) priority actions; and

(d) the division of responsibilities in the area of animal health. [Am. 42]

Those rules provide for:

- (a) the prioritisation and categorisation of diseases of Union concern and for establishing responsibilities for animal health in Part I;
- (b) the early detection, notification and reporting of diseases, surveillance, eradication programmes and disease-free status in Part II;
- (c) disease awareness, preparedness and control in Part III;
- (d) the registration and approval of establishments and transporters, movements and traceability of consignments of animals, germinal products and products of animal origin within the Union in Part IV;
- (e) the entry of consignments of animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union in Part V;
- (f) the emergency measures to be taken in the event of a disease emergency situation in Part VI.

2. The rules referred to in paragraph 1:

(a) ensure

- (i) a sustainable agricultural and aquaculture production in the Union;
- (ii) the effective functioning of the internal market, **and food and feed safety; [Am. 43]**
- (iii) a reduction in the adverse effects on **animal health, public health and** the environment of: **[Am. 44]**
 - certain diseases **and risk factors leading up to diseases; [Am. 45]**
 - the measures taken to prevent and control diseases;

(b) take into account

- (i) the relationship between animal health and:
 - public health;
 - the environment as well as the impacts of climate change;
 - **biodiversity; [Am. 46]**
 - food and feed safety;
 - animal welfare;
 - **antimicrobial resistance; [Am. 47]**
 - food security;
 - **the need to protect and conserve rare animal breeds, and to preserve genetic diversity; [Am. 48]**
- (ii) the economic, social, cultural and environmental consequences arising from the application of disease control and prevention measures.

Tuesday 15 April 2014

Article 2

Scope of this Regulation

1. This Regulation shall apply to:
 - (a) kept, *non-kept* and wild animals; [Am. 49]
 - (b) germinal products;
 - (c) products of animal origin;
 - (d) animal by-products and derived products, without prejudice to the rules laid down in Regulation (EC) No 1069/2009;
 - (e) facilities, means of transport, equipment and all other paths of infection and material involved or potentially involved in the spread of transmissible animal diseases.
2. This Regulation shall apply to transmissible diseases, including zoonoses, without prejudice to the rules laid down in:
 - (a) Decision No 2119/98/EC;
 - (b) Regulation (EC) No 999/2001;
 - (c) Directive 2003/99/EC;
 - (d) Regulation (EC) No 2160/2003.

Article 3

Scope of Part IV on registration, approval, traceability and movements

1. Title I of Part IV shall apply to:
 - (a) terrestrial animals, and animals that are not terrestrial animals but which may transmit diseases affecting terrestrial animals;
 - (b) germinal products from terrestrial animals;
 - (c) products of animal origin from terrestrial animals.
2. Title II of Part IV shall apply to:
 - (a) aquatic animals, and animals that are not aquatic animals but which may transmit diseases affecting aquatic animals;
 - (b) products of animal origin from aquatic animals.
3. Title III of Part IV shall apply to:
 - (a) animals other than those defined as terrestrial animals and aquatic animals in Article 4(1)(4);
 - (b) germinal products and products of animal origin from the other animals referred to in point (a).
4. Chapters 1 and 3 of Title I and Chapters 1 and 2 of Title II of Part IV shall not apply to pet animals.

Article 4

Definitions

1. For the purpose of this Regulation, the following definitions shall apply:
 - (1) 'animals' means vertebrate and invertebrate animals;

Tuesday 15 April 2014

- (2) 'terrestrial animals' means birds, terrestrial mammals, bees and bumble bees;
- (3) 'aquatic animals' means animals of the following species, at all life stages, including eggs, sperm and gametes:
- (i) fish belonging to the superclass Agnatha and to the classes Chondrichthyes, Sarcopterygii and Actinopterygii;
 - (ii) aquatic molluscs belonging to the phylum Mollusca;
 - (iii) aquatic crustaceans belonging to the subphylum Crustacea;
- (4) 'other animals' means animals of species other than those defined as terrestrial and aquatic animals;
- (5) 'kept animals' means **living** animals which are kept by humans; in the case of aquatic animals, aquaculture animals; [Am. 50]
- (5a) '**non-kept animals of domesticated species**' means **animals which are not, or are no longer, under human supervision**; [Am. 51]
- (6) 'aquaculture' means the rearing of aquatic animals using techniques designed to increase the production of those animals beyond the natural capacity of the environment and where the animals remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting, excluding the harvesting or catching for the purposes of human consumption of wild aquatic animals which are subsequently temporarily kept awaiting slaughter without being fed;
- (7) 'aquaculture animals' means aquatic animals subject to **aquaculture techniques designed to increase production above the natural capacity of the environment in question**; [Am. 52]
- (8) 'wild animals' means animals which are ~~not~~ **neither** kept animals **nor non-kept animals of domesticated species**; [Am. 53]
- (9) 'poultry' means birds that are reared or kept in captivity for:
- (a) the production of:
 - (i) meat;
 - (ii) eggs for consumption;
 - (iii) other products;
 - (b) restocking supplies of game birds;
 - (c) the purposes of breeding of birds used for the types of production referred to in point (a);
- (10) 'captive birds' means any birds other than poultry that are kept in captivity for any reason other than those referred to in point (9) including those that are kept for shows, races, exhibitions, competitions, breeding or selling;
- (11) 'pet animal' means an animal of the species listed in Annex I, which:
- (a) is kept in a household, or in the case of aquatic animals, kept in non-commercial ornamental aquaria;
 - (b) when moved, accompanies for the purpose of a non-commercial movement the pet keeper, or a natural person acting on behalf of and in agreement with the pet keeper, and which remains during such non-commercial movement under the responsibility of the pet keeper or such person;
- (12) 'pet keeper' means a natural person keeping a pet animal;

Tuesday 15 April 2014

- (13) 'non-commercial movement' means ~~any movement of pet animals which does not involve or aim, directly or indirectly, at a financial gain or a transfer of ownership~~ **for non-commercial purposes as defined in point (a) of Article 3 of Regulation (EU) No 576/2013; [Am. 54]**
- (14) 'disease' means the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents transmissible to animals or to humans;
- (15) 'listed diseases' mean diseases listed in accordance with Article 5(2);
- (16) 'emerging disease' means a disease other than a listed disease which has the potential to meet the criteria for listed diseases provided for in Article 6(1)(a) due to:
- (a) a new disease resulting from the evolution or change of an existing disease agent;
 - (b) a known disease spreading to a new geographic area or a new population; or
 - (c) a previously unrecognised disease agent or a disease diagnosed for the first time;
- (17) 'disease profile' means the criteria of a disease referred to in Article 6(1)(a);
- (18) 'listed species' means animal species or group of animal species listed in accordance with Article 7(2), or, in the case of emerging diseases, animal species or groups of animal species, which meet the criteria for listed species laid down in Article 7(2);
- (19) 'hazard' means a disease agent in, or a condition of, an animal or product with the potential to have an adverse health effect in humans or animals;
- (20) 'risk' means the likelihood of the **scientifically demonstrated or demonstrable** occurrence and the likely magnitude of the biological and economic consequences of ~~an~~ **scientifically proven or provable** adverse effect on animal or public health; [Am. 56]
- (21) 'biosecurity' means the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases **or microorganisms that have developed resistance to antimicrobials** to, from and within: [Am. 57]
- (a) an animal population, or
 - (b) an establishment, zone, compartment, means of transport or any other facilities, premises or location;
- (22) 'operator' means a natural or legal person, having animals and products under their responsibility, including animal keepers and transporters, but excluding pet keepers and veterinarians;
- (23) 'animal professional' means a natural or legal person, with an occupational relationship with animals or products, other than operators or veterinarians;
- (24) 'establishment' means any premises, structure, or any environment, in which animals or germinal products are kept, except for:
- (a) households keeping pet animals;
 - (b) non-commercial aquaria keeping aquatic animals;
 - (c) veterinary practices or clinics;

Tuesday 15 April 2014

- (25) 'germinal products' means:
- (a) sperm, semen, oocytes and embryos intended for artificial reproduction;
 - (b) hatching eggs;
- (26) 'products of animal origin' means:
- (a) food of animal origin, including honey and blood;
 - (b) live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption; and
 - (c) animals other than those referred to in (b) destined to be prepared with a view to being supplied live to the final consumer;
- (27) 'animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals which are not intended for human consumption, excluding germinal products;
- (28) 'derived products' means products obtained from one or more treatments, transformations or steps of the processing of animal by-products;
- (29) 'products' means:
- (a) germinal products;
 - (b) products of animal origin;
 - (c) animal by-products and derived products;
- (30) 'official control' means an official control as defined in point (1) of Article 2 of Regulation (EU) No XXX/XXX (*) [official controls Regulation];
- (31) 'health status' means the disease status as regards all the listed diseases for a particular listed species with respect to:
- (a) an animal;
 - (b) the animals within:
 - (i) an establishment;
 - (ii) a compartment;
 - (iii) a zone;
 - (iv) a Member State;
 - (v) a third country or territory;
- (32) 'zone' means:
- (a) for terrestrial animals a clearly defined part of a Member State, third country or territory containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;
 - (b) for aquatic animals a contiguous hydrological system with a distinct health status with respect to a specific disease or specific diseases that forms an area that is referred to in one of the following:
 - (i) an entire water catchment from the source of a waterway to the estuary or lake;

(*) Reference number of 2013/0140(COD).

Tuesday 15 April 2014

- (ii) more than one water catchment;
 - (iii) part of a water catchment from the source of a waterway to a barrier that prevents the introduction of a specific disease or diseases;
 - (iv) part of a coastal area with a precise geographical delimitation;
 - (v) an estuary with a precise geographical delimitation;
- (33) 'water catchment' means an area or basin of land bounded by natural features such as hills or mountains, into which all run-off water flows;
- (34) 'compartment' means an animal subpopulation contained in one or more establishments and in the case of aquatic animals in one or more aquaculture establishments, under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;
- (35) 'quarantine' means the maintaining of animals in isolation under the control of the competent authority with no direct or indirect contact with other animals, for the purposes of ensuring that there is no spread of diseases while the animals are undergoing observation for a specified length of time and, if appropriate, testing and treatment;
- (36) 'epidemiological unit' means a group of animals with the same likelihood of exposure to a disease agent;
- (37) 'outbreak' means one or more cases in an establishment, ~~household~~ or other place where animals are kept or located;
[Am. 59]
- (38) 'case' means the official confirmation of the presence of a listed disease or an emerging disease in a live or dead animal;
- (39) 'restricted zone' means a zone in which restrictions on the movements of certain animals or products and other disease control measures are applied, with a view to preventing the spread of a particular disease into areas where no restrictions are applied; a restricted zone may, when relevant, include protection and surveillance zones;
- (40) 'protection zone' means a zone with one or more disease cases which is established after the official confirmation of an outbreak, and where disease control measures are applied in order to prevent the spread of the disease from that zone;
- (41) 'surveillance zone' means a zone, established after the official confirmation of an outbreak and which is situated around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from that zone and the protection zone;
- (42) 'hatching eggs' means eggs, laid by poultry, intended for incubation;
- (43) 'ungulates' means the animals listed in Annex II;
- (44) 'germinal product establishment' means:
- (a) an establishment for the collection, production, processing and storage of germinal products;
 - (b) a hatchery;
- (45) 'hatchery' means an establishment which collects, stores, incubates and hatches eggs for the supply of:
- (a) eggs for incubation;
 - (b) day-old chicks or hatchlings of other species;
- (46) 'transporter' means an operator transporting animals on its own account, or for a third party;

Tuesday 15 April 2014

- (47) 'confined establishment' means any permanent, geographically limited establishment, created on a voluntary basis, and approved for the purpose of movements, where the animals are:
- (a) kept or bred for the purposes of exhibitions, education, the conservation of species or research;
 - (b) confined and separated from the surrounding environment;
 - (c) subject to strict animal health surveillance and biosecurity measures;
- (48) 'assembly operation' means the assembling of kept terrestrial animals from more than one establishments for a period shorter than the required residency period for that species of animals;
- (49) 'residency period' means the minimum period an animal is required to stay at an establishment prior to being moved from that establishment;
- (50) 'IMSOC' means the computerised information management system provided for by Article 130(1) of Regulation (EU) No XXX/XXX (*) [official controls Regulation];
- (50a) 'processing establishment' means a food business approved in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council⁽¹⁾; [Am. 60]**
- (50b) 'disease control aquatic food establishment' means a food business approved in accordance with Article 177 and with Title II of Part IV; [Am. 61]**
- ~~(51) 'disease control aquatic food establishment' means a food business approved in accordance with the following provisions:~~
- ~~(a) Article 4 of Regulation (EC) No 853/2004, for processing aquaculture animals for food purposes;~~
 - ~~(b) Article 177 of this Regulation for the slaughter of aquatic animals for disease control purposes in accordance with Title II of Part III. [Am. 62]~~
- (51a) 'veterinarian' means a professional with a comprehensive scientific education, licensed by the legal authority, to carry out, in an independent, ethical and personally responsible capacity, all aspects of veterinary medicine, in the interest of the animals, the client and society; [Am. 63]**
- (51b) 'official veterinarian' means a veterinarian appointed by the competent authorities and appropriately qualified to perform the official controls and other official activities in accordance with the provisions laid down in Regulation (EU) No xxxx/xxxx (**) (official controls Regulation. [Am. 64]**
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amendments to the list of:
- (a) pet animals set out in Annex I;
 - (b) ungulates set out in Annex II.

Chapter 2

Listed diseases and emerging diseases and listed species

Article 5

Listing of diseases

1. The disease specific rules for the prevention and control of diseases provided for in this Regulation shall apply to:
- (a) **the diseases listed diseases in Annex -I; [Am. 65]**

(*) Reference number of 2013/0140(COD).

⁽¹⁾ **Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).**

(**) Reference number of 2013/0140(COD).

Tuesday 15 April 2014

(b) emerging diseases.

2. **A table of listed diseases, as referred to in point (a) of paragraph 1, is set out in Annex -I.** The Commission shall, ~~by means of implementing acts, establish a list of~~ **be empowered to adopt delegated acts, taking due account of the opinions of the European Food Safety Authority, and after due public consultation with stakeholders and experts, in accordance with Article 253, concerning amendments to the** listed diseases, ~~as referred to in paragraph 1(a) set out in this Annex to take account of technical and scientific progress, of the developments of relevant international standards and of the changed circumstances in public and animal health.~~ [Am. 66]

That ~~list~~ **table** shall ~~comprise~~ **cover** diseases which meet with the conditions laid down in the following points (a) and (b) of this paragraph, taking into account the **evaluation of the** criteria for listing diseases laid down in Article 6: [Am. 67]

(a) diseases which are likely to have a significant impact on at least one of the following:

- (i) public health;
- (ii) agricultural or aquaculture production or related sectors of the economy;
- (iii) the society in Member States and **regions, and**, where appropriate, in third countries or territories; [Am. 68]
- (iv) the environment;
- (iva) animal welfare and animal health; [Am. 69]**

(b) diseases for which risk mitigating measures are available, or can be developed and are proportionate to the risks posed by such diseases.

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).~~ [Am. 70]

~~On duly justified imperative grounds of urgency relating to~~ **Where in the case of** a disease representing an emerging risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the ~~procedure referred to in Article 255(3),~~ **imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to delegated acts adopted pursuant to this Article.** [Am. 71]

Article 6

Criteria for listing diseases

1. **When modifying the list of diseases in accordance with Article 5(2),** the Commission shall take account of the following criteria in determining whether a disease meets the conditions to be listed ~~in accordance with Article 5(2):~~ [Am. 72]

(a) the disease profile, which shall comprise the following:

- (i) the animal species concerned by the disease;
- (ii) the morbidity and mortality rates of the disease in animal populations;
- (iii) the zoonotic character of the disease;
- (iv) the capacity **of pathogens** to develop resistance to treatments **with a focus on antimicrobial resistance;** [Am. 73]
- (v) the persistence of the disease in an animal population or in the environment;
- (vi) the routes and speed of transmission of the disease between animals and when relevant between animals and humans;
- (vii) the absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union;
- (viii) the existence of diagnostic and disease control tools;

Tuesday 15 April 2014

- (b) the impact of the disease on:
 - (i) agricultural and aquaculture production and other parts of the economy:
 - the level of presence of the disease in the Union;
 - the loss of production due to the disease;
 - other losses;
 - (ii) human health:
 - transmissibility between animals and humans;
 - transmissibility between humans;
 - the severity of human forms of the disease;
 - the availability of effective prevention or medical treatment in humans;
 - (iii) animal welfare;
 - (iv) biodiversity and environmental pollution;
- (c) its potential to generate a crisis situation and its potential use in bioterrorism;
- (d) the feasibility, availability and effectiveness of the following disease prevention and control measures:
 - (i) diagnostic tools and capacities;
 - (ii) vaccination;
 - (iii) medical treatments;
 - (iv) biosecurity measures;
 - (v) restrictions on the movement of animals and products;
 - (vi) culling and disposal of animals;
- (e) the impact of disease prevention and control measures as regards to:
 - (i) the direct and indirect costs for the affected sectors and the economy as a whole;
 - (ii) their societal acceptance;
 - (iii) the welfare of affected subpopulations of kept **animals, non-kept animals of domesticated species** and **the health of** wild animals; [Am. 74]
 - (iv) the environment and biodiversity.

2. The Commission shall be empowered, **after due public consultation with stakeholders and experts**, to adopt delegated acts in accordance with Article 253 concerning amendments to the criteria provided for in paragraph 1 of this Article to take account of technical and scientific progress and the developments of relevant international standards. [Am. 75]

Article 7

Listing of species

1. The disease specific rules for listed diseases ~~provided for in this Regulation~~ and the rules adopted pursuant to this Regulation shall apply to ~~listed~~ **the species listed in Annex -I.** [Am. 76]

Tuesday 15 April 2014

2. The Commission shall, ~~by means of implementing acts, establish a~~ **be empowered to adopt delegated acts in accordance with Article 253 concerning amendments to the list of species, as referred to in paragraph 1 and set out in a table in Annex -I, to take account of technical progress, scientific developments and changed circumstances in public and animal health, after due public consultation with stakeholders and experts and taking due account of the opinions of the European Food Safety Authority.** [Am. 77]

That list shall ~~comprise~~ **cover** those animal species or groups of animal species, which pose a considerable risk for the spread of specific listed diseases, taking into account the following criteria: [Am. 78]

- (a) the susceptibility of the animal population at risk;
- (b) the duration of the incubation and infective period for the animals;
- (c) the capability of those animals to carry those specific diseases;

(ca) the use of those animals for breeding, production or slaughter. [Am. 79]

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).~~ [Am. 80]

~~On duly justified imperative grounds of urgency relating to~~ **Where in the case of** a disease representing an emerging risk of highly significant impact ~~the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3),~~ **imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to delegated acts adopted pursuant to this Article.** [Am. 81]

Article 8

Application of disease prevention and control rules to listed diseases

1. The Commission shall, ~~by means of implementing acts, determine~~ **be empowered to adopt delegated acts in accordance with Article 253, with due regard to the opinions of the European Food Safety Authority and after due public consultation with stakeholders and experts, modifying Annex -I and concerning** the application of the disease prevention and control rules referred to in the following points to listed diseases: [Am. 82]

- (a) listed diseases **for which immediate eradication measures must be taken as soon as they are detected**, subject to rules on: [Am. 83]
 - (i) disease awareness and preparedness provided for in Title I of Part III and disease control measures provided for in Chapter 1 of Title II of Part III;
 - (ii) compartmentalisation provided for in Article 37(1);
- (b) listed diseases **which should be controlled in all Member States with the long-term goal of eradicating them throughout the Union**, subject to the disease prevention and control rules on: [Am. 84]
 - (i) compulsory eradication programmes provided for in Article 30(1);
 - (ii) disease-free Member States and zones provided for in Article 36;
 - (iii) compartmentalisation provided for in Article 37(2);
 - (iv) disease control measures provided for in Chapter 2 of Title II of Part III;
- (c) listed diseases **that are of relevance for certain Member States, and for which measures are needed to prevent them spreading to parts of the Union that are officially disease-free or have eradication programmes**, subject to the disease prevention and control rules on: [Am. 85]
 - (i) voluntary eradication provided for in Article 30(2);
 - (ii) disease-free Member States and zones provided for in Article 36;
 - (iii) compartmentalisation provided for in Article 37(2);

Tuesday 15 April 2014

- (iv) disease control measures provided for in Chapter 2 of Title II of Part III;
- (d) listed diseases **that are subject to the provisions of points (a), (b) and (c) above, and other diseases for which measures are needed to prevent them spreading on account of their introduction into the Union or movements between Member States**, subject to the disease prevention and control rules on: [Am. 86]
 - (i) movement within the Union provided for in Chapters 3 to 7 of Title I and Chapters 2, 3 and 4 of Title II of Part IV;
 - (ii) entry into the Union and export from the Union provided for in Part V;
- (e) listed diseases **that are subject to the provisions of points (a) and (b) above, and other diseases for which there is a need for monitoring within the Union**, subject to the disease prevention and control rules on: [Am. 87]
 - (i) notification and reporting provided for in Chapter 1 of Part II;
 - (ii) surveillance provided for in Chapter 2 of Part II.

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).~~
[Am. 88]

~~On duly justified imperative grounds of urgency relating to~~ **Where, in the case of** a disease representing an emerging risk of highly significant impact ~~the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3),~~ **imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to delegated acts adopted pursuant to this Article.** [Am. 89]

2. The Commission shall take into account the following criteria when adopting ~~implementing~~ **delegated** acts provided for in paragraph 1: [Am. 90]

- (a) the level of impact of the disease on animal and public health, animal welfare and the economy;
- (b) the prevalence, incidence and distribution of the disease in the Union;
- (c) the availability, feasibility and effectiveness of the different sets of disease prevention and control measures provided for in this Regulation with respect to the disease, **paying strict attention to the prevailing regional conditions.** [Am. 91]

Chapter 3

Responsibilities for animal health

SECTION 1

OPERATORS, ANIMAL PROFESSIONALS AND PET KEEPERS

Article 9

Responsibilities for animal health and biosecurity measures

1. Operators, animal professionals and pet keepers shall:
 - (a) be responsible for the health of kept animals and products under their responsibility;
 - (b) take appropriate biosecurity measures, **assisted by professional guides to good practice, especially applying good microbiological practice**, taking into account the risks involved, to ensure the health of those kept animals and products and to prevent the introduction into, development and multiplication within and spread between and from such kept animals and products under their responsibility of diseases, except where that is specifically authorised for scientific purposes, as appropriate for: [Am. 92]
 - (i) the categories and species of kept animals and products;
 - (ii) the type of production.

Tuesday 15 April 2014

(ba) observe the principle of good animal husbandry; [Am. 93]

(bb) ensure controlled use of veterinary medicines. [Am. 94]

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning biosecurity measures supplementing the rules laid down in paragraph 1(b) of this Article.

Article 10

Basic knowledge of animal health

1. Operators ~~and~~, animal professionals **and pet keepers** shall acquire knowledge of: **[Am. 95]**

(a) animal diseases, including those that are transmissible to humans;

(b) biosecurity principles, **good animal husbandry and responsible use of veterinary medicines; [Am. 96]**

(c) the interaction between animal health, animal welfare and human health.

2. The content and the level of knowledge required in accordance with paragraph 1 shall depend on:

(a) the categories and species of kept animals or products under their responsibility;

(b) the type of production;

(c) the tasks performed.

3. The knowledge provided for in paragraph 1 shall be acquired ~~in one of the following ways:~~ **through professional experience or training in accordance with the requirements laid down in the respective Member State. Such training can also be provided by professional organisations.**

~~(a) professional experience or training;~~

~~(b) existing programmes in agricultural or aquaculture sectors that are relevant for animal health;~~

~~(c) formal education. [Am. 97]~~

Section 2

Veterinarians and aquatic animal health professionals

Article 11

Responsibilities of veterinarians and aquatic animal health professionals

1. Veterinarians shall in the course of their activities which fall within the scope of this Regulation:

(a) take all appropriate measures to prevent the introduction, development and spread of diseases;

(aa) advise operators about measures to minimise the risk of zoonotic diseases, food borne pathogens, residues, contaminants in order to ensure safe food; [Am. 98]

(b) ensure the early detection of diseases by carrying out proper diagnosis and differential diagnosis to rule out or confirm a disease before symptomatic treatment is commenced;

Tuesday 15 April 2014

- (c) play an active role in:
- (i) raising animal health *and animal welfare* awareness; [Am. 99]
 - (ii) disease prevention;
 - (iii) the early detection and rapid response to diseases;
 - (iiia) continuous education on disease prevention, and the early detection and control of diseases; [Am. 100]**
 - (iiib) raising awareness on antimicrobial resistance and implications that might follow; [Am. 101]**
- (d) cooperate with the competent authority, operators, animal professionals and pet keepers in the application of the disease prevention and control measures provided for in this Regulation;
- (da) advise operators and animal professionals on the basis of the latest knowledge available on matters concerning protection against biological hazards and other animal health aspects that are of importance to the type of establishment and the categories and species of animals kept there. [Am. 102]**
2. Aquatic animal health professionals may undertake activities attributed to veterinarians under this Regulation in relation to aquatic animals provided that they are authorised to do so under national legislation. In that event, paragraph 1 shall apply to those aquatic animal health professionals.
- 2a. Bee health professionals may undertake activities attributed to veterinarians under this Regulation in relation to bees and bumble bees provided that they are authorised to do so under national legislation. In that event, paragraph 1 shall apply to those bee health professionals. [Am. 103]**
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the qualifications of veterinarians, **in accordance with Directive 2005/36/EC of the European Parliament and of the Council**⁽¹⁾, and aquatic animal health professionals undertaking activities which fall within the scope of this Regulation. [Am. 104]

SECTION 3

Member States

Article 12

Member States responsibilities

1. In order to ensure the competent authority for animal health has the capability to take the necessary and appropriate measures, and carry out the activities, required by this Regulation, the Member States shall ensure that it has:
- (a) qualified personnel, facilities, equipment, financial resources and an effective organisation covering the whole territory of the Member State;
 - (b) access to laboratories with qualified personnel, facilities, equipment and financial resources to ensure the rapid and accurate diagnosis and differential diagnosis of listed diseases and emerging diseases;

⁽¹⁾ **Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).**

Tuesday 15 April 2014

(c) sufficiently trained veterinarians involved in performing the activities referred to in Article 11 which fall within the scope of this Regulation.

2. Member States shall support operators and animal professionals in acquiring, maintaining and developing the basic knowledge of animal health provided for in Article 10 through relevant programmes in agricultural or aquaculture sectors or formal education, **and ensure that the necessary level of knowledge is attained.** [Am. 105]

2a. Member States shall establish the conditions under which the acquisition, maintenance and development of the basic knowledge of animal health under Article 10 by operators, animal professionals and pet owners can be ensured. [Am. 106]

Article 12a

Strategic measures for non-listed diseases

Member States shall take strategic measures for the monitoring, prevention and control of infectious animal diseases, including those not listed in the Annex to this Regulation, also with the aim of reducing the risk of development of antimicrobial resistance. These measures shall be adopted as part of the national control plans and control programme provided for in Article X of Regulation (EU) No xxxx/xxxx (*) (official controls Regulation) or Article 5 of Regulation (EC) No 2160/2003. [Am. 107]

Article 12b

Border controls

Member States shall, with technical assistance at Union level as regards animal diseases listed in Annex -I to this Regulation, ensure that appropriate preventive, risk-based biosecurity measures are applied along their external borders, in cooperation with the competent authorities of the third countries concerned. [Am. 108]

Article 13

Competent authority's delegation of other official activities

1. The competent authority may delegate one or more of the following activities to veterinarians **or to qualified professional organisations:** [Am. 109]

(a) activities concerning notification and reporting as provided for in Chapter 1 of Part II and surveillance as provided for in Chapter 2 of that Part;

(b) activities related to:

(i) disease awareness, preparedness and control as provided for in Part III;

(ii) registration, approval, traceability and movements as provided for in Part IV;

(iii) emergency measures as provided for in Part VI.

1a. The competent authority may delegate one or more of the activities laid down in paragraph 1 to bee health professionals. [Am. 110]

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253, concerning:

(a) the circumstances and conditions for delegating the activities provided for in paragraph 1 **and paragraph 1a;** [Am. 111]

(*) Reference number of 2013/0140(COD).

Tuesday 15 April 2014

- (b) which other activities may be delegated to veterinarians in addition to those provided for in paragraph 1 of this Article, and under which circumstances and under which conditions;
- (c) minimum requirements for the training of veterinarians provided for in Article 12(1)(c), **in accordance with Directive 2005/36/EC**. [Am. 112]

The Commission shall take account of the nature of those tasks and the international obligations of the Union and the Member States, when adopting those delegated acts.

Article 14

Public information

Where ~~there are reasonable grounds to suspect that animals or products may present a risk~~ **measures are required with respect to the probable outbreak of a disease**, the competent authority shall take appropriate steps to inform the general public of the nature of the risk and the measures which are taken or about to be taken to prevent or control that risk, ~~taking into account the nature, seriousness~~ **the need to avoid spreading panic unnecessarily** and extent of that risk and the public interest in being informed. [Am. 113]

The competent authority shall adopt all the necessary measures to inform citizens on the basic principles in the field of preventing the outbreak and spread of animal diseases, with a particular focus on the risk of persons travelling outside the Union bringing disease agents into the Union. [Am. 114]

Section 4

Laboratories, facilities and other natural and legal persons handling disease agents, vaccines and other biological products

Article 15

Obligations of laboratories, facilities and others handling disease agents, vaccines and other biological products

1. Laboratories, facilities and other natural or legal persons handling disease agents for the purpose of research, education, diagnosis or the production of vaccines and other biological products shall, whilst taking into account international standards where they exist:

- (a) take appropriate biosecurity, biosafety and bio-containment measures to prevent the escape of the disease agents and their subsequent contact with animals outside the laboratory or other facility handling disease agents for the purpose of research;
- (b) ensure that the movement of disease agents, vaccines and other biological products between laboratories or other facilities does not give rise to a risk of the spread of listed and emerging diseases.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the safety measures for the laboratories, facilities and other natural or legal persons handling the disease agents, vaccines and other biological products in relation to:

- (a) biosecurity, biosafety and bio-containment measures;
- (b) movement requirements for disease agents, vaccines and other biological products.

Tuesday 15 April 2014

PART II

DISEASE NOTIFICATION AND REPORTING, SURVEILLANCE, ERADICATION PROGRAMMES, DISEASE-FREE STATUS

Chapter 1

Disease notification and reporting

Article 16

Notification within Member States

1. ~~Natural and legal persons~~ **Operators, animal professionals and pet keepers** shall immediately notify: [Am. 115]
 - ~~(a) the competent authority in the event of an outbreak or suspicion of an outbreak of a listed disease referred to in Article 8(1)(e); [Am. 116]~~
 - (b) a veterinarian **or aquatic animal health professional** of abnormal mortalities and other serious **transmissible** disease signs or significant decreased production rates with an undetermined cause in animals for further investigation, including sampling for laboratory examination when the situation so warrants. [Am. 117]
- 1a. Veterinarians or aquatic animal health professionals shall immediately notify the competent authority in the event of an outbreak or suspicion of an outbreak of a listed disease referred to in point (e) of Article 8(1).** [Am. 118]
- 1b. Doctors shall immediately inform the competent authority of any sign of a zoonotic disease.** [Am. 119]
2. Member States may decide that notifications provided for in paragraph 1(b) shall be directed to the competent authority.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) criteria to determine whether the circumstances requiring notification described in paragraph 1(b) of this Article occur;
 - (b) detailed rules for the further investigation provided for in paragraph 1(b) of this Article.

Article 17

Union notification

1. Member States shall immediately notify the Commission and the other Member States of any outbreaks of listed diseases referred to in Article 8(1)(e) for which an immediate notification is required to ensure the timely implementation of necessary risk management measures, taking into account the disease profile.
2. The notification provided for in paragraph 1 shall contain the following information on the outbreak:
 - (a) the disease agent and, where relevant, the subtype;
 - (b) the dates of the suspicion and confirmation of the outbreak;
 - (c) the location of the outbreak;
 - (d) any related outbreaks;

Tuesday 15 April 2014

- (e) the animals affected by the outbreak;
- (f) any disease control measures taken in relation to the outbreak;
- (g) the possible or known origin of the listed disease;
- (h) the diagnostic methods used.

3. The Commission shall ~~by means of implementing~~ **be empowered to adopt delegated** acts **in accordance with Article 253 to** establish which of the listed diseases referred to in in Article 8(1)(e) shall be subject to immediate notification by the Member States in accordance with paragraph 1 of this Article. **[Am. 120]**

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).~~
[Am. 121]

Article 18

Union reporting

1. Member States shall report to the Commission and to the other Member States the information on listed diseases referred to in in Article 8(1)(e) for which:

- (a) an immediate notification of outbreaks is not required in accordance with Article 17(1);
- (b) an immediate notification of outbreak is required in accordance with Article 17(1), but additional information is required to be reported to the Commission and the other Member States on:
 - (i) surveillance in accordance with the rules laid down in an implementing act adopted in accordance with Article 29;
 - (ii) an eradication programme in accordance with the rules laid down in an implementing act adopted in accordance with Article 35.

2. The reports provided for in paragraph 1 shall include information on:

- (a) the detection of the listed diseases referred to in paragraph 1;
- (b) the results of surveillance when required in accordance with rules adopted in accordance with Article 29(b)(ii);
- (c) the results of surveillance programmes when required in accordance with Article 27(3) and rules adopted in accordance with Article 29(b)(ii);
- (d) eradication programmes when required in accordance with Article 33 and rules laid down in an implementing act adopted in accordance with Article 35.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning ~~amending~~ **and** supplementing the requirements of paragraph 2 of this Article and reporting on other matters where necessary to ensure an efficient application of the disease prevention and control rules of this Regulation. **[Am. 122]**

Article 19

Common rules for Union notification and Union reporting

1. The Union notification and Union reporting provided for in Articles 17(1) and 18(1) shall be done at times and frequencies which ensure transparency and the timely application of the necessary risk management measures, taking into account:

- (a) the disease profile;

Tuesday 15 April 2014

(b) the type of outbreak.

2. The Member States shall establish notification and reporting regions for the purpose of the Union notification and Union reporting provided for in Articles 17(1) and 18(1).

Article 20

Computerised information system for Union notification and Union reporting of diseases

The Commission shall set up and manage a computerised information system for the operation of the mechanisms and tools for the Union notification and Union reporting requirements provided for in Articles 17, 18 and 19.

Article 21

Implementing powers concerning Union notification and Union reporting and the computerised information system

The Commission shall, by means of implementing acts, lay down rules for the Union notification and Union reporting requirements and the computerised information system provided for in Articles 17 to 20 with respect to:

- (a) the information to be provided by the Member States in the Union notification and Union reporting provided for in Articles 17(1) and 18(1);
- (b) procedures for the establishment and use of the computerised information system provided for in Article 20 and transitional measures for the migration of the data and the information from existing systems into the new system and its full operability;
- (c) the format and structure of the data to be entered into the computerised information system provided for in Article 20;
- (d) the deadlines and frequencies of Union notification and Union reporting provided for in Articles 17(1) and 18(1);
- (e) Union notification and Union reporting regions provided for in Article 19(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 2

Surveillance

Article 22

Operators' obligation for surveillance

For the purpose of detecting the presence of listed diseases and emerging diseases, operators shall:

- (a) observe the health and ~~behaviour~~ **welfare** of animals under their responsibility; [Am. 123]
- (aa) **observe any changes in animal products under their responsibility, that may give rise to a suspicion of being caused by a listed disease or emerging disease;** [Am. 124]
- (b) observe any changes in the normal production parameters in the establishments, animals or germinal products under their responsibility, that may give rise to a suspicion of being caused by a listed disease or emerging disease;

Tuesday 15 April 2014

- (c) look for abnormal mortalities and other **signs of serious transmissible** disease signs in animals under their responsibility; [Am. 125]
- (ca) **agree to animal health visits from a veterinarian for the purpose of preventing the occurrence of listed diseases and emerging diseases, in accordance with the criteria laid down in Article 23; such visits shall also serve as a means of providing advice to the operator on biosecurity matters.** [Am. 126]

Operators may take part in any existing voluntary collective steps to monitor animal diseases. [Am. 127]

Article 23

Animal health visits

1. Operators shall ensure that establishments under their responsibility receive animal health visits from a veterinarian ~~when~~ **or other qualified professionals as** appropriate due to the risks posed by the establishment, taking into account: [Am. 128]

- (a) the type of establishment;
- (b) the categories and species of kept animals on the establishment;

(ba) the epidemiological situation in the zone or region; [Am. 129]

- (c) any other relevant surveillance, quality assurance schemes or official controls that the kept animals and type of establishment are subject to.

Those animal health visits shall be at frequencies that **ensure a satisfactory prevention of animal diseases and** are proportionate to the risks posed by the establishment. **The competent authority shall lay down detailed rules as regards the content and frequency of animal health visits for the different types of risk posed by the different types of establishments.** [Am. 130]

They may be combined with visits for other purposes.

2. The animal health visits provided for in paragraph 1 shall be for the purposes of:

- (a) the ~~detection of any~~ **information on** signs indicative of the occurrence of listed diseases or emerging diseases; [Am. 131]
- (b) providing advice to the operator on biosecurity and other animal health matters, as relevant for the type of establishment and the categories and species of kept animals on the establishment;

(ba) providing information to the competent authority to complement the surveillance provided for in Article 25. [Am. 132]

Article 24

Delegation of powers concerning animal health visits

~~The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:~~

~~(a) supplementing:~~

~~(i) the criteria laid down in Article 23(1) to be taken into account when determining:~~

- ~~— which type of establishments must be subject to animal health visits;~~
- ~~— the frequency of such animal health visits;~~

~~(ii) the requirements laid down in Article 23(2) as regards the content and frequency of animal health visits for the different types of establishments, to ensure that the purposes of the animal health visits are achieved;~~

~~(b) determining the types of establishments to be subject to animal health visits.~~ [Am. 133]

Tuesday 15 April 2014

Article 25

The competent authority's obligation for surveillance

1. The competent authority shall conduct surveillance for the presence of listed diseases referred to in Article 8(1)(e) and for emerging diseases.
2. The surveillance shall be designed to ensure the timely detection of the presence of the listed diseases referred to in Article 8(1)(e) and emerging diseases by collecting, collating and analysing relevant information relating to the disease situation. ***This surveillance shall complement and be based on the surveillance carried out by operators both on an individual basis and in the framework of collective voluntary programmes.*** [Am. 134]
3. The competent authority shall ensure that the surveillance information provided for in paragraph 1 is collected and used in an effective and efficient manner.

Article 26

Methodology, frequency and intensity of surveillance

The design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 25(1) shall be appropriate and proportionate to the objectives of the surveillance, taking into account:

- (a) the disease profile;
- (b) the risk factors involved;
- (c) the health status in:
 - (i) the Member State, zone or compartment thereof subject to the surveillance;
 - (ii) the Member States and third countries or territories, which either border on, or from which animals and products enter into that Member State, zone or compartment thereof;
- (d) surveillance conducted by operators in accordance with Article 22, or by other public authorities.

Article 27

Surveillance programmes

1. The competent authority shall undertake surveillance provided for in Article 25(1) in the framework of a surveillance programme, when structured surveillance is necessary due to:
 - (a) the disease profile;
 - (b) the risk factors involved;***(ba) the historical experience with diseases in the Member State, zone or compartment.*** [Am. 135]
2. Member State establishing a surveillance programme in accordance with paragraph 1 shall inform the Commission and the other Member States thereof.
3. Member State undertaking a surveillance programme in accordance with paragraph 1 shall submit regular reports on the results of that surveillance programme to the Commission.

Article 28

Delegation of powers

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) the design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance as provided for in Article 26;

Tuesday 15 April 2014

(b) the criteria for the official confirmation and case definitions of listed diseases referred to in Article 8(1)(e) and where relevant emerging diseases;

(ba) establishing which of the listed diseases referred to in point (e) of Article 8(1) are to be subject to surveillance programmes; [Am. 136]

(c) requirements for surveillance programmes provided for in Article 27(1) regarding:

(i) the contents of surveillance programmes;

(ii) the information to be included in the submission of surveillance programmes in accordance with Article 27(2) and regular reports in accordance with Article 27(3);

(iii) the period of application of surveillance programmes.

Article 29

Implementing powers

The Commission shall, by means of implementing acts, lay down requirements concerning surveillance and surveillance programmes provided for in Articles 26 and 27 and rules adopted pursuant to Article 28 on:

~~(a) establishing which of the listed diseases referred to in Article 8(1)(e) are to be subject to surveillance programmes; [Am. 137]~~

(b) the format and procedure for:

(i) the submission of surveillance programmes ~~for information~~ to the Commission and other Member States; **[Am. 138]**

(ii) the reporting to the Commission on the results of the surveillance;

(iia) the programme evaluation tools used by the Commission and the Member States. [Am. 139]

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 3

Eradication programmes

Article 30

Compulsory and voluntary eradication programmes

1. Member States which are not free or not known to be free from one or more of the listed diseases referred to in Article 8(1)(b) in their whole territory or in zones or compartments thereof, shall:

(a) establish a programme for the eradication of or demonstration of freedom from that listed disease, to be carried out in the animal populations concerned by that disease and covering the relevant parts of their territory or the relevant zones or compartments thereof ('compulsory eradication programme');

(b) submit the draft compulsory eradication programme to the Commission, for approval.

Tuesday 15 April 2014

2. Member States which are not free or not known to be free from one or more of the listed diseases referred to in Article 8(1)(c) and which decide to establish a programme for the eradication of that listed disease to be carried out in the animal populations concerned by it and covering the relevant parts of their territory or zones or compartments thereof ('voluntary eradication programme') shall submit it to the Commission for approval **where:**

(a) the Member State asks the recognition of animal health guarantees within the Union as regards movements of animals or products for that disease; or

(b) the voluntary eradication programme is a candidate for a Union financial contribution. [Am. 140]

3. The Commission shall, by means of implementing acts, approve:

(a) draft compulsory eradication programmes submitted to it for approval in accordance with paragraph 1;

(b) draft voluntary eradication programmes submitted to it for approval in accordance with paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

On duly justified imperative grounds of urgency relating to a listed disease representing a risk of highly significant impact the Commission shall adopt immediately applicable implementing acts provided for in point (a) of this paragraph in accordance with the procedure provided for in Article 255(3).

The Commission may, by means of implementing acts, **require the Member States to** amend or terminate where necessary eradication programmes approved in accordance with points (a) and (b). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2). **[Am. 141]**

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) the objectives, disease control strategies and intermediate targets of compulsory and voluntary eradication programmes;

(b) derogations from the requirement for the submission of compulsory eradication programmes and voluntary eradication programmes for approval, as provided for in paragraph 1(b) and paragraph 2 of this Article, where such approval is not necessary due to the adoption of rules regarding those programmes in accordance with Articles 31(2) and 34(2) and Article 35;

(c) the information to be provided by Member States to the Commission and to the other Member States concerning derogations from the requirement for approval of compulsory eradication programmes and voluntary eradication programmes provided for in (b).

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 amending or terminating rules adopted pursuant to point (b) of this paragraph.

Article 31

Measures under the compulsory and voluntary eradication programmes

1. Compulsory eradication programmes and voluntary eradication programmes shall consist of at least the following measures:

(a) disease control measures for the eradication of the disease agent from establishments, compartments and zones in which the disease occurs and to prevent re-infection;

(b) surveillance carried out in accordance with the rules laid down in Article 26 to 29 to demonstrate:

(i) the effectiveness of the disease control measures provided for in point (a);

(ii) freedom from the listed disease;

(c) disease control measures to be taken in the event of positive surveillance results.

Tuesday 15 April 2014

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) disease control measures as provided for in paragraph 1(a);
 - (b) disease control measures to be taken to avoid re-infection of the targeted animal population with the disease in question in establishments, zones and compartments;
 - (c) the surveillance design, means, diagnostic methods, frequency, intensity, targeted animal population and sampling patterns as provided for in Article 26;
 - (d) disease control measures to be taken in the event of the occurrence of positive results for the listed disease as provided for in paragraph 1(c);
 - (e) vaccination.

Article 32

Content of the submission of compulsory and voluntary eradication programmes

Member States shall include the following information in applications for compulsory and voluntary eradication programmes submitted to the Commission for approval in accordance with Article 30(1) and (2):

- (a) a description of the epidemiological situation of the listed disease covered by the compulsory or voluntary eradication programme;
 - (b) a description and demarcation of the geographical and administrative area covered by the compulsory or voluntary eradication programme;
 - (c) a description of the disease control measures of the compulsory or voluntary eradication programme as provided for in Article 31(1) and the rules adopted pursuant to Article 31(2);
 - (d) the estimated duration of the compulsory or voluntary eradication programme;
 - (e) the intermediate targets and the disease control strategies for undertaking the compulsory or voluntary eradication programme;
 - (f) an analysis of the estimated costs and benefits of the compulsory or voluntary eradication programme;
- (fa) a precise indication of the various public authorities and/or private parties variously involved in the programmes, as well as clear information regarding their respective roles and responsibilities in the implementation thereof. [Am. 142]**

Article 33

Reporting

The Member State undertaking the compulsory or voluntary eradication programme shall submit to the Commission:

- (a) regular intermediate reports to monitor the intermediate targets referred to in Article 32(e) of the on-going compulsory or voluntary programmes;
- (b) a final report after its completion.

Article 34

Period of application of eradication programmes

1. Compulsory and voluntary eradication programmes shall apply until:
 - (a) the conditions to apply for disease-free status in the territory of the Member State or zone as provided for in Articles 36 (1), or compartment, as provided for in Article 37(1) are fulfilled; or

Tuesday 15 April 2014

(b) in the case of voluntary eradication programmes, the conditions to apply for disease-free status cannot be achieved and that programme no longer fulfils its purpose; in that event it shall be withdrawn by the competent authority or by the Commission in accordance with the procedure under which it was established.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning supplementing and amending the requirements provided for in paragraph 1 of this Article as regards the period of application of compulsory and voluntary eradication programmes.

Article 35

Implementing powers *and delegation of powers concerning performance indicators* [Am. 143]

The Commission shall by means of implementing acts, lay down the information, format and procedural requirements concerning the rules provided for in Articles 30 to 33 on:

(a) the submission of draft compulsory and draft voluntary eradication programmes for approval;

~~(b) performance indicators;~~ [Am. 144]

(c) the reporting to the Commission and other Member States on the results of the implementation of compulsory or voluntary eradication programmes.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the establishment of indicators measuring the performance of compulsory or voluntary eradication programmes provided for in Articles 30, 31 and 32. [Am. 145]

Chapter 4

Disease-free status

Article 36

Disease-free Member States and zones

1. A Member State may apply to the Commission for approval of the disease-free status for one or more of the listed diseases referred to in Article 8(1)(b) and (c) for its entire territory, or for one or more zones thereof provided that one or more of the following conditions are fulfilled:

(a) none of the listed species for the disease covered by the application for disease-free status is present in the entire territory of the Member State or in the relevant zone or zones covered by that application;

(b) the disease agent is known not to be able to survive in the entire territory of the Member State, or in the relevant zone or zones covered by that application;

(c) in the event of listed diseases only transmitted by vectors, none of the vectors are present, or are known not to be able to survive in the entire territory of the Member State, or in the relevant zone or zones covered by that application;

(d) freedom from the listed disease has been demonstrated by:

(i) an eradication programme complying with the rules laid down in Article 31(1) and rules adopted pursuant to paragraph 2 of that Article; or

(ii) historical and surveillance data.

Tuesday 15 April 2014

2. Applications by Member States for disease-free status shall include evidence to substantiate that the conditions for disease-free status laid down in paragraph 1 are fulfilled.
3. The Commission shall, by means of an implementing act approve, subject to amendments where necessary, applications by Member States for disease-free status, when the conditions provided for in paragraph 1 and 2 are fulfilled.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 37

Compartments

1. A Member State may apply to the Commission for the recognition of the disease-free status of compartments for listed diseases referred to in Article 8(1)(a), and for the protection of such disease-free status of that compartment in the event of outbreaks of one or more of those listed diseases in its territory provided that:

- (a) the introduction of the listed disease or listed diseases covered by that application can be effectively prevented at compartment level, taking into account the disease profile;
- (b) the compartment covered by the application is subject to a single common biosecurity management system to ensure the disease-free status of all establishments forming part of it;
- (c) the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:
 - (i) Articles 94 and 95 for compartments keeping terrestrial animals and products thereof;
 - (ii) Articles 181 and 182 for compartments keeping aquaculture animals and products thereof.

2. A Member State may apply to the Commission for the recognition of disease-free status of compartments for one or more of the listed diseases referred to in Article 8(1)(b) and (c), provided that:

- (a) the introduction of the listed disease or listed diseases covered by that application can be effectively prevented at compartment level, taking into account the disease profile;
- (b) one or more of the following conditions are complied with:
 - (i) the conditions provided for in Article 36(1)(a) to (d);
 - (ii) the establishments of the compartment start or resume their activities and have established a common biosecurity management system to ensure the disease freedom of the compartment;
- (c) the operators in control of the establishments of the compartment have a common biosecurity management system in place to ensure that the disease-free status of the compartment is guaranteed;
- (d) the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:
 - (i) Articles 94 and 95 for compartments keeping terrestrial animals and products thereof;
 - (ii) Articles 181 and 182 for compartments keeping aquaculture animals and products thereof.

Tuesday 15 April 2014

3. Applications by Member States for the recognition of disease-free status of compartments in accordance with paragraphs 1 and 2 shall include evidence to substantiate that the conditions laid down in those paragraphs are fulfilled.

4. The Commission shall, by means of implementing acts recognise, subject to amendments where necessary, the disease-free status of compartments, when the conditions provided for in paragraphs 1 or 2 and 3 are fulfilled.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) the requirements for the recognition of the disease free status of compartments as provided for in paragraphs 1 and 2 of this Article, taking into account the profile of the listed diseases referred to in Article 8(1)(a), (b) and (c), concerning at least:

(i) surveillance and other evidence needed to substantiate disease-freedom;

(ii) biosecurity measures;

(b) the detailed rules for the approval by the competent authority of the disease-free status of compartments provided for in paragraphs 1 and 2 of this Article;

(c) compartments, which are located in the territory of more than one Member State.

Article 38

Lists of disease-free zones or compartments

Each Member State shall establish and maintain an updated list of:

(a) disease-free territory or zones as provided for in Article 36(1);

(b) disease-free status of compartments as provided for in Article 37(1) and (2).

Member States shall make those lists publicly available.

Article 39

Delegation of powers concerning the disease-free status of Member States and zones

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) detailed rules for the disease-free status of Member States and zones thereof taking into account the different disease profiles concerning:

(i) the criteria to be used to substantiate claims by Member States that no listed species are present or able to survive and the evidence required to substantiate such claims, as provided for in Article 36(1)(a);

(ii) the criteria to be used to substantiate that a disease agent or vector is not able to survive and the evidence required to substantiate such claims as provided for in Article 36(1)(b) and (c);

(iii) the criteria to be used to determine freedom from the disease, as referred to in Article 36(1)(d);

(iv) surveillance and other evidence needed to substantiate disease freedom;

(v) biosecurity measures;

Tuesday 15 April 2014

- (vi) restrictions and conditions for vaccination in disease free Member States and zones thereof;
- (vii) establishment of the zones separating the disease-free zones or zones under the eradication programme from the restricted zones ('buffer zones');
- (viii) zones which extend over the territory of more than one Member State;
- (b) derogations from the requirement for the approval by the Commission of disease-free status for one or more listed diseases referred to in Article 8(1)(b) and (c) as provided for in Article 36(1), where such approval is not necessary due to detailed rules for disease freedom having been laid down in rules adopted pursuant to point (a) of this Article;
- (c) the information to be provided by Member States to the Commission and the other Member States to substantiate the declarations of disease-free status, without the adoption of an implementing act in accordance with Article 36(3), as provided for in point (b) of this Article.

Article 40

Implementing powers

The Commission shall by means of implementing acts, lay down requirements for the disease-free status of territories, zones and compartments concerning the rules provided for in Articles 36, 37 and 38, and rules laid down in delegated acts adopted pursuant to Article 39 concerning:

- (a) establishing for which of the listed diseases referred to in Article 8(1)(a), (b) and (c), the disease-free compartments may be established in accordance with Article 37;
- (b) requirements concerning the information to be submitted, and the format and procedures for:
 - (i) the applications for the disease-free status of the entire territory of the Member State, or zones and compartments thereof;
 - (ii) the information exchange between the Member States and the Commission on disease-free Member States, or zones and compartments thereof.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 41

Maintenance of disease-free status

1. Member States shall only maintain disease-free status for their territories, or zones or compartments thereof as long as:
 - (a) the conditions for disease-free status laid down in Article 36(1) and 37(1) and (2), and rules laid down pursuant to paragraph 3 of this Article and Article 39 remain fulfilled;
 - (b) surveillance, taking into account the requirements provided for in Article 26, is undertaken to verify that the territory, zone or compartment remains free of the listed disease for which it was approved or recognised for disease-free status;
 - (c) restrictions are applied on movements of animals, and where relevant their products, of listed species for the listed disease for which the disease-free status was approved or recognised, into the territory, zone or compartment, in accordance with the rules laid down in Parts IV and V;
 - (d) other biosecurity measures are applied to prevent the introduction of the listed disease for which it was approved or recognised for disease-free status.

Tuesday 15 April 2014

2. A Member State shall immediately inform the Commission if the conditions referred to in paragraph 1 for maintaining disease-free status no longer apply.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the following conditions for maintaining disease-free status:

(a) surveillance as provided for in paragraph 1(b);

(b) biosecurity measures as provided for in paragraph 1(c).

Article 42

Suspension, withdrawal and restoration of disease-free status

1. Where a Member State has reason to suspect, **or is alerted by a notification from the Commission**, that any of the conditions for maintaining its status as a disease-free Member State, or zone or compartment thereof have been breached, it shall immediately: **[Am. 146]**

(a) ~~suspend~~ **take the appropriate measures based on the risk that animal movements of may constitute for the listed species, for the listed disease for which it was approved or recognised for disease free status, to other Member States, zones or compartments with a higher health status for that listed disease in question;** **[Am. 147]**

(b) where relevant for the prevention of the spread of a listed disease for which disease-free status was approved or recognised, apply the disease control measures provided for in Title II of Part III.

2. The measures provided for in paragraph 1 shall be lifted where further investigation confirms that:

(a) the suspected breach has not taken place; or

(b) the suspected breach did not have significant impact and the Member State can provide assurances that the conditions for maintaining its disease-free status are again fulfilled.

3. Where further investigation by the Member State confirms a significant likelihood that the listed disease for which it obtained the disease-free status or other significant breaches of the conditions for maintaining disease-free status have occurred, the Member State shall immediately inform the Commission.

4. The Commission shall, by means of implementing acts, **then immediately** withdraw the approval of the disease-free status of a Member State or zone granted in accordance with Article 36(3) or the recognition of the disease-free status of a compartment granted in accordance with Article 37(4) ~~after obtaining the information from the Member State referred to in paragraph 3 of this Article that the conditions for maintaining the disease-free status are no longer met.~~ **[Am. 148]**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

On duly justified imperative grounds of extreme urgency, where the listed disease referred to in paragraph 3 of this Article spreads in a rapid manner with risk of highly significant impact on animal or public health, the economy or society, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 255(3).

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the ~~rules for the suspension, withdrawal and restoration of disease free status~~ **measures to be taken and the investigations to be carried out by the Member State concerned as** provided for in paragraphs 1 and 2 of this Article. **[Am. 149]**

Tuesday 15 April 2014

Chapter 4a

Official animal health laboratories [Am. 150]

Article 42a

European network of laboratories

1. *The European network of laboratories shall consist of Union reference laboratories, national reference laboratories and official animal health laboratories.*
2. *European network laboratories shall, in fulfilling their tasks and responsibilities, cooperate to ensure that the surveillance of animal diseases and control and eradication programmes provided for in this Regulation are based on state of the art scientific standards and sound and reliable diagnosis. [Am. 151]*

Article 42b

Union reference laboratories

1. *The Commission shall designate Union reference laboratories for illnesses for which, owing to their impact on health or the economy, this is necessary to achieve the objectives of this Regulation.*
2. *That designation shall take the form of a public selection process that is reviewed regularly.*
3. *Union reference laboratories shall:*
 - (a) *operate in accordance with the standard EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’ and be assessed and accredited in accordance with that standard by a national accreditation body, operating in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽¹⁾;*
 - (b) *be impartial and free of conflict of interests as regards the exercise of its tasks as Union reference laboratories;*
 - (c) *have suitably qualified staff with adequate training in analytical, testing and diagnostic techniques applied in their area of competence, and support staff as appropriate;*
 - (d) *possess or have access to the infrastructure, equipment and products necessary to carry out the tasks assigned to them;*
 - (e) *ensure that their staff have good knowledge of international standards and practices and that the latest developments in research at national, Union and international level are taken into account in their work;*
 - (f) *be equipped to perform their tasks in emergency situations;*
 - (g) *where relevant, be equipped to comply with the biosecurity standards relating to their work and take into account the latest developments in research at national, Union and international level; be equipped to perform their tasks in emergency situations; where relevant, be equipped to comply with relevant biosecurity standards.*
4. *The Commission shall be responsible, by means of implementing acts, for establishing the specific tasks and responsibilities of the Union reference laboratories and, where necessary, the minimum requirements in terms of the facilities, equipment and personnel needed. [Am. 152]*

⁽¹⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

Tuesday 15 April 2014

*Article 42c**National reference laboratories*

1. *Member States shall designate one or more national reference laboratories for each Union reference laboratory designated in accordance with Article 42b(1).*
2. *The national reference laboratories must meet the requirements of Article 42b (2).*
3. *The Commission shall be responsible, by means of implementing acts, for establishing the specific tasks and responsibilities of the national reference laboratories and, where necessary, the minimum requirements in terms of the facilities, equipment and personnel needed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2). [Am. 153]*

*Article 42d**General coordination of the laboratories*

1. *The Union reference laboratories and the national reference laboratories shall, within the limits of their competencies:*
 - (i) *ensure that the official animal health laboratories provided for in Article 42e receive updated information on the available methods.*
 - (ii) *organise comparative tests between laboratories and insist on their active participation;*
 - (iii) *identify and satisfy the training needs of the laboratories' personnel.*
 - (iv) *assess the quality and the suitability of the reagents and kits used in laboratory diagnoses, and produce and distribute reference materials.*
2. *The Union reference laboratories and the national reference laboratories shall be responsible for the general coordination of the network of animal health laboratories which come under their territorial jurisdiction. [Am. 154]*

*Article 42e**Official animal health laboratories*

1. *The competent authorities shall designate official laboratories to conduct laboratory analyses and diagnoses of animal diseases.*
2. *The competent authorities may only designate as an official laboratory a laboratory which:*
 - (a) *has the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;*
 - (b) *has a sufficient number of suitably qualified, trained and experienced staff;*
 - (c) *is impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory;*
 - (d) *can deliver the results of the analysis, test or diagnosis in a timely manner;*
 - (e) *has a quality assurance system in place to ensure sound and reliable results from the methods used for laboratory analysis and diagnosis.*

Tuesday 15 April 2014

3. *The official animal health laboratories shall work with the national reference laboratories of the Member States to ensure that their tasks and responsibilities are pursued in accordance with state of the art scientific and quality standards.* [Am. 155]

PART III

DISEASE AWARENESS, PREPAREDNESS AND CONTROL

TITLE I

Disease awareness and preparedness

Chapter 1

Contingency plans and simulation exercises

Article 43

Contingency plans

1. The Member States shall draw up and keep up-to-date contingency plans and where necessary detailed instruction manuals laying down the measures to be taken in the Member State in the event of the occurrence of a case or an outbreak of a listed disease referred to in Article 8(1)(a) or an emerging diseases in order to ensure a high level of disease awareness, preparedness and rapid response.
2. The contingency plans and where applicable detailed instruction manuals shall cover at least the following matters:
 - (a) the establishment of a chain of command within the competent authority and with other public authorities to ensure a rapid and effective decision-making process at Member State, regional and local level;
 - (b) the framework for cooperation between the competent authority and the other public authorities involved to ensure that actions are taken in a coherent and coordinated manner;
 - (c) access to:
 - (i) facilities;
 - (ii) laboratories;
 - (iii) equipment;
 - (iv) personnel;
 - (v) ~~emergency~~ **budget resources and, where necessary, the establishment of special** funds; [Am. 156]
 - (vi) all other appropriate materials and resources necessary for the rapid and efficient eradication of the listed diseases referred to in Article 8(1)(a) or the emerging diseases;
 - (d) the availability of the following centres and groups with the necessary expertise to assist the competent authority:
 - (i) a functional central disease control centre;
 - (ii) regional and local disease control centres, as appropriate for the administrative and geographical situation of the Member States;
 - (iii) operational expert groups;

Tuesday 15 April 2014

- (e) the implementation of the disease control measures provided for in Chapter 1 of Title II for the listed diseases referred to in Article 8(1)(a) and for emerging diseases;
- (f) provisions on emergency vaccination where appropriate;
- (g) principles for the geographical demarcation of the restricted zones established by the competent authority in accordance with Article 64(1);
- (h) coordination with neighbouring Member States and neighbouring third countries and territories, where appropriate.

2a. *The Member States shall consult relevant stakeholders when drawing up and updating contingency plans.*
[Am. 157]

Article 44

Delegation of powers and implementing powers for contingency plans

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed requirements and conditions for the contingency plans provided for in Article 43(1) and to supplement the requirements laid down in Article 43(2), taking into account:

- (a) the objectives of the contingency plans to ensure a high level of disease awareness, preparedness and rapid response;
- (b) the disease profile of the listed diseases referred to in Article 8(1)(a);
- (c) new knowledge of and developments ***on the listed diseases and*** in disease control tools. [Am. 158]

2. The Commission shall, by means of implementing acts, lay down requirements concerning the practical implementation in the Member States of the contingency plans provided for in Article 43(1) with regard to:

- (a) the matters provided for in Article 43(2)(a) and (c) to (h);
- (b) other operational aspects of the contingency plans in the Member States;
- (c) detailed requirements and conditions for the practical implementation of the delegated acts adopted pursuant to paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 45

Simulation exercises

1. The competent authority shall ensure that simulation exercises concerning the contingency plans provided for in Article 43(1) are carried out regularly:

- (a) to ensure a high level of disease awareness, preparedness and rapid response in the Member State;
- (b) to verify the functionality of those contingency plans.

2. Where feasible and appropriate, simulation exercises shall be carried out in close collaboration with the competent authorities of neighbouring Member States and neighbouring third countries and territories.

Tuesday 15 April 2014

3. Member States shall make available on request a report on the main results of the simulation exercises to the Commission and to the other Member States.

4. When appropriate and necessary the Commission shall, by means of implementing acts, lay down rules concerning the practical implementation of simulation exercises in the Member States on:

- (a) the frequencies, contents and format of simulation exercises;
- (b) simulation exercises covering more than one listed disease referred to in Article 8(1)(a);
- (c) collaboration between neighbouring Member States and with neighbouring third countries and territories.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 2

The use of veterinary medicinal products for disease prevention and control

Article 46

The use of veterinary medicinal products for disease prevention and control

1. The Member States ~~may~~ **shall** take measures concerning the **responsible** use of veterinary medicinal products for ~~listed~~ **infectious** diseases, to ensure the most efficient disease prevention or control for those diseases, provided that such measures comply with the rules on the use of veterinary medicinal products laid down in delegated acts adopted pursuant to Article 47. **[Am. 159]**

Those measures may cover the following:

- (a) prohibitions and restrictions on the use of veterinary medicinal products;
- (b) the compulsory use of veterinary medicinal products.

2. Member States shall take the following criteria into consideration when determining whether or not to use and how to use veterinary medicinal products as disease prevention and control measures for a specific ~~listed~~ disease: **[Am. 160]**

- (a) the disease profile;
- (b) the distribution of the listed disease in:
 - (i) the Member State;
 - (ii) the Union;
 - (iii) where relevant, in neighbouring third countries and territories;
 - (iv) third countries and territories from which animals and products are brought into the Union;
- (c) the availability, effectiveness and risks of the veterinary medicinal products, **as well as the detrimental effects of antimicrobial resistance**; **[Am. 161]**
- (d) the availability of diagnostic tests for detecting infections in animals treated with the veterinary medicinal products;
- (e) the economic, social, animal welfare and environmental impact of the use of the veterinary medicinal products compared to other available disease prevention and control strategies.

3. Member States shall take appropriate preventive measures concerning the use of veterinary medicinal products for scientific studies or for the purposes of developing and testing them under controlled conditions to protect animal and public health.

Tuesday 15 April 2014

3a. With the view to reduce antimicrobial resistance and in accordance with action No. 5 of the Communication from the Commission to the European Parliament and the Council — Action plan against the rising threats from Antimicrobial Resistance, Member States shall within two years after the entry into force of this Regulation, at the latest, report to the Commission on the usage of veterinary medicinal products containing antibiotics in their territory. The Union shall thereafter proceed to establish appropriate reduction targets, within three years after the entry into force of this Regulation, at the latest. [Am. 162]

Article 47

Delegation of powers for the use of veterinary medicinal products

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) prohibitions and restrictions on the use of veterinary medicinal products;
 - (b) specific conditions for the use veterinary medicinal products for a specific ~~listed~~ disease; [Am. 163]
 - (c) the compulsory use of veterinary medicinal products;
 - (d) risk mitigating measures to prevent the spread of ~~listed~~ diseases through animals treated with the veterinary medicinal products or products from such animals; [Am. 164]
 - (e) surveillance following the use of vaccines and other veterinary medicinal products for specific ~~listed~~ diseases; [Am. 165]
- (ea) provisions specifying the purpose to which animals which have undergone emergency vaccination may be put. [Am. 166]**
2. The Commission shall take into account the criteria provided for in Article 46(2) when laying down the rules provided for in paragraph 1 of this Article.
3. Where in the case of emerging risks, imperative grounds of urgency so require, the procedure provided for in Article 254 shall apply to rules adopted pursuant to paragraph 1 of this Article.

Chapter 3

Antigen, vaccine and diagnostic reagent banks

Article 48

The establishment of Union antigen, vaccine and diagnostic reagent banks

1. For listed diseases referred to in Article 8(1)(a) for which vaccination is not prohibited by a delegated act adopted pursuant to Article 47(1), the Commission may establish and be responsible for managing Union antigen, vaccine and diagnostic reagent banks for the storage and replacement of stocks of one or more of the following biological products:
 - (a) antigens;
 - (b) vaccines;
 - (c) vaccine master seed-stocks;
 - (d) diagnostic reagents.

1a. The Commission shall ensure a fast track development and registration process for newly emerging disease agents and/or import appropriately registered animal health products. [Am. 167]

Tuesday 15 April 2014

2. The Commission shall ensure that the Union antigen, vaccine and diagnostic reagent banks provided for in paragraph 1:
 - (a) store sufficient stocks of the appropriate type of antigens, vaccines, vaccine master seed-stocks and diagnostic reagents for the specific listed disease, taking into account the needs of Member States estimated in the context of the contingency plans provided for in Article 43(1);
 - (b) receive regular supplies and timely replacements of antigens, vaccines, vaccine master seed-stocks and diagnostic reagents;
 - (c) are maintained and moved under the appropriate biosecurity, biosafety and bio-containment standards as provided for in Article 15(1) and delegated acts adopted pursuant to Article 15(2);
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks as provided for in paragraphs 1 and 2;
 - (b) the biosecurity, biosafety and bio-containment requirements for their operation taking into account the requirements provided for in Article 15(1) and delegated acts adopted pursuant to Article 15(2).

Article 49

Access to the Union antigen, vaccine and diagnostic reagent banks

1. The Commission shall provide for the delivery of the biological products referred to in Article 48(1) from the Union antigen, vaccine and diagnostic reagent banks upon request, provided that stocks are available, to:
 - (a) Member States;
 - (b) third countries or territories, provided that it is primarily intended to prevent the spread of a disease into the Union.
2. The Commission shall prioritise the access provided for in paragraph 1 in the event of the limited availability of stocks taking into account:
 - (a) the disease circumstances under which the request is made;
 - (b) the existence of a national antigen, vaccine and diagnostic reagent bank in the requesting Member State or third country or territory;
 - (c) the existence of Union measures for compulsory vaccination laid down in delegated acts adopted pursuant to Article 47(1).

Article 50

Implementing powers concerning the Union antigen, vaccine and diagnostic reagent banks

The Commission shall, by means of implementing acts, lay down rules for Union antigen, vaccine and diagnostic reagent banks specifying for the biological products referred to in Article 48(1):

- (a) which of those biological products are to be included in the Union antigen, vaccine and diagnostic reagent banks and for which of the listed diseases referred to in Article 8(1)(a);

Tuesday 15 April 2014

- (b) the types of those biological products that are to be included in the Union antigen, vaccine and diagnostic reagent bank and in what quantities for each specific listed disease referred to in Article 8(1)(a), for which the bank exists;
- (c) the requirements concerning the supply, storage and replacement of those biological products;
- (d) the delivery of those biological products from the Union antigen, vaccine and diagnostic reagent banks to the Member States and to third countries and territories;
- (e) procedural and technical requirements for the inclusion of those biological products in the Union antigen, vaccine and diagnostic reagent banks and for requesting access to them.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

On duly justified imperative grounds of urgency relating to a listed disease referred to in Article 8(1)(a) representing a risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 255(3).

Article 51

Confidentiality of information concerning the Union antigen, vaccine and diagnostic reagent banks

Information on the quantities and subtypes of the biological products referred to in Article 48(1) stored in the Union antigen, vaccine and diagnostic reagent banks shall be treated as classified information and shall not be published.

Article 52

National antigen, vaccine and diagnostic reagent banks

1. Member States that have established national antigen, vaccine and diagnostic reagent banks for listed diseases referred to in Article 8(1)(a) for which Union antigen, vaccine and diagnostic reagent banks exist, shall ensure that their national antigen, vaccine and diagnostic reagent banks comply with the biosecurity, biosafety and bio-containment requirements provided for in Article 15(1)(a) and delegated acts adopted in accordance with Article 15(2) and Article 48(3)(b).
2. Member States shall provide the Commission and the other Member States with up-to-date information on:
 - (a) the existence or the establishment of national antigen, vaccine and diagnostic reagent banks referred to paragraph 1;
 - (b) the types of antigens, vaccines, vaccine master seed stocks and diagnostic reagents and their quantities in such banks;
 - (c) any changes in their operation.
3. The Commission may, by means of implementing acts, lay down rules specifying the content, frequency, and format of the submission of the information provided for in paragraph 2 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Tuesday 15 April 2014

TITLE II

Disease control measures

Chapter 1

Listed diseases referred to in Article 8(1)(a)

Section 1

Disease control measures in the event of suspicion of a listed disease in kept animals

Article 53

Obligations of operators, animal professionals and pet keepers

1. In the event of suspicion of a listed disease referred to in Article 8(1)(a) in kept animals, animal professionals, operators and pet keepers shall, in addition to notifying the signs or suspicion to the competent authority and veterinarians in accordance with Article 16(1) and pending any disease control measures being taken by the competent authority in accordance with Articles 54(1) and 55(1), take the appropriate disease control measures provided for in Article 55(1)(c), (d) and (e) to prevent the spread of that listed disease from the affected animals, establishments and locations under their responsibility to other animals or to humans.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules for supplementing the disease control measures to be taken by the operators, animal professionals and pet keepers as provided for in paragraph 1 of this Article.

Article 54

Investigation by the competent authority in the event of suspicion of a listed disease

1. The competent authority shall in the event of the suspicion of a listed disease referred to in Article 8(1)(a) in kept animals, conduct without delay an investigation to confirm or rule out the presence of that listed disease.

2. For the purpose of the investigation provided for in paragraph 1, the competent authority shall, when appropriate, ensure that official veterinarians:

- (a) carry out a clinical examination of a representative sample of the kept animals of listed species for that particular listed disease;
- (b) take appropriate samples from those kept animals of listed species and other samples for laboratory examination in laboratories designated for that purpose by the competent authority;
- (c) carry out laboratory examination to confirm or rule out the presence of the particular listed disease.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing the rules for the investigation by the competent authority provided for in paragraph 1 of this Article.

Tuesday 15 April 2014

Article 55

Preliminary disease control measures by the competent authority

1. The competent authority shall in the event of a suspicion of a listed disease referred to in Article 8(1)(a) in kept animals carry out the following preliminary disease control measures pending the results of the investigation provided for in Article 54(1) and the carrying out of the disease control measures in accordance with Article 61(1):

- (a) place the establishment, ~~household~~, food and feed business, **transport business, livestock trading business** or animal by-products establishment, or any other location where the disease suspicion occurs under official surveillance; [Am. 168]
- (b) compile an inventory of:
 - (i) the kept animals in the establishment, ~~household~~, food and feed business, **transport business, livestock trading business** or animal by-products establishment, or any other location; [Am. 169]
 - (ii) the products in the establishment, ~~household~~, food and feed business, **transport business, livestock trading business** or animal by-products establishment, or any other location, where relevant for the spread of that listed disease; [Am. 170]
- (c) ~~apply~~ **ensure that** appropriate biosecurity measures **are applied** to prevent the spreading of that listed disease agent to other animals or to humans; [Am. 171]
- (d) when appropriate to prevent the further spread of the disease agent, keep the kept animals of listed species for that listed disease isolated, and prevent contact with wildlife;
- (e) restrict the movements of kept animals, products and, if appropriate, people, vehicles and any material or other means by which the disease agent could have spread to or from the establishment, ~~households~~, food and feed business establishments, **transport businesses, livestock trading businesses**, animal by-products establishments or any other location where that listed disease is suspected, as far as necessary to prevent its spread of the listed disease; [Am. 172]
- (f) take any other necessary disease control measures, taking into account the disease control measures provided for in Section 4, **and ensure that any control measures spare the affected animals avoidable pain and suffering**, concerning: [Am. 173]
 - (i) the application of the investigation by the competent authority provided for in Article 54(1) and disease control measures provided for in points (a) to (d) of this paragraph to other establishments, epidemiological units therein, ~~households~~, food and feed businesses, **transport businesses, livestock trading businesses** or animal by-products establishments; [Am. 174]
 - (ii) the establishment of temporary restricted zones, which are appropriate taking into account the disease profile;
- (g) initiate the epidemiological enquiry provided for in Article 57(1).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing those laid down in paragraph 1 of this Article as regards the specific and detailed disease control measures to be taken depending on the listed disease referred to in Article 8(1)(a), taking into account the risks involved for:

- (a) the species or category of animals;
- (b) the type of production.

Tuesday 15 April 2014

Article 56

Review and extension of the preliminary disease control measures

The disease control measures provided for in Article 55(1) shall be:

- (a) reviewed by the competent authority, as appropriate, following the findings of:
 - (i) the investigation provided for in Article 54(1);
 - (ii) the epidemiological enquiry provided for in Article 57(1);
- (b) further extended to other locations as referred to in Article 55(1)(e), where necessary.

SECTION 2

Epidemiological Enquiry

Article 57

Epidemiological enquiry

1. The competent authority shall carry out an epidemiological enquiry in event of the suspicion or confirmation of a listed disease referred to in Article 8(1)(a) in animals.
2. The epidemiological enquiry provided for in paragraph 1 shall aim at:
 - (a) identifying the likely origin of the listed disease and the means of its spread;
 - (b) calculating the likely length of time that the listed disease has been present;
 - (c) identifying contact establishments and epidemiological units therein, ~~households~~, food and feed business, **transport business, livestock trading business** or animal by-products establishment or any other locations where animals of listed species for the suspected listed disease may have become infected, infested or contaminated; [**Am. 175**]
 - (d) obtaining information on the movements of kept animals, persons, products, vehicles, any material or other means by which the disease agent could have been spread during the relevant period preceding the notification of the suspicion or confirmation of the listed disease;
 - (e) obtaining information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors.

Section 3

Disease confirmation in kept animals

Article 58

Official confirmation by the competent authority of a listed disease referred to in Article 8(1)(a)

1. The competent authority shall base an official confirmation of a listed disease referred to in Article 8(1)(a) on the following information:
 - (a) the results of the clinical and laboratory examinations provided for in Article 54(2);
 - (b) the epidemiological enquiry provided for in Article 57(1);

Tuesday 15 April 2014

(c) other available epidemiological data.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1 of this Article.

Article 59

Lifting of preliminary disease control measures where the presence of the listed disease **or an emerging disease** has been ruled out [Am. 176]

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 55(1) and Article 56, until the presence of the listed diseases referred to in Article 8(1)(a) **or an emerging disease** has been ruled out based on the information referred to in Article 58(1) or rules adopted pursuant to Article 58(2). [Am. 177]

Section 4

Disease control measures in the event of disease confirmation in kept animals

Article 60

Immediate disease control measures to be taken by the competent authority

In the event of official confirmation in accordance with Article 58(1) of an outbreak of a listed disease referred to in Article 8(1)(a) in kept animals, the competent authority shall immediately:

- (a) declare the affected establishment, ~~household~~, food or feed business, **transport business, livestock trading business**, animal by-products establishment or other location as officially infected with that listed disease; [Am. 178]
- (b) establish a restricted zone, as appropriate for that listed disease;
- (c) implement the contingency plan provided for in Article 43(1) to ensure full coordination of the disease control measures.

Article 61

Affected establishments and other locations

1. In the event of an outbreak of a listed disease referred to in Article 8(1)(a) in kept animals in an establishment, ~~household~~, food or feed business, **transport business, livestock trading business**, animal by-products establishment or any other location, the competent authority shall immediately take one or more of the following disease control measures in order to prevent the further spread of that listed disease: [Am. 179]

- (a) movement restrictions for persons, animals, products, vehicles or any other material or substance that may be contaminated and contribute to the spread of the listed disease;
- (b) the **humane** killing and disposal or slaughtering of animals that may be contaminated and contribute to the spread of the listed disease, **provided that this is done in such a way as to spare the animals any avoidable pain, distress or suffering**; [Am. 180]
- (c) the destruction, processing, transformation or treatment of products, feed, or any other substances, or the treatment of equipment, means of transport, plants or plant products, or water which may be contaminated, as appropriate to ensure that any disease agent or vector of the disease agent is destroyed;
- (d) the vaccination or treatment with other veterinary medicinal products of kept animals in accordance with Article 46(1) and any delegated acts adopted pursuant to Article 47(1), **preferably vaccination which involves animals remaining alive and has no adverse impact on trade within the Union and with third countries**; [Am. 181]

Tuesday 15 April 2014

- (e) the isolation, quarantine or treatment of animals and products that are likely to be contaminated and contribute to the spread of the listed disease;
- (f) the cleaning, disinfection, disinfestation or other necessary biosecurity measures to be applied to the affected establishment, ~~household~~, food or feed business, **transport business, livestock trading business**, animal by-products establishment or other locations to minimise the risk of spread of the listed disease; [Am. 182]
- (g) the taking of a sufficient number of appropriate samples needed to complete the epidemiological enquiry provided for in Article 57(1);
- (h) the laboratory examination of samples.

2. When determining which of the disease control measures provided for in paragraph 1 are appropriate to take, the competent authority shall take the following into account:

- (a) the disease profile;
- (b) the type of production, and epidemiological units within the affected establishment, ~~household~~, food or feed business, **transport business, livestock trading business**, animal by-products establishment or other location; [Am. 183]

(ba) the effect of the measures on farm animal genetic diversity and the need to conserve farm animal genetic resources. [Am. 184]

3. The competent authority shall only authorise the repopulation of the establishment, ~~household~~ or any other location when: [Am. 185]

- (a) all appropriate disease control measures and laboratory examinations provided for in paragraph 1 have been successfully completed;
- (b) a sufficient period of time has elapsed to prevent re-contamination of the affected establishment, ~~household~~, food or feed business, **transport business, livestock trading business**, animal by-products establishment and other location with the listed disease that caused the outbreak referred to in paragraph 1. [Am. 186]

Article 62

Epidemiologically linked establishments and locations

1. The competent authority shall extend the disease control measures provided for in Article 61(1) to other establishments, epidemiological units therein, ~~households~~, food or feed businesses, **transport businesses, livestock trading businesses** or animal by-products establishments, or any other location, or means of transport where the epidemiological enquiry provided for in Article 57(1), or the results of clinical or laboratory investigations or other epidemiological data give reason to suspect the spread to, from or through them of the listed disease referred to in Article 8(1)(a) for which such measures were taken. [Am. 187]

2. If the epidemiological enquiry provided for in Article 57(1) shows that the likely origin of the listed disease referred to in Article 8(1)(a) is another Member State or it is likely that that listed disease has spread to another Member State, the competent authority shall inform that Member State **and the Commission**. [Am. 188]

3. In the events referred to in paragraph 2, the competent authorities of the different Member States shall cooperate in a further epidemiological enquiry and in the application of disease control measures.

Tuesday 15 April 2014

Article 63

Delegating power for the disease control measures in affected and epidemiologically linked establishments and locations

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules on the disease control measures to be taken by the competent authority in accordance with Articles 61 and 62 in affected and epidemiologically linked establishments, food or feed businesses or animal by-products establishments and locations for any listed disease referred to in Article 8(1)(a).

Those detailed rules shall cover the following matters:

- (a) the conditions and requirements for the disease control measures, provided for in Article 61(1)(a) to (e);
- (b) the procedures for cleaning, disinfection and disinfestation provided for in of Article 61(1)(f), specifying, where appropriate the use of biocidal products for those purposes;
- (c) the conditions and requirements for sampling and laboratory examination provided for in Article 61(1)(g) to (h);
- (d) the detailed conditions and requirements of repopulation provided for in Article 61(3);
- (e) the necessary disease control measures provided for in Article 62 to be carried out in epidemiologically linked establishments, locations and means of transport.

Article 64

Establishment of restricted zones by the competent authority

1. The competent authority shall establish a restricted zone around the affected establishment, ~~household~~, food or feed business, **transport business, livestock trading business**, animal by-products establishment or other location where the outbreak of a listed disease referred to in Article 8(1)(a) in kept animals has occurred, where appropriate, taking into account: [**Am. 189**]

- (a) the disease profile;
- (b) the geographical situation of the restricted zones;
- (c) the ecological and hydrological factors of the restricted zones;
- (d) the meteorological conditions;
- (e) the presence, distribution and type of vectors in the restricted zones;
- (f) the results of the epidemiological enquiry provided for in Article 57(1) and other studies carried out and epidemiological data;
- (g) the results of laboratory tests;
- (h) the disease control measures applied;

(ha) the direct and indirect costs for the affected sectors and the economy as a whole. [**Am. 190**]

The competent authority shall establish the restricted zone in a manner consistent with the principle of proportionality. [**Am. 191**]

The restricted zone shall include, when appropriate, a protection and surveillance zone of a defined size and configuration.

Tuesday 15 April 2014

2. The competent authority shall continuously assess and review the situation and, when appropriate in order to prevent the spread of the listed disease referred to in Article 8(1)(a):

- (a) adapt the boundaries of the restricted zone;
- (b) establish additional restricted zones.

3. Where the restricted zones are situated in the territory of more than one Member State, the competent authorities of those Member States shall cooperate in establishing the restricted zones provided for in paragraph 1.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules for the establishment and amendment of restricted zones, including protection or surveillance zones.

Article 65

Disease control measures in a restricted zone

1. The competent authority shall take one or more of the following disease control measures in the restricted zone in order to prevent the further spread of the listed disease referred to in Article 8(1)(a):

- (a) the identification of establishments, ~~households~~, food or feed businesses, **transport businesses, livestock trading businesses**, animal by-products establishments or other locations with kept animals of listed species for that listed disease; [**Am. 192**]
- (b) visits to establishments, ~~households~~, food or feed businesses, **transport businesses, livestock trading businesses**, animal by-products establishments or other locations with kept animals of listed species for that listed disease, and where necessary examinations, sampling and laboratory examination of the samples; [**Am. 193**]
- (c) movement conditions for the movement of persons, animals, products, feed, vehicles and any other material or substance that may be contaminated or contribute to the spread of that listed disease within and from the restricted zones and transport through the restricted zones;
- (d) biosecurity requirements for:
 - (i) the production, processing and distribution of products of animal origin;
 - (ii) the collection and disposal of animal by-products;
 - (iii) artificial insemination.
- (e) the vaccination and treatment with other veterinary medicinal products of kept animals in accordance with Article 46 (1) and any delegated acts adopted pursuant to Article 47(1);
- (f) cleaning, disinfection and disinfestation;
- (g) the designation or where relevant, approval of a food business establishment for the purposes of the slaughtering, **using pre-stunning**, of animals or the treatment of products of animal origin originating from the restricted zones; [**Am. 194**]
- (h) the identification and traceability requirements for the movement of animals, germinal products or products of animal origin;
- (i) other necessary biosecurity and risk mitigating measures to minimise the risks of the spread of that listed disease.

2. The competent authority shall take all necessary measures to fully inform the persons in the restriction zones of the restrictions in force and the nature of the disease control measures.

Tuesday 15 April 2014

3. When determining which of the disease control measures provided for in paragraph 1 are to be taken, the competent authority shall take the following into account:

- (a) the disease profile;
- (b) the types of production;
- (c) the feasibility, availability and effectiveness of those disease control measures.

Article 66

Operators obligations in restricted zones

1. Operators keeping animals and products in the restricted zone provided for in Article 64(1) shall notify any intended movement of kept animals and products, within or out of the restricted zone, to the competent authority.
2. They shall only move the kept animals and products in accordance with the instructions of the competent authority.

Article 67

Delegation of powers concerning the disease control measures in restricted zones

The Commission shall be empowered to adopt delegated acts in accordance with Article 253, concerning detailed rules on the disease control measures to be taken in a restricted zone provided for in Article 65(1) for each listed disease referred to in Article 8(1)(a).

Those detailed rules shall cover the following matters:

- (a) the conditions and requirements for the disease control measures, provided for in Article 65(1) (a), (c), (d), (e), (g), (h) and (i);
- (b) **principles concerning** the procedures for cleaning, disinfection and disinfestation provided for in Article 65(1)(f), specifying, where appropriate the use of biocidal products for those purposes; [Am. 195]
- (c) the necessary surveillance which is to be conducted following the application of the disease control measures and laboratory examinations provided for in Article 65(1)(b);
- (d) other specific disease control measures to limit the spread of specific listed diseases referred to in Article 8(1)(a).

Article 68

Maintaining disease control measures in restricted zones and delegated acts

1. The competent authority shall continue to apply the disease control measures provided for in this Section until:
 - (a) the disease control measures, appropriate to the listed disease referred to in Article 8(1)(a) for which the restrictions were applied have been carried out;
 - (b) the final cleaning, disinfection or disinfestation has been carried out as appropriate for:
 - (i) the listed disease referred to in Article 8(1)(a) for which the disease control measures have been applied;
 - (ii) the affected species of kept animals;
 - (iii) the type of production;
 - (c) adequate surveillance, as appropriate for the listed disease referred to in Article 8(1)(a) for which the disease control measures have been applied, and the type of establishment or location has been carried out in the restricted zone substantiating the eradication of that listed disease.

Tuesday 15 April 2014

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules for the disease control measures to be taken by the competent authority as provided for in paragraph 1 of this Article in relation to:

- (a) the final cleaning, disinfection or disinfestation procedures, and where appropriate the use of biocidal products for those purposes;
- (b) the design, means, methods, frequency, intensity, targeted animal population and sampling patterns of surveillance to regain disease-free status after the outbreak;
- (c) the repopulation of the restricted zones after the completion of the disease control measures provided for in paragraph 1 of this Article, taking into account the conditions for repopulation provided for in Article 61(3);
- (d) other disease control measures necessary in order to regain the disease-free status.

Article 69

Emergency vaccination

1. Where relevant for the effective control of the listed disease referred to in Article 8(1)(a) for which the disease control measures due to the outbreak apply, the competent authority may:

- (a) develop a vaccination plan;
- (b) establish vaccination zones.

2. The competent authority shall, when deciding on the vaccination plan and the establishment of vaccination zones provided for in paragraph 1 of this Article, take the following into account:

- (a) the requirements for emergency vaccination provided for in the contingency plans provided for in Article 43(1);
- (b) the requirements for the use of vaccines provided for in Article 46(1) and any delegated acts adopted pursuant to Article 47(1).

3. Vaccination zones provided for in paragraph 1(b) of this Article shall comply with the requirements on risk mitigating measures to prevent the spread of listed diseases and surveillance as laid down in any delegated acts adopted in accordance with Article 47(1)(d) and (e).

3a. *Animals which have undergone emergency vaccination may be used for a specific purpose in accordance with the provisions of Article 47(1)(f).* [Am. 196]

3b. *Where the vaccine used is certified as safe for human consumption, subsequent slaughter of non-infected, vaccinated animals should be avoided.* [Am. 197]

Section 5

Wild animals **and stray domestic animals** [Am. 198]

Article 70

Wild animals **and stray domestic animals** [Am. 199]

1. In the event of the suspicion or official confirmation of a listed disease referred to in Article 8(1)(a) in wild animals **or stray domestic animals**, the affected Member State shall: [Am. 200]

- (a) conduct, where relevant for that particular listed disease, surveillance in the wild animal population;

Tuesday 15 April 2014

(aa) **monitor the population of stray domestic animals where this is relevant for this specific listed disease;** [Am. 201]

(b) take the necessary disease prevention and control measures to avoid the further spread **or bring about the eradication** of that listed disease **and ensure that any control measures spare the affected animals avoidable pain and suffering.** [Am. 202]

2. The disease prevention and control measures provided for in paragraph 1(b) shall take the following matters into account:

(a) the disease profile;

(b) the affected wild animals **and non-kept domestic animals;** [Am. 203]

(ba) **contact between wild and kept animals and the associated risk of mutual infection;** [Am. 204]

(bb) **direct contact between the affected animals and people and physical proximity to people;** [Am. 205]

(c) the disease control measures to be taken in the event of suspicion or official confirmation of a listed disease referred to in Article 8(1)(a) in restricted zones in kept animals pursuant to rules laid down in Sections 1 to 4.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) surveillance pursuant to paragraph 1(a);

(b) disease prevention and control measures pursuant to paragraph 1(b).

When adopting those delegated acts, the Commission shall take into consideration the disease profile and the listed species for the listed disease referred to paragraph 1.

Section 6

Additional disease control measures by the Member States, Coordination by the Commission and temporary special disease control rules

Article 71

Additional disease control measures by the Member States, coordination of measures by the Commission and temporary special disease control rules concerning Sections 1 to 5

1. Member States may take additional disease control measures to those provided for in Article 61(1), Article 62, Article 65(1) and (2) and Article 68(1) and in delegated acts adopted pursuant to Article 67 and Article 68(2), provided that such measures are in line with the rules laid down in this Regulation and they are necessary and proportionate to control the spread of the listed disease referred to in Article 8(1)(a), taking into account:

(a) the particular epidemiological circumstances;

(b) the type of establishments, other locations and production;

(c) the categories and species of animals involved;

(d) economic or social conditions.

Tuesday 15 April 2014

2. Member States shall inform the Commission without delay of:
 - (a) the disease control measures taken by the competent authority as provided for in Articles 58, 59, 61, 62, 64 and 65, Article 68(1), Article 69 and Article 70(1) and (2) and delegated acts adopted pursuant to Articles 63 and 67 and Articles 68(2) and 70(3);
 - (b) any additional disease control measures taken by it as provided for in paragraph 1.
3. The Commission shall review the disease situation and the disease control measures taken by the competent authority and any additional disease control measures taken by the Member State, in accordance with this Chapter and may, by means of implementing acts, lay down special disease control measures for a limited period of time, under conditions appropriate to the epidemiological situation, where:
 - (a) those disease control measures are found not to be suited to the epidemiological situation;
 - (b) the listed disease referred to in Article 8(1)(a) appears to be spreading despite the disease control measures taken in accordance with this Chapter.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

4. On duly justified imperative grounds of urgency relating to a disease representing an emerging risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).

Chapter 2

Listed diseases referred to in Article 8(1)(b) and (c)

Article 71a

Scope of Chapter 2

As regards diseases listed in Article 8(1)(c), the following provisions of Chapter 2 shall apply only to Member States which have drawn up a national programme. [Am. 206]

Section 1

Disease control measures in the event of suspicion of disease in kept animals

Article 72

Obligations of operators, animal professionals and pet keepers

1. In the event of suspicion of listed diseases referred to in Article 8(1)(b) and (c) in kept animals, operators, animal professionals and pet keepers shall, in addition to notifying the signs and suspicion to the competent authority and veterinarians in accordance with Article 16(1) and pending any disease control measures being taken by the competent authority in accordance with Article 74(1), take appropriate disease control measures referred to in Article 74(1)(a) and any delegated acts adopted pursuant to Article 74(3) to prevent the spread of that listed disease from the affected animals, establishments and locations under their responsibility to other animals or to humans.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules for supplementing the disease control measures to be taken by the operators, animal professionals and pet keepers as provided for in paragraph 1 of this Article.

Tuesday 15 April 2014

Article 73

Investigation by the competent authority in the event of suspicion of a listed disease

1. The competent authority shall, in the event of the suspicion of a listed disease referred to in Article 8(1)(b) and (c) in kept animals, conduct without delay an investigation to confirm or rule out the presence of that listed disease.
2. For the purpose of the investigation provided for in paragraph 1, the competent authority shall, when appropriate, ensure that official veterinarians:
 - (a) carry out a clinical examination of a representative sample of the kept animals of listed species for that particular listed disease;
 - (b) take appropriate samples from the kept animals of listed species and other samples for laboratory examination in laboratories designated for that purpose by the competent authority;
 - (c) carry out a laboratory examination to confirm or rule out the presence of the particular listed disease.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing rules for the investigation provided for in paragraph 1 of this Article.

Article 74

Preliminary disease control measures by the competent authority

1. The competent authority shall, in the event of a suspicion of a listed disease referred to in Article 8(1)(b) or (c) in kept animals carry out the following preliminary disease control measures, pending the results of the investigation provided for in Article 73(1) and the carrying out of disease control measures in accordance with Article 78(1) and (2):
 - (a) apply disease control measures to limit the spread of that listed disease from the affected territory, establishment, ~~household~~, food or feed business, **transport business, livestock trading business**, animal by-products establishment or other location; [Am. 207]
 - (b) initiate where necessary, an epidemiological enquiry, taking into account the rules for such investigation provided for in Article 57(1) and any rules adopted pursuant to Article 57(2).
2. The preliminary disease control measures provided for in paragraph 1 shall be appropriate and proportionate to the risk posed by the listed disease referred to in Article 8(1)(b) or (c) taking into account the following:
 - (a) the disease profile;
 - (b) the kept animals affected;
 - (c) the health status of the Member State, zone, compartment or establishment in which that listed disease is suspected;
 - (d) the preliminary disease control measures provided for in Article 55(1) and Article 56 and any delegated act adopted pursuant to Article 55(2).
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules supplementing those laid down in paragraph 1 of this Article, while taking into account the matters referred to in paragraph 2 of this Article, as regards:
 - (a) the preliminary disease control measures to be taken to prevent the spread of the listed disease, as provided for in paragraph 1(a);

Tuesday 15 April 2014

- (b) the application of the preliminary disease control measures provided for in paragraph 1(a) to other establishments, epidemiological units therein, ~~households~~, food or feed businesses, **transport businesses, livestock trading businesses** and animal by-products establishments or other locations; [Am. 208]
- (c) the establishment of temporary restricted zones, which are appropriate due to the disease profile.

Article 75

Review and extension of the preliminary disease control measures

The disease control measures provided for in Article 74(1) shall be:

- (a) reviewed by the competent authority as appropriate following the findings of the investigation provided for in Article 73(1) and, where relevant the epidemiological enquiry provided for in Article 74(1)(b);
- (b) further extended to other locations, as referred to in Article 74(3)(b) where necessary.

Section 2

Disease confirmation in kept animals

Article 76

Official confirmation of disease by the competent authority

1. The competent authority shall base an official confirmation of a listed disease referred to in Article 8(1)(b) or (c) on the following information:
 - (a) the results of the clinical and laboratory examinations provided for in Article 73(2);
 - (b) the epidemiological enquiry provided for in Article 74(1)(b), where relevant;
 - (c) other available epidemiological data.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1 of this Article.

Article 77

Lifting preliminary disease control measures when disease occurrence is ruled out

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 74(1) and Article 75 until the presence of the listed diseases referred to in Article 8(1)(b) or (c) has been ruled out in accordance with Article 76(1) or rules adopted pursuant to Article 76(2).

Section 3

Disease Control measures in the event of disease confirmation in kept animals

Article 78

Disease control measures by the competent authority

1. In the event of an official confirmation in accordance with Article 76(1) of an outbreak of a listed disease referred to in Article 8(1)(b) in kept animals the competent authority shall:
 - (a) in a Member State, zone or compartment subject to a compulsory eradication programme provided for in Article 30(1) for that listed disease, apply the disease control measures laid down in that compulsory eradication programme;

Tuesday 15 April 2014

- (b) in a Member State, area, zone or compartment that is not yet subject to a compulsory eradication programme provided for in Article 30(1) for that listed disease, initiate that compulsory eradication programme and apply the disease control measures laid down therein.
2. In the event of an official confirmation in accordance with Article 76(1) of an outbreak of a listed disease referred to in Article 8(1)(c) in kept animals the competent authority shall:
- (a) in a Member State, zone or compartment subject to a voluntary eradication programme provided for in Article 30(2) for that listed disease, apply the disease control measures laid down in that voluntary eradication programme.
- ~~(b) in a Member State, area, zone or compartment that is not subject to a voluntary eradication programme provided for in Article 30(2) for that listed disease, apply, when appropriate, measures to control and prevent its spread. [Am. 209]~~
3. The measures provided for in paragraph 2(b) of this Article shall be proportionate to the risk posed by the listed disease referred to in Article 8(1)(c) in question taking into account:
- (a) the disease profile;
- (b) the kept animals affected, **particularly when they belong to an endangered race or variety**; [Am. 210]
- (c) the health status of the Member State, area, zone, compartment or establishment in which the listed disease has been officially confirmed;
- (d) the disease control measures to be taken in the establishments, other locations and restricted zones provided for in Section 4 of Chapter 1 of this Title.

Article 79

Delegation of powers for the disease control measures to be taken by the competent authority

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 laying down detailed rules concerning the disease control measures to be taken in the event of outbreaks of a listed disease referred to in Article 8(1)(b) or (c) in kept animals as provided for in Article 78(2)(b) taking into account the criteria provided for in Article 78(3).

Section 4

Wild animals **and animals of domestic species which are not kept** [Am. 211]

Article 80

Wild animals **and animals of domestic species which are not kept** [Am. 212]

1. In the event of suspicion or official confirmation of a listed disease referred to in Article 8(1)(b) in wild animals **and animals of domestic species which are not kept**, the competent authority of the affected Member State shall: [Am. 213]
- (a) in the entire territory of the Member State, area or, zone subject to a compulsory eradication programme provided for in Article 30(1) for that listed disease, apply the disease control measures laid down in that compulsory eradication programme;
- (b) in the entire territory of the Member State, area or zone that is not subject to a compulsory eradication programme provided for in Article 30(1) for that listed disease, initiate that compulsory eradication programme and apply the disease control measures laid down therein where appropriate, to control and prevent its spread.

Tuesday 15 April 2014

2. In the event of an outbreak of a listed disease referred to in Article 8(1)(e) in wild animals **and animals of domestic species which are not kept and are not covered by the provisions of Article 8(1)(b)**, the competent authority of the affected Member State shall: [Am. 214]

- (a) in the entire territory of the Member State, area, zone or compartment subject to a voluntary eradication programme provided for in Article 30(2) for that listed disease, apply the disease control measures laid down in that voluntary eradication programme;
- (b) in the entire territory of the a Member State, area, zone or compartment that is not subject to an voluntary eradication programme provided for in Article 30(2) for that listed disease, apply, when appropriate, measures to control and prevent its spread.

3. The disease control measures referred to in paragraph 2(b) shall take the following matters into account:

- (a) the disease profile;
- (b) the affected wild animals **and animals of domestic species which are not kept**; [Am. 215]
- (ba) contact between animals living in the wild and kept animals, and the associated risk of mutual infection;** [Am. 216]
- (bb) direct contact between the animals concerned and human beings, and spatial proximity to people;** [Am. 217]
- (c) the disease control measures to be taken in the event of suspicion or official confirmation of a listed disease in restricted zones in kept animals pursuant to rules laid down in Sections 1 to 4 of Chapter 1 of this Title.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules supplementing the disease control measures to be taken in the event of outbreaks of a listed disease referred to in Article 8(1)(b) or (c) in wild animals **and animals of domesticated species which are not kept** as provided for in paragraph 2(b) of this Article. [Am. 218]

Section 5

Coordination by the Commission and temporary special disease control rules

Article 81

Coordination of measures by the Commission and temporary special rules concerning Sections 1 to 4

1. Member States shall inform the Commission of the disease control measures taken by the competent authority in respect of a listed disease referred to in Article 8(1)(b) or (c), in accordance with Article 76(1), Articles 77 and 78 and Article 80(1) and (2) and delegated acts adopted pursuant to Article 76(2), Article 79 and Article 80(4).

2. The Commission shall review the disease situation and the disease control measures taken by the competent authority in accordance with this Chapter and may, by means of implementing acts, lay down special rules for disease control measures for a limited period of time in respect of a listed disease referred to in Article 8(1)(b) and (c), under conditions appropriate to the epidemiological situation, where:

- (a) those disease control measures taken by the competent authority are found not to be suited to the epidemiological situation;

Tuesday 15 April 2014

- (b) that listed disease referred to in Article 8(1)(b) or (c) appears to be spreading despite the disease control measures taken in accordance with this Chapter, where relevant.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

3. On duly justified imperative grounds of urgency relating to a listed disease referred to in Article 8(1)(b) and (c) representing an emerging risk of highly significant impact the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).

PART IV

REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS

TITLE I

Terrestrial animals, germinal products and products of animal origin from terrestrial animals

Chapter 1

Registration, approval, record keeping and registers

SECTION 1

REGISTRATION OF ESTABLISHMENTS AND TRANSPORTERS

Article 82

Obligation of operators to register establishments

1. Operators of establishments keeping terrestrial animals or collecting, producing, processing or storing germinal products shall, in order to be registered in accordance with Article 88, before they commence such activities:

- (a) inform the competent authority of any such establishment under their responsibility;
- (b) provide the competent authority with information on:
 - (i) the name and address of the operator;
 - (ii) the location and a description of the facilities;
 - (iii) the categories, species and numbers of kept terrestrial animal or germinal products on the establishment and the capacity of the establishment;
 - (iv) the type of establishment;
 - (v) other aspects of the establishment, which are relevant in determining the risk posed by it.

2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of any:

- (a) significant changes in the establishment concerning the matters referred to in paragraph 1(b);
- (b) cessation of activity in the establishment.

3. Establishments which are subject to approval in accordance with Article 89(1) shall not be required to provide the information referred to in paragraph 1 of this Article.

Tuesday 15 April 2014

Article 83

Derogations from the obligation of operators to register establishments

By way of derogation from Article 82(1), Member States may exempt certain categories of establishments from the registration requirement, taking into account the following criteria:

- (a) the categories, species and numbers of kept terrestrial animals and germinal products on the establishment and the capacity of the establishment;
- (b) the type of establishment;
- (c) the movements of kept terrestrial animals or germinal products into and out of the establishment.

Article 84

Implementing powers concerning the obligation of operators to register establishments

The Commission may, by means of implementing acts, lay down rules concerning:

- (a) the information to be provided by operators for the purpose of the registration of the establishments as provided for in Article 82(1);
- (b) the types of establishments that may be exempted by the Member States from the registration requirement in accordance with Article 83 provided that those establishments pose an insignificant risk and taking into account the criteria provided for in that Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 85

Registration obligations of transporters of kept ungulates and delegated acts

1. Transporters of kept ungulates, transporting those animals between Member States shall in order to be registered in accordance with Article 88, before they commence such activities:

- (a) inform the competent authority of their activity;
- (b) provide the competent authority with information on:
 - (i) the name and address of the transporter;
 - (ii) the categories, species and numbers of kept terrestrial animals transported;
 - (iii) the type of transport;
 - (iv) the means of transport.

2. Transporters shall inform the competent authority of any:

- (a) significant changes concerning the matters referred to in paragraph 1(b);
- (b) cessation of the transport activity.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning supplementing and amending the rules provided for in paragraph 1 concerning the obligation of other types of transporters to provide the information for the purposes of registration of its activity, taking into account the risks involved with such transports.

Tuesday 15 April 2014

~~Article 86~~~~Derogations from the obligation to register transporters of kept ungulates~~

~~By way of derogation from Article 85(1), Member States may exempt certain categories of transporters from the registration requirement, taking into account the following criteria:~~

- ~~(a) the distances over which they transport those kept terrestrial animals;~~
- ~~(b) the categories, species and number of kept terrestrial animals, which they transport. [Am. 219]~~

Article 87

Implementing acts concerning the obligation to register transporters

The Commission shall be empowered to adopt implementing acts concerning:

- (a) the information to be provided by the transporter for the purposes of registration of its activity, as provided for in Article 85(1);
- ~~(b) the types of transporters that may be exempted by the Member States from the registration requirement in accordance with Article 86 provided that the type of transport poses an insignificant risk and taking into account the criteria provided for in that Article. [Am. 220]~~

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 88

Obligation of the competent authority concerning the registration of establishments and transporters

The competent authority shall register:

- (a) establishments in the register of establishments and transporters provided for in Article 96(1), where the operator has provided the information required in accordance with Article 82(1);
- (b) transporters in that register of establishments and transporters provided for in Article 96(1), where the transporter has provided the information required in accordance with Article 85(1).

Section 2

Approval of certain types of establishments

Article 89

Approval of certain establishments and delegated acts

1. Operators of the following types of establishments shall apply to the competent authority for approval in accordance with Article 91(1) and they shall not commence their activities until their establishment has been approved in accordance with Article 92(1):

- (a) establishments for assembly operations of ungulates and poultry, from which those animals are moved to another Member State;
- (b) germinal product establishments for bovine, porcine, ovine, caprine and equine animals, from which germinal products of those animals are moved to another Member State;
- (c) hatcheries, from which hatching eggs or poultry are moved to another Member State;
- (d) establishments keeping poultry, from which poultry intended for purposes other than slaughter or hatching eggs are moved to another Member State;

Tuesday 15 April 2014

- (e) any other type of establishment for kept terrestrial animals which poses a significant risk and is required to be approved in accordance with rules laid down in a delegated act adopted in accordance with paragraph 3(b) of this Article.
2. Operators shall cease activity at an establishment referred to in paragraph 1 where:
- (a) the competent authority withdraws or suspends its approval in accordance with Article 95(2); or
- (b) in the event of conditional approval, granted in accordance with Article 94(3), the establishment fails to comply with the outstanding requirements referred to in Article 94(3) and does not obtain a final approval in accordance with Article 92(1).
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning supplementing and amending the rules for the approval of establishments provided for in paragraph 1 of this Article concerning:
- (a) derogations from the requirement for operators of the types of establishments referred to in paragraph 1(a) to (d) to apply to the competent authority for approval by the competent authority, where those establishments pose an insignificant risk;
- (b) the types of establishments which must be approved in accordance with paragraph 1(e);
- (c) special rules for the cessation of activities for germinal product establishments referred to in paragraph 1(b).
4. The Commission shall take the following criteria into account, when adopting delegated acts provided for in paragraph 3:
- (a) the categories and species *or races* of kept terrestrial animals or germinal products in an establishment; [Am. 221]
- (b) the number of species and number of kept terrestrial animals or germinal products kept in an establishment;
- (c) the type of establishment and type of production;
- (d) the movements of kept terrestrial animals or germinal products into and out of those types of establishments.

Article 90

Approval of status of confined establishments

Operators of establishments, who want to obtain the status of confined establishment shall:

- (a) apply to the competent authority for approval in accordance with Article 91(1);
- (b) not move kept animals to a confined establishment in accordance with the requirements provided for in Article 134(1) and any delegated acts adopted in accordance with Article 134(2) until their establishment obtains an approval of that status by the competent authority in accordance with Articles 92 and 94.

Article 91

Information obligation of operators in view to obtaining approval and implementing acts

1. Operators shall for the purposes of their application for the approval of their establishment provided for in Article 89(1) and Article 90(a), provide the competent authority with information on:
- (a) the name and address of the operator;
- (b) the location of the establishment and a description of the facilities;
- (c) the categories, species and numbers of kept terrestrial animals or germinal products on the establishment;

Tuesday 15 April 2014

- (d) the type of establishment;
 - (e) other aspects of the establishment, related to its specificity, which are relevant in determining the risk posed by it.
2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of any:
- (a) significant changes in the establishments concerning the matters referred to in paragraph 1(a), (b) and (c);
 - (b) the cessation of activity in the establishment.
3. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by the operators in their application for the approval of their establishment in accordance with paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 92

Granting of and conditions for approval of establishments and delegated acts

1. The competent authority shall ~~only~~ grant approval of establishments as provided for in Article 89(1) and Article 90(a) where such establishments: **[Am. 222]**
- (a) comply with the following requirements, where appropriate, on:
 - (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in Article 9(1)(b) and rules adopted pursuant to Article 9(2);
 - (ii) surveillance requirements provided for in Article 22, and where relevant for the type of establishment and the risk involved in Article 23 and the rules adopted pursuant to Article 24;
 - (iii) record keeping provided for in Articles 97 and 98 and the rules adopted pursuant to Articles 100 and 101;
 - (b) have facilities and equipment that are:
 - (i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment;
 - (ii) of adequate capacity for the number of kept terrestrial animals or volume of germinal products;
 - (c) do not pose an unacceptable risk regarding the spread of diseases, taking into account the risk mitigation measures in place;
 - (d) have a sufficient number of adequately trained personnel for the activity of the establishment;
 - (e) have a system in place which enables the operator to demonstrate compliance with points (a) to (d) to the competent authority.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the requirements provided for in paragraph 1 of this Article as regards:
- (a) quarantine, isolation and other biosecurity measures referred to in paragraph 1(a)(i);
 - (b) surveillance referred to in paragraph 1(a)(ii);
 - (c) facilities and equipment referred to in paragraph 1(b);
 - (d) responsibilities, competence and training of personnel and veterinarians provided for in paragraph 1(d);
 - (e) the necessary supervision and control by the competent authority.

Tuesday 15 April 2014

3. The Commission shall take into account the following matters when establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2:

- (a) the risks posed by each type of establishment;
- (b) the categories and species of kept terrestrial animals;
- (c) the type of production;
- (d) typical movement patterns of the type of establishment and species and categories of animals kept in those establishments.

Article 93

Scope of the approval of establishments

The competent authority shall expressly specify in the approval of an establishment granted pursuant to Article 92(1) following an application made in accordance with Article 89(1) and Article 90(a):

- (a) for which of the types of establishments referred to in Article 89(1), Article 90 and the rules adopted pursuant to 89(3) (b), the approval applies;
- (b) for which categories and species of kept terrestrial animals or germinal products of those species the approval applies.

Article 94

Procedures for granting the approval by the competent authority

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Articles 89(1), Article 90 and Article 91(1) **and deadlines for the on-the-spot inspections referred to in the paragraph below.** [Am. 223]

2. Upon receipt of an application for approval from an operator, the competent authority shall, in accordance with Article 89(1)(a) and Article 90(a) make an on-site visit.

2a. The competent authority grants approval of an establishment where it appears, based on the application of the operator and the subsequent on-site visit of the establishment by the competent authority as provided for in paragraph 1 and 2 of this Article, that it meets all the requirements for approval provided for in Article 92(1) and the rules adopted pursuant to Article 92(2). [Am. 224]

3. The competent authority may grant conditional approval of an establishment where it appears, based on the application of the operator and the subsequent on-site visit of the establishment by the competent authority as provided for in paragraph 2 of this Article, that it meets all the main requirements that provide sufficient guarantees that such an establishment does not represent a significant risk, with a view to ensuring compliance with all the requirements for approval provided for in Article 92(1) and the rules adopted pursuant to Article 92(2).

4. Where conditional approval has been granted by the competent authority in accordance with paragraph 3 of this Article, it shall grant full approval only where it appears from another on-site visit of the establishment, carried out within three months of the date of granting conditional approval, that the establishment meets all the requirements for approval provided for in Article 92(1) and the rules adopted pursuant to Article 92(2).

Where that on-site visit shows that clear progress has been made but the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval **and shall provide the necessary effective guidance in order to contribute to the successful resolve of the deficiency.** However, conditional approval shall not exceed a total period of six months. [Am. 225]

Tuesday 15 April 2014

Article 95

Review, suspension and withdrawal of approvals by the competent authority

1. The competent authority shall keep the approvals of establishments granted in accordance with Articles 92 and 94 under review. ***The competent authority, based on the risk factor, shall define review frequency or minimum and maximum review deadlines, as well as those instances in which such deadlines cannot be met.*** [Am. 226]

2. Where the competent authority identifies serious deficiencies in the establishment as regards compliance with the requirements laid down in Article 92(1) and the rules adopted pursuant to Article 92(2) and the operator is not able to provide adequate guarantees that those deficiencies will be resolved, the competent authority shall initiate procedures to withdraw the establishment's approval.

However, the competent authority may suspend an establishment's approval where the operator can guarantee that it will resolve those deficiencies within a reasonable period of time.

3. Approval shall only be restored after withdrawal or suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

Section 3

register of the competent authority of establishments and transporters

Article 96

Establishment and transporter register

1. The competent authority shall establish and keep up-to-date a register of:

- (a) all establishments and transporters registered pursuant to Article 88;
- (b) all establishments approved in accordance with Articles 92 and 94.

It shall make that register available to ***the Commission, to*** other Member States and to the public. [Am. 227]

2. Where appropriate and relevant, the competent authority may combine the registration referred to in paragraph 1(a) and approval referred to in paragraph 1(b) with registration for other purposes.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) the information to be included in the register provided for in paragraph 1;
- (b) additional requirements for registers of germinal products establishments, after they cease activities;
- (c) public availability of the register provided for in paragraph 1.

4. The Commission may, by means of implementing acts, lay down rules on the format of and procedures for the register of establishments and transporters and approved establishments provided for in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Tuesday 15 April 2014

Section 4
Record keeping

Article 97

Record keeping obligations of operators of establishments other than germinal products establishments

1. Operators of establishments subject to registration in accordance with Article 88, or approval in accordance with Article 92(1) shall keep and maintain records containing at least the following information:

- (a) the species, categories, numbers and, **where applicable**, identification, of kept terrestrial animals on their establishment; [Am. 228]
- (b) the movements of kept terrestrial animals into and out of their establishment, stating as appropriate:
 - (i) their place of origin or destination;
 - (ii) the date of such movements;
- (c) the documents in paper or electronic form required to accompany kept terrestrial animals arriving at or leaving their establishment in accordance with Articles 106(b), 107(b), 109(c), 110(b), 113(b), Article 140(1) and (2), Article 162(2) and rules adopted pursuant to Articles 114 and 117 and Article 141(1)(b) and (c);
- (d) ~~any~~ **treatments of** animal health problems concerning kept animals on their establishment; [Am. 229]
- (e) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:
 - (i) the category and species of kept terrestrial animals on the establishment;
 - (ii) the type of production;
 - (iii) the type and size of the establishment;
- (f) the results of any animal health visits required in accordance with Article 23(1) and rules adopted pursuant to Article 24.

2. Establishments which are exempted from the registration requirement in accordance with Article 83 may be exempted by the Member State from the requirement to keep records of the information listed in paragraph 1 of this Article. **Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory.** [Am. 230]

3. Operators of establishments shall keep the records provided for in paragraph 1 on the establishment and:

- (a) make them available to the competent authority on request;
- (b) retain them for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Article 98

Record keeping for germinal product establishments

1. Operators of germinal product establishments shall keep and maintain records containing at least the following information:

- (a) the breed, age and identification of donor animals used for the production of germinal products;

Tuesday 15 April 2014

- (b) the time and place of collection, processing and storage of germinal products collected, produced or processed;
- (c) the identification of the germinal products together with details of their place of destination, if known;
- (d) the documents in paper or electronic form required to accompany germinal products arriving at or leaving the establishment in accordance with Article 159 and Article 162(2) and rules adopted pursuant to Article 160(3) and (4);

(da) the results of clinical and laboratory tests; [Am. 231]

- (e) laboratory techniques used.

2. Establishments which are exempted from the registration requirement in accordance with Article 84 may be exempted by the Member State from the requirement to keep records of the information listed in paragraph 1 of this Article. **Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory. [Am. 232]**

3. The operators of germinal product establishments shall keep the records provided for in paragraph 1 on the establishment and:

- (a) make them available to the competent authority on request;
- (b) retain them for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Article 99

Record keeping for transporters

1. Transporters of germinal products shall keep and maintain records containing at least the following information:

- (a) the establishments visited by them;
- (b) the categories, species and number of germinal products transported by them;
- (c) the cleaning, disinfection and disinfestation of the means of transport.

2. Transporters which are exempted from the registration requirement in accordance with Article 86 may be exempted by the Member State from the requirement to keep records of the information listed in paragraph 1 of this Article. **Member States shall notify the Commission of any exemptions made and keep a record of all the exempted establishments on their territory. [Am. 233]**

3. Transporters shall keep the records provided for in paragraph 1:

- (a) in a manner that they can be made immediately available to the competent authority on request.
- (b) for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Article 100

Delegation of powers concerning record keeping

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules supplementing the record keeping requirements provided for in Articles 97, 98 and Article 99, as regards:

~~(a) derogations from the record keeping requirements for:~~

- ~~(i) operators of certain types of establishments and certain types of transporters;~~

Tuesday 15 April 2014

~~(ii) establishments keeping, or transporters handling a small number of kept terrestrial animals or small volume of germinal products;~~

~~(iii) certain categories or species of kept terrestrial animals or germinal products; [Am. 234]~~

(b) information to be recorded in addition to that provided for in Articles 97(1), 98(1) and 99(1);

(c) additional requirements for record keeping for germinal products collected, produced or processed in a germinal products establishment, after they ceased their activities.

2. The Commission shall take into account the following matters when establishing the rules to be laid down in delegated acts provided for in paragraph 1:

(a) the risks posed by each type of establishment or transporter;

(b) the categories and species of kept terrestrial animals or germinal products in the establishment or transported;

(c) the type of production on the establishment or the type of transport;

(d) the typical movement patterns of the type of establishment and category of animals concerned;

(e) the number of kept terrestrial animals or volume of germinal products kept in the establishment or transported by the transporter.

Article 101

Implementing powers concerning record keeping

The Commission shall by means of implementing acts, lay down rules concerning:

(a) the format of records provided for in Articles 97(1), 98(1) and 99(1) and rules adopted pursuant to Article 100;

(b) electronic keeping of records provided for in Articles 97(1), 98(1) and 99(1) and rules adopted pursuant to Article 100;

(c) procedures for record keeping provided for in Articles 97(1), 98(1) and 99(1) and rules adopted pursuant to Article 100.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 2

Traceability requirements for kept terrestrial animals and germinal products

Section 1

kept terrestrial animals

Article 102

Member States' responsibility for establishing a system for the identification and registration of kept terrestrial animals

1. The Member States shall have in place a system for the identification and registration of kept terrestrial animals and, when appropriate, for the recording of their movements, taking into account:

(a) the species or category of kept terrestrial animals;

(b) the risk posed by that species or category.

Tuesday 15 April 2014

2. The system provided for in paragraph 1 shall include the following elements:
 - (a) the means to identify kept terrestrial animals individually or in groups;
 - (b) identification documents, movement documents and other documents for identifying and tracing kept terrestrial animals referred to in Article 104;
 - (c) up-to-date records in establishments as provided for Article 97(1)(a) and (b);
 - (d) a computer database of kept terrestrial animals provided for in Article 103(1).
3. The system provided for in paragraph 1 shall be designed in a manner that it:
 - (a) ensures the efficient application of the disease prevention and control measures provided for in this Regulation;
 - (b) facilitates the traceability of kept terrestrial animals and their movements within and between Member States and their entry into the Union;
 - (c) ensures the efficient interoperability, integration and compatibility of the elements of that system;
 - (d) ensures that the system, to the extent appropriate, is adapted to:
 - (i) the computerised information system for Union notification and reporting provided for in Article 20;
 - (ii) IMSOC;
 - (e) ensures a coherent approach for the different animal species covered by the system.
4. Member States may when appropriate:
 - (a) use the whole or part of the system provided for in paragraph 1 for purposes other than those referred to in paragraph 3(a) and (b);
 - (b) integrate the identification documents, movement documents and other documents referred to in Article 104 with the animal health certificates or self- declaration document provided for in Article 140(1) and (2) and Article 148(1) and rules adopted pursuant to Article 141(b) and (c) and Article 148(3) and (4);
 - (c) designate another authority or authorise another body or a natural person for the practical application of the identification and registration system provided for in paragraph 1.

Article 103

Member States obligation for establishing a computer database of kept terrestrial animals

1. The Member States shall establish and maintain a computer database, for the recording of:
 - (a) the following information related to kept animals of the bovine, ovine and caprine species:
 - (i) their individual identification as provided for in Articles 106(a) and 107(a);
 - (ii) the establishments keeping them;
 - (iii) their movements into and from establishments;
 - (b) **the following** information related to kept animals of the porcine species ~~and the establishments keeping them;~~
 - (i) **the establishments keeping them;**

Tuesday 15 April 2014

(ii) their movements into and from establishments; [Am. 235]

- (c) the following information related to kept animals of the equine species:
- (i) their unique life number as provided for in Article 109(1)(a);
 - (ii) the means of identification linking that animal with the identification document referred to in (iii), where relevant;
 - (iii) the identification document provided for in Article 109(1)(c);
 - (iv) the establishments where those animals are habitually kept;
- (d) information related to kept terrestrial animals of species other than those referred to in (a), (b) and (c), when this is provided for in rules adopted pursuant to paragraph 2.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the recording of information related to animal species other than those referred to in paragraph 1(a),(b) and (c) of this Article, in the computer database provided for in that paragraph where necessary, taking into account the risks posed by those species, to:

- (a) ensure the efficient application of the disease prevention and control measures provided for in this Regulation;
- (b) facilitate the traceability of kept terrestrial animals, their movements within and between Member States and their entry into the Union.

2a. By 1 January 2018, Member States shall introduce a registration requirement for dogs. The Commission shall submit to the European Parliament and the Council, by 31 July 2019, a report on the experience of the Member States with the registration and identification of dogs, with particular reference to stray animals. This report shall, if appropriate, be accompanied by a proposal concerning the minimum requirements applicable to databases pursuant to paragraph 1. [Am. 236]

Article 104

Obligation of the competent authority for identification documents, movement documents and other documents for identifying and tracing kept terrestrial animals

The competent authority shall issue:

- (a) identification documents for kept terrestrial animals when required by Articles 106(b) and 109(c), Article 112(1)(b) and (2)(b), and Article 113(b) and rules adopted pursuant to Articles 114 and 117;
- (b) movement documents and other documents for identifying and tracing kept terrestrial animals, when required by Articles 107(b), 110(b), 113(b) and rules adopted pursuant to Articles 114 and 117.

Article 105

Public availability of information on means of identification

The competent authority shall inform the Commission and make publicly available information on:

- (a) contact points for the computer databases established by the Member States in accordance with Article 103(1);
- (b) the authorities or bodies responsible for issuing identification documents, movement documents and other documents in accordance with Article 104, taking into account Article 102(4)(c);

Tuesday 15 April 2014

- (c) the means of identification that are to be used for each category and species of kept terrestrial animals in accordance with Articles 106(a) and 107(a), Article 109(1), Article 110(a), Article 112(1)(a) and (2)(a) and Article 113(a) and rules adopted pursuant to Articles 114 and 117;
- (d) the prescribed format for the issuing of the identification documents and other documents referred to in Article 104.

Article 106

Operators obligations for the identification of kept animals of the bovine species

Operators keeping animals of the bovine species shall:

- (a) ensure that those kept animals are identified individually by a physical means of identification;
- (b) ensure that those kept animals are issued with an identification document from the competent authority or designated authority or authorised body, which is a single lifetime document and that that document:
 - (i) is kept, correctly completed and updated by the operator;
 - (ii) accompanies those kept terrestrial animals at the time of movement;
- (c) transmit the information on movements of those kept animals from and into the establishment to the computer database provided for in Article 103(1) and the rules adopted pursuant to Articles 114 and 117.

Article 107

Operators obligations for the identification of kept animals of the ovine and caprine species

Operators keeping kept animals of the ovine and caprine species shall:

- (a) ensure that those kept animals are identified individually by a physical means of identification;
- (b) ensure that those kept animals are accompanied by a correctly completed movement document issued by the competent authority in accordance with Article 104 when moved from the establishment keeping those animals;
- (c) transmit the information on movements from and into the establishment of those kept animals to the computer database provided for in Article 103(1) and the rules adopted pursuant to Articles 114 and 117.

Article 108

Derogations concerning identification documents and movement documents for kept animals of the bovine, ovine and caprine species

By way of derogation from Article 104 and from Articles 106(b) and 107(b), Member States may exempt operators from the requirement to ensure that kept animals of the bovine, ovine and caprine species are accompanied by identification documents or movement documents during movements within the Member State, provided that:

- (a) the information contained in the movement document or identification document is included in the computer database provided for in Article 103(1);
- (b) the system for the identification and registration of kept animals of the bovine, ovine and caprine species provides an equivalent level of traceability as that provided by identification documents and movements documents.

Tuesday 15 April 2014

Article 109

Operators obligations for the identification and registration of kept animals of the equine species

1. Operators keeping kept animals of the equine species shall ensure that those animals are individually identified by:
 - (a) an unique life number, which is recorded in the computer database provided for in Article 103(1);
 - (b) a method which unequivocally links the kept animal and with the identification document provided for in point (c) of this paragraph and issued by the competent authority in accordance with Article 104;
 - (c) a correctly completed single lifetime identification document.
2. Operators of kept animals of the equine species shall transmit the information on those animals to the computer database provided for in Article 103(1) and by the rules adopted pursuant to Articles 114 and 117.

Article 110

Operators obligations for the identification and registration of kept animals of the porcine species

Operators keeping kept animals of the porcine species shall:

- (a) ensure that those kept animals are identified by a means of physical identification;
- (b) ensure that those kept animals are accompanied by a correctly completed movement document issued by the competent authority in accordance with Article 104(b) when moved from the establishment keeping those animals;
- (c) transmit the information related to the establishment keeping those animals to the computer database provided for in Article 103(1) and in the rules adopted pursuant to Articles 114 and 117.

Article 111

Derogations concerning movements of kept animals of the porcine species

By way of derogation from Article 110(b), the Member States may exempt operators from the requirement to ensure that kept animals of the porcine species are accompanied by correctly completed movement documents issued by the competent authority for movements within the Member State, provided that:

- (a) the information on such movement documents is included in the computer database established by the Member State in accordance with Article 103(1);
- (b) the system for the identification and registration of kept terrestrial animals of the porcine species provides an equivalent level of traceability as that provided by such movement documents.

Article 112

Pet keepers' obligation for the identification and registration of terrestrial pet animals

1. Pet keepers shall ensure that terrestrial pet animals of the species listed in Part A of Annex I which are moved from one Member State to another Member State **comply with the requirements of Regulation (EU) No 576/2013. [Am. 239]**

~~(a) are individually identified by a physical means of identification; [Am. 240]~~

Tuesday 15 April 2014

~~(b) are accompanied by a correctly completed and updated identification document issued by the competent authority in accordance with Article 104. [Am. 241]~~

2. Pet keepers shall ensure that terrestrial pet animals of the species listed in Part B of Annex I when moved from one Member State to another Member State, ~~and when required by rules adopted pursuant to Articles 114 and 117, are:~~ **comply with the requirements of Regulation (EU) No 576/2013. [Am. 242]**

~~(a) identified, either individually or in groups; [Am. 243]~~

~~(b) accompanied by correctly completed and updated identification documents, movement documents or other documents for identifying and tracing animals, as appropriate for the animal species concerned. [Am. 244]~~

Article 113

Operators obligation for the identification of kept terrestrial animals other than animals of the bovine, ovine, caprine, porcine and equine species and pet animals

Operators shall ensure that kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and other than pet animals, comply with the following requirements, when required by the rules adopted pursuant to Articles 114 and 117:

(a) they are identified, either individually or in groups;

(b) they are accompanied by correctly completed and updated identification documents, movement documents or other documents for identifying and tracing animals, as appropriate for the animal species concerned.

Article 114

Delegation of powers concerning identification and registration

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

~~(a) the designation of other authorities, the authorisation of bodies or natural persons, as provided for in Article 102(4)(c); [Am. 245]~~

(b) detailed requirements for:

(i) the means of identification of kept terrestrial animals provided for in Articles 106(a) and 107(a), Article 109(1), Article 110(a), Article 112(1)(a) and (2)(a), and Article 113(a);

(ii) the application and use of that means of identification;

(c) the information to be included in:

(i) the computer databases provided for in Article 103(1);

(ii) the identification document for kept animals of the bovine species provided for in Article 105(b);

(iii) the movement document for kept animals of the caprine and ovine species provided for in Article 107(b);

(iv) the identification document for kept animals of the equine species provided for in 109(1)(c);

(v) the movement document for kept animals of the porcine species provided for in Article 110(b);

~~(vi) identification documents for terrestrial pet animals provided for in Article 112(1)(b) or identification documents, movement documents or other documents for kept terrestrial pet animals provided for in Article 112(2)(b); [Am. 246]~~

Tuesday 15 April 2014

- (vii) identification documents or movement documents for kept terrestrial animals other than animals of the bovine, ovine, caprine, porcine, equine species and pet animals provided for in Article 113(b);
- (d) detailed requirements for different species and categories of kept terrestrial animals to ensure the efficient operation of the identification and registration system provided for in Article 102(1);
- (e) detailed requirements for kept terrestrial animals entering the Union from third countries and territories.
- ~~(f) identification and registration requirements for kept terrestrial pet animals of the species listed in Part B of Annex I and kept terrestrial animals of species other than the bovine, ovine, caprine, porcine and equine species where necessary, taking into account the risks posed by that species, to:
 - ~~(i) ensure the efficient application of the disease prevention and control measures provided for in this Regulation;~~
 - ~~(ii) facilitate the traceability of kept terrestrial animals, and their movements within and between Member States and their entry into the Union. [Am. 247]~~~~

Article 115

Delegation of powers concerning derogations from the traceability requirements

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations for operators from the identification and registration requirements provided for in Articles 106, 107 and 109 and 110 **provided that full traceability is ensured**: [Am. 248]

- (a) in cases where one or more of these elements are not necessary to meet the requirements provided for in Article 102(3) (a) and (b);
- (b) when other traceability measures in place in the Member States guarantee that the level of traceability of the animals in questions is not compromised.

Article 116

Matters to be taken into account when adopting delegated acts provided for in Articles 114 and 115

The Commission shall take the following matters into account, when establishing the rules to be laid down in the delegated acts provided for in Articles 114 and 115:

- (a) the categories and species of kept terrestrial animals;
- (b) the risks involved for those kept terrestrial animals;
- (c) the number of animals in the establishment;
- (d) the type of production in the establishments where those terrestrial animals are kept;
- (e) movement patterns for the species and categories of kept terrestrial animals;
- (f) considerations concerning the protection and conservation of species of kept terrestrial animals;
- (g) the performance of the other traceability elements of the system for the identification and registration of kept terrestrial animals referred to in Article 102(2).

Article 117

Implementing powers concerning traceability of kept terrestrial animals

The Commission shall by means of implementing acts, lay down rules for the implementation the requirements provided for in Articles 106, 107, 109, 110, 112 and 113 and those laid down in delegated acts adopted pursuant to Article 103(2) and Articles 114 and 115 concerning:

- (a) technical specifications, formats and operational rules of:
 - (i) means, methods and the use of identification;

Tuesday 15 April 2014

- (ii) the identification document or movement document for kept animals of the bovine, ovine, caprine species;
 - (iii) identification document for kept animals of the equine species;
 - (iv) identification, movement and other documents for kept terrestrial animals of species; other than of the bovine, ovine, caprine and equine species
 - (v) computer databases.
- (b) the deadlines for:
- (i) the transmission of information by operators into the computer database;
 - (ii) the registration of kept terrestrial animals;
 - (iii) the identification of kept terrestrial animals and the replacement of identification marks;
- (c) practical application of exemptions from the identification and registration provided for in the rules adopted pursuant to Article 115.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Section 2

Germinal products

Article 118

Traceability requirements for germinal products of kept animals of the bovine, ovine, caprine, equine and porcine species and poultry

1. Operators producing, processing or storing germinal products shall mark germinal products of kept animals of the bovine, caprine, ovine, equine and porcine species in such a way that they can be clearly traced to:

- (a) the donor animals;
- (b) the date of collection;

(ba) the breed; [Am. 249]

- (c) the germinal product establishments where they were collected, produced, processed and stored.

2. The marking provided for in paragraph 1 shall be designed in such a way as to ensure:

- (a) the efficient application of the disease prevention and control measures provided for in this Regulation;
- (b) the traceability of the germinal products and their movements within and between Member States and their entry into the Union.

Article 119

Delegation power concerning traceability requirements for germinal products

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) traceability requirements for germinal products of kept terrestrial animals of the bovine, caprine, ovine, porcine and equine species amending and supplementing the rules laid down in Article 118;
- (b) traceability requirements for germinal product of kept terrestrial animals of species other than of the bovine, caprine, ovine, equine and porcine species, where necessary for:
 - (i) the efficient application of the disease prevention and control measures provided for in this Regulation;

Tuesday 15 April 2014

(ii) the traceability of those germinal products, their movements within and between Member States and their entry into the Union.

2. The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 1:

- (a) the species of kept terrestrial animals from which the germinal products originate;
- (b) the health status of donor animals;
- (c) the risk involved with such germinal products;
- (d) the type of germinal products;
- (e) the type of collection, processing or storage;
- (f) movement patterns for the species and categories of kept terrestrial animals and their germinal products;
- (g) considerations concerning the protection and conservation of species of kept terrestrial animals;
- (h) other elements that may contribute to the traceability of germinal products.

Article 120

Implementing powers concerning traceability requirements for germinal products

The Commission shall, by means of implementing acts, lay down rules concerning:

- (a) technical requirements and specifications for marking provided for in Article 118(1);
- (b) operational requirements for the traceability requirements provided for in delegated acts adopted pursuant to Article 119(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 3

Movements within the Union of kept terrestrial animals other than terrestrial pet animals

Section 1

General requirements for movements

Article 121

General requirements for movements of kept terrestrial animals

1. Operators shall take appropriate preventive measures to ensure that the movement of kept terrestrial animals does not jeopardise the health status at the place of destination with regard to:

- (a) the listed diseases referred to in Article 8(1)(d);
- (b) emerging diseases.

2. Operators shall only move kept terrestrial animals from establishments and receive such animals, if they comply with the following conditions:

- (a) they come from establishments that have been:
 - (i) entered in the register of establishments by the competent authority in accordance with Article 88(a) and no derogation has been granted by the Member State of origin in accordance with Article 83;

Tuesday 15 April 2014

- (ii) approved by the competent authority in accordance with Article 92(1), when required by Article 89(1) or Article 90;
 - (b) they comply with the identification and registration requirements of Articles 106, 107, 109, 110 and 113 and the rules adopted pursuant to Article 114(a) to (d) and Article 117.
- (ba) the movement complies with Council Regulation (EC) No 1/2005 ⁽¹⁾. [Am. 250]**

Article 122

Preventive measures in relation to transport

1. Operators shall take the appropriate and necessary preventive **and health-promotion** measures to ensure that: [Am. 251]
- (a) the health status of kept terrestrial animals is not jeopardised during transport;
 - (b) transport operations of kept terrestrial animals do not cause the potential spread of listed diseases referred to in Article 8(1)(d) to humans and animals at places of assembly, **loading, unloading, reloading**, resting and destination; [Am. 252]
 - (c) cleaning, disinfection, disinfestations of equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport;
- (ca) the relevant requirements of Regulation (EC) No 1/2005 are taken into account. [Am. 253]**
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
- (a) the cleaning, disinfection and disinfestations of equipment and means of transport and the use of biocidal products for those purposes;
 - (b) other adequate biosecurity measures as provided for in paragraph 1(c).

Section 2

Movements between Member States

Article 123

General requirements for movements of kept terrestrial animals between Member States

1. Operators shall only move kept terrestrial animals to another Member State if they comply with following conditions:
- (a) they come from an establishment:
 - (i) where there are no abnormal mortalities or other disease symptoms with an undetermined cause;
 - (ii) which is not subject to movement restrictions affecting the species to be moved in accordance with the rules laid down in Articles 55(1)(d), 61(1)(a), Article 62, Article 65(1)(c), Article 74(1) and Article 78(1) and (2) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Article 71(3), Article 74(3), Article 79 and Article 81(2) or the emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248, unless derogations have been granted for movement restrictions in accordance with those rules;

⁽¹⁾ Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

Tuesday 15 April 2014

- (iii) which is not situated in a restricted zone in accordance with rules laid down in Article 55(1)(f)(ii), Articles 64 and 65, Article 74(1), Article 78 and rules adopted pursuant to Article 67, Article 71(3), Article 74(3), Article 79 and Article 81(2) or the emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248, unless derogations have been granted in accordance with those rules;
 - (b) they have not been in contact with kept terrestrial animals subject to movement restrictions referred to in point (a)(ii) and (iii) or kept terrestrial animals of a listed species of a lower health status, for an adequate period of time, prior to the date of the intended movement to another Member State, thereby minimising the possibility of spreading disease, taking into account the following matters:
 - (i) the incubation period and routes of transmission of the listed diseases and emerging diseases;
 - (ii) the type of establishment;
 - (iii) the species and category of kept terrestrial animals moved;
 - (iv) other epidemiological factors;
 - (c) they comply with the relevant requirements provided for in Sections 3 to 8.
2. Operators shall take all necessary measures to ensure that kept terrestrial animals moved to another Member State are consigned directly to their place of destination in another Member State unless they need to stop at a place of resting for animal welfare reasons.

Article 124

Obligations of operators at the place of destination

1. Operators of establishments and slaughterhouses receiving kept terrestrial animals from another Member State shall:
 - (a) check that:
 - (i) the means of identification provided for in Articles 106(a) and 107(a), Article 109(1) and Articles 110(a) and 113(a) and the rules adopted pursuant to Articles 114 and 117 are present;
 - (ii) the identification documents provided for in Articles 106(b) and 107(b), Article 109(1)(c), Article 113(b) and the rules adopted pursuant to Articles 114 and 117 are present and are correctly completed;
 - (b) check that the animal health certificates provided for in Article 140 and rules adopted pursuant to Article 141(b) and (c) or the self-declaration documents provided for in Article 148 and the rules adopted pursuant to Article 148(2) are present;
 - (c) inform the competent authority of any irregularity with regard to:
 - (i) the kept terrestrial animals received;
 - (ii) the presence of the means of identification referred to in point (a)(i);
 - (iii) the documents referred to in point (a)(ii) and (b).
2. In the event of any irregularity as referred to in paragraph 1(c), the operator shall isolate the animals concerned by that irregularity until the competent authority has taken a decision regarding them.

Tuesday 15 April 2014

Article 125

Prohibition on movements of kept terrestrial animals between Member States

Operators shall not move kept terrestrial animals to another Member State, unless the Member State of destination ~~gives~~ **and the Member States of transit give** express authorisation prior to the movement in the event of animals which are intended to be slaughtered for disease eradication purposes as a part of an eradication programme provided for in Article 30(1), (2) and (3). [Am. 254]

Article 126

General requirements for operators for movements of kept terrestrial animals passing through Member States but intended for export from the Union to third countries or territories

Operators shall ensure that kept terrestrial animals intended for export to a third country or territory and passing through the territory of another Member State fulfil the requirements laid down in Articles 121, 122, 123 and 125.

Section 3

Specific requirements for movements to other Member States of ungulates and poultry

Article 127

Movement of kept ungulates and poultry to other Member States

Operators shall only move kept ungulates and poultry from an establishment in one Member State to another Member State if they comply with following conditions as regards the listed diseases referred to in Article 8(1)(d):

- (a) they show no clinical symptoms or signs of listed diseases referred to in Article 8(1)(d) at the time of movement;
- (b) they have been subject to a residency period appropriate to those listed diseases taking into account the species and category of kept ungulates and poultry to be moved;
- (c) for a period of time appropriate for those listed diseases and the species and category of ungulates or poultry to be moved, no kept ungulates or poultry have been introduced into the establishment of origin, **except in cases where appropriate biosecurity measures have been taken**; [Am. 255]
- (d) they do not pose a significant risk for the spread of those listed diseases at the place of destination.

Article 128

Delegation of powers for movement of kept ungulates and poultry to other Member States

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) residency periods **and biosecurity measures** provided for in Article 127(b); [Am. 256]
 - (b) the period of time necessary for limiting the introduction of kept ungulates or poultry into establishments prior to movement provided for in Article 127(c);
 - (c) supplementary requirements to ensure that the kept ungulates and poultry do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d), as provided for in Article 127(d);
 - (d) other risk mitigating measures amending and supplementing the requirements laid down in Article 127.

Tuesday 15 April 2014

2. The Commission shall take the following matters into account, when establishing the rules to be laid down in the delegated acts provided for in paragraph 1:

- (a) the listed diseases referred to in Article 8(1)(d) relevant for the listed species or the category of kept ungulates or poultry to be moved;
- (b) the health status as regards listed diseases referred to in Article 8(1)(d) at the establishments, compartments, zones and Member States of origin and destination;
- (c) the type of establishment and the type of production at the places of origin and destination;
- (d) the type of movement;
- (e) the categories and species of kept ungulates or poultry to be moved;
- (f) the age of the kept ungulates or poultry to be moved;
- (g) other epidemiological factors.

Article 129

Kept ungulates and poultry moved to another Member State and intended for slaughter

1. Operators of slaughterhouses receiving kept ungulates and poultry from another Member State shall slaughter, **using pre-stunning**, those animals as soon as possible following their arrival and at the latest within a timeframe to be laid down in delegated acts adopted pursuant to paragraph 2. [Am. 257]

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the time of slaughter provided for in paragraph 1 of this Article.

Section 4

Assembly operations for kept ungulates and poultry

Article 130

Derogation for assembly operations

1. By way of derogation from Article 123(2), operators may subject kept ungulates and poultry to a maximum of: **three assembly lines**.

- ~~(a) one assembly operation in the Member State of origin;~~
- ~~(b) one assembly operation in the Member State of passage;~~
- ~~(c) one assembly operation in the Member State of destination. [Am. 258]~~

2. The assembly operations provided for in paragraph 1 of this Article shall only take place in an establishment approved for that purpose in accordance with Article 92(1) and Article 94(3) and (4).

However, the Member State of origin may allow assembly operations in their territory to take place on means of transport, collecting kept ungulates and poultry directly from their establishments of origin, provided that they are not unloaded again following those operations before:

- (a) arriving at their establishment or final place of destination; or
- (b) an assembly operation provided for in paragraph 1(b) and (c).

Tuesday 15 April 2014

Article 131

Disease prevention requirements for assembly operations

Operators conducting assembly operations shall ensure that:

- (a) the kept ungulates and poultry assembled are of the same health status or where they are not of the same health status, the lower health status shall apply to all such animals assembled;
- (b) the kept ungulates and poultry are assembled and moved to their final place of destination ~~in another Member State~~ as soon as possible after leaving their establishment of origin, and at the latest within a timeframe to be laid down in delegated acts adopted pursuant to Article 132(c); **[Am. 259]**
- (c) the necessary biosecurity measures are taken to ensure that the kept ungulates and poultry assembled:
 - (i) do not come into contact with kept ungulates or poultry of a lower health status;
 - (ii) do not pose a significant risk for the spread of the listed diseases referred to in Article 8(1)(d) to the kept ungulates or poultry at the place of the assembly operation;
- (d) the kept ungulates or poultry are identified and, where required, accompanied with the following documents:
 - (i) the identification and registration documents where provided for in Articles 106(b), 107(b), 109(c), 110(b) and Article 113(b) and rules adopted pursuant to Articles 114 and 117, unless derogations are provided for according to Article 115;
 - (ii) the animal health certificates where provided for in Article 140 and Article 141(c), unless derogations are provided for in the rules adopted pursuant to Article 141(a);
 - (iii) the self-declaration document where provided for in Article 148.

Article 132

Delegation of powers concerning assembly operations

The Commission shall be empowered to adopt delegated acts in accordance with Article 253, **provided that such acts are based on scientific facts and due regard for the opinions of the European Food Safety Authority**, concerning: **[Am. 260]**

- (a) specific rules for assembly operations, where other risk mitigating measures, in addition to those provided for in Article 131(b) and (c), are in place;
- (b) criteria under which Member States of origin may allow assembly operations to take place on means of transport, as provided for in the second subparagraph of Article 130(2);
- (c) the timeframe between the time of departure of the kept ungulates or poultry from their establishment of origin and their departure from the assembly operation to their final destination ~~in another Member State~~ as referred to in Article 131(b); **[Am. 261]**
- (d) biosecurity measures provided for in Article 131(c).

Section 5

Movements to other Member States of kept terrestrial animals other than kept ungulates and poultry

Article 133

Movement of kept terrestrial animals other than kept ungulates and poultry to other Member States and delegated acts

1. Operators shall only move kept terrestrial animals other than kept ungulates or poultry from an establishment in one Member State to another Member State if they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) at the place of destination.

Tuesday 15 April 2014

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed rules to ensure that the kept terrestrial animals other than kept ungulates or poultry do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) provided for in paragraph 1 of this Article.
3. The Commission shall take the following matters into account, when establishing the detailed rules to be laid down in the delegated acts provided for in paragraph 2:
 - (a) the listed diseases referred to in Article 8(1)(d) relevant for the listed species or the category of kept terrestrial animals to be moved;
 - (b) the health status as regards the listed diseases referred to in Article 8(1)(d) at the establishments, compartments, zones and Member States of origin and the place of destination;
 - (c) the types of establishment and the types of production at the place of origin and the place of destination;
 - (d) the types of movement in respect of the final use of animals at destination;
 - (e) the categories and species of kept terrestrial animals to be moved;
 - (f) the age of the kept terrestrial animals to be moved;
 - (g) other epidemiological factors.

Section 6

Derogating from and supplementing risk mitigation measures

Article 134

Animals intended for confined establishments and delegated acts

1. Operators shall only move kept terrestrial animals to a confined establishment if they comply with the following conditions:
 - (a) they originate from another confined establishment;
 - (b) they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) to listed species or to categories of animals at the confined establishment of destination, except where such movement is authorised for scientific purposes.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) detailed rules for movements of kept terrestrial animals into confined establishments in addition to those provided for in paragraph 1 of this Article;
 - (b) specific rules for movements of kept terrestrial animals into confined establishments where the risk mitigating measures in place guarantee that such movements do not pose a significant risk for the health of kept terrestrial animals within that confined establishment and the surrounding establishments.

Article 135

Derogations for movements of kept terrestrial animals for scientific purposes and delegated acts

1. The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements into the territory of the Member State of kept terrestrial animals for scientific purposes, which do not comply with the requirements of Sections 1 to 5, with the exception of Articles 121 and 122, Article 123(1)(a)(ii) and Article 124.

Tuesday 15 April 2014

2. The competent authorities shall only grant derogations provided for in paragraph 1 under the following conditions:
- (a) the competent authorities of the place of destination and origin:
 - (i) have agreed on the conditions for such movements;
 - (ii) have taken the necessary risk mitigating measures to ensure that those movements do not jeopardise the health status en route and the places of destination with regard to the listed diseases referred to in Article 8(1)(d);
 - (iii) have notified, where relevant, the competent authority of Member States of passage of the derogation granted and the conditions under which it is granted;
 - (b) those movements of those animals take place under the supervision of the competent authorities of places of origin and destination, and where relevant, the competent authority of the Member State of passage.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amending and supplementing the rules for derogations by the competent authorities provided for in paragraphs 1 and 2 of this Article.

Article 136

Derogations concerning recreational use, sporting and cultural events, grazing and work near borders

1. The competent authority of the place of destination may grant derogations from the requirements of Sections 2 to 5, with the exception of Article 123(a) and (b) and Articles 124 and 125, for intra-Union movements of kept terrestrial animals between Member States where such movements are for:
- (a) recreational use near borders;
 - (b) exhibitions, and for sporting, cultural and similar events organised near borders;
 - (c) grazing of kept terrestrial animals in grazing areas shared between Member States;
 - (d) work of kept terrestrial animals near borders of Member States.
2. Derogations by the competent authority of the place of destination for movements of kept terrestrial animals for the purposes provided for in paragraph 1 shall be agreed on between the Member States of origin and destination and appropriate risk mitigating measures taken to ensure that such movements do not pose a significant risk.
3. The Member States referred to in paragraph 2 shall inform the Commission of the granting of derogations provided for in paragraph 1.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amending and supplementing the rules for derogations by the competent authority of the place of destination provided for in paragraph 1 of this Article.

Article 137

Delegation of power concerning derogations for circuses, exhibitions, sporting events and recreational use, zoos, pet shops, and wholesalers

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) specific requirements supplementing the rules laid down in Sections 2 to 5 for the movements of kept terrestrial animals for the following purposes:
 - (i) circuses, zoos, pet shops, animal shelters and wholesalers;

Tuesday 15 April 2014

(ii) exhibitions and for sporting, cultural and similar events;

(b) derogations from Sections 2 to 5 with the exception of Article 123(a) and (b) and Articles 124 and 125 for the movements of kept terrestrial animals referred to in point (a).

Article 138

Implementing power for temporary derogations for movements of specific species or categories of kept terrestrial animals

The Commission may, by means of implementing acts lay down rules concerning temporary derogations from the rules laid down in this Chapter for movements of specific species or categories of kept terrestrial animals where:

(a) the movement requirements provided for in Article 127, Article 129(1), Articles 130 and 131, Articles 133(1), 134(1) and 135(1) and (2) and Article 136 and the rules adopted pursuant to Articles 128(1) and 129(2), Article 132, Articles 133(2), 134(2), 135(3) and 136(4) and Article 137 are not effectively mitigating the risks posed by the movement of such animals; or

(b) the listed disease referred to in Article 8(1)(d) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 6.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

On duly justified imperative grounds of urgency relating to diseases representing a risk of highly significant impact and taking into account the matters referred to in Article 139 the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 255(3).

Article 139

Matters to be taken into account when adopting delegated and implementing acts provided for in this Section

The Commission shall take the following matters into account, when establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 134(2), 135(3) and 136(4) and Articles 137 and 138:

(a) the risks involved with the movements referred to in those provisions;

(b) the health status as regards the listed diseases referred to in Article 8(1)(d) at the places of origin and destination;

(c) listed animal species for the listed diseases referred to in Article 8(1)(d);

(d) biosecurity measures in place at the places of origin, destination and en route;

(e) any specific conditions in establishments under which the kept terrestrial animals are kept;

(f) specific movement patterns of the type of establishment and the species and category of kept terrestrial animals concerned;

(g) other epidemiological factors.

Tuesday 15 April 2014

Section 7

Animal health certification

Article 140

Obligation of operators to ensure that animals are accompanied by an animal health certificate

1. Operators shall only move the following species and categories of kept terrestrial animals to another Member State if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 146(1):

- (a) ungulates;
- (b) poultry;
- (c) kept terrestrial animals other than ungulates and poultry, intended for a confined establishment;
- (d) kept terrestrial animals other than those referred to in points (a), (b) and (c) of this paragraph, when required in accordance with delegated acts adopted pursuant to Article 141(1)(c).

2. Operators shall not move kept terrestrial animals ~~within a Member State or from one Member State to another Member State~~ unless they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 146(1), where the conditions referred to in the following points (a) and (b) are met: [**Am. 262**]

- (a) the kept terrestrial animals are allowed to leave a restricted zone provided for in Article 55(1)(f)(ii), Article 56 and Article 64(1) and are subject to disease control measures provided for in Articles 55(1), 65(1), 74(1) or Article 78(1) and (2) or rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(3), Article 79, Article 81(3) or Article 248;
- (b) the kept terrestrial animals are of species subject to those disease control measures.

3. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 of this Article accompanies the kept terrestrial animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 144.

Article 141

Delegation of powers concerning the obligation of operators to ensure that animals are accompanied by an animal health certificate

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) derogations from the animal health certification requirements provided for in Article 140(1), for movements of kept terrestrial animals, which do not pose a significant risk for the spread of a disease due to:
 - (i) the species or categories of the kept terrestrial animals that are being moved and the listed diseases referred to in Article 8(1)(d) for which they are listed species;
 - (ii) the methods of keeping and the type of production of those species and categories of kept terrestrial animals;
 - (iii) the intended use of the kept terrestrial animals;
 - (iv) the place of destination of the kept terrestrial animals; or

Tuesday 15 April 2014

- (b) special rules for animal health certification requirements provided for in Article 140(1) where specific risk mitigating measures concerning surveillance or biosecurity are taken by the competent authority, taking into account the matters provided for in paragraph 2 of this Article, which ensure:
 - (i) the traceability of the kept terrestrial animals being moved;
 - (ii) that the kept terrestrial animals being moved comply with required animal health requirements for movements provided for in Sections 1 to 6;
 - (c) the requirement for animal health certification for movements of species and categories of kept terrestrial animals other than those referred to in Article 140(1)(a)(b) and (c) in cases where animal health certification is imperative to ensure that the movement in question complies with the animal health requirements for movements provided for in Sections 1 to 6.
2. When establishing the special rules provided for in paragraph 1(b), the Commission shall take the following matters into account:
- (a) the confidence of the competent authority about the biosecurity put in place by operators as provided for in Article 9(1)(b) and rules adopted pursuant Article 9(2);
 - (b) the capability of the competent authority to take necessary and appropriate measures and activities required by this Regulation as provided for in Article 12(1);
 - (c) the level of obtained basic knowledge of animal health as provided for in Article 10 and the support provided for in Article 12(2);
 - (d) the performance of the animal health visits as provided for in Article 23 and rules adopted pursuant to Article 24, where other relevant surveillance, quality assurance schemes or official controls as referred to in Article 23(1)(c) are not in place;
 - (e) the performance of the Union notification and reporting as provided for in Articles 17 to 20 and the rules adopted pursuant to Articles 17(3) and 18(3) and Article 21 applied by the competent authority;
 - (f) the application of surveillance as provided for in Article 25 and surveillance programmes as provided for in Article 27 and rules adopted pursuant to Articles 28 and 29.
3. The Commission shall take the matters referred to in paragraph 1(a)(i) to (iv) into account, when establishing the requirements for animal health certification provided for in paragraph 1(c) of this Article.

Article 142

Contents of animal health certificates

1. The animal health certificate shall contain the following information:
- (a) the establishment or place of origin, the establishment or place of destination and, where relevant, establishments for assembly operations or for rests of the kept terrestrial animals;
 - (b) a description of kept terrestrial animals;
 - (c) the number of kept terrestrial animals;
 - (d) the identification and registration of kept terrestrial animals, where required by Articles 106, 107, 109, 110 and 113 and rules adopted pursuant to Articles 114 and 117, unless derogations are provided for in accordance with Article 115; and
 - (e) the necessary information needed to demonstrate that the kept terrestrial animals comply with the relevant animal health requirements for movements provided for in Sections 1 to 6.

Tuesday 15 April 2014

2. The animal health certificate may include other information required under other Union legislation.

Article 143

Delegation of powers and implementing acts concerning the contents of animal health certificates

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) detailed rules on the content of animal health certificates provided for in Article 142(1) for different categories and species of kept terrestrial animals and for specific types of movements provided for in the rules adopted pursuant to Article 144;
 - (b) additional information to be contained in the animal health certificate provided for in Article 142(1).
2. The Commission may, by means of implementing acts, lay down rules for model forms of animal health certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 144

Delegation of powers concerning specific types of movements of kept terrestrial animals

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning specific measures supplementing the obligation of operators to ensure that animals are accompanied by an animal health certificate provided for in Article 140 and the rules adopted pursuant to Article 141 for the following types of movements of kept terrestrial animals:

- (a) movements of kept ungulates and poultry passing through the assembly operations provided for in Article 130 prior to reaching their final place of destination;
- (b) movements of kept terrestrial animals, which may not continue their route to their final place of destination and are required to return to their place of origin or to be moved to a different destination, for one or more of the following reasons:
 - (i) their intended route was unexpectedly interrupted for animal welfare reasons;
 - (ii) unpredicted accidents or events en route;
 - (iii) the kept terrestrial animals were rejected at the place of destination in a Member State or at the external border of the Union;
 - (iv) the kept terrestrial animals were rejected at a place of assembly or resting;
 - (v) the kept terrestrial animals were rejected in a third country;
- (c) movements of kept terrestrial animals intended for exhibitions and sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 145

Operators obligations to cooperate with the competent authority for animal health certification

Operators shall:

- (a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Article 140(1) and (2) and rules adopted pursuant to Article 143(1) or Article 144;
- (b) where necessary, subject the kept terrestrial animals to documentary, identity and physical checks as provided for in Article 146(3).

Tuesday 15 April 2014

Article 146

Competent authority responsibility for animal health certification

1. The competent authority shall, upon request by the operator issue an animal health certificate for the movement of kept terrestrial animals to another Member State, where required by Article 140 or by delegated acts adopted pursuant to Articles 141(1) and 143(2) provided that the following movement requirements have been complied with:
 - (a) those provided for in Article 121, Article 122(1), Articles 123, 125, 126, 127, 129, 130 and 131, Articles 133(1) and 134(1), Article 135 and Article 136;
 - (b) those provided for in delegated acts adopted pursuant to Articles 122(2) and 128(1), Article 132, and Articles 133(2), 134(2), 135(4) and 136(4) and Article 137;
 - (c) those provided for in implementing acts adopted pursuant to Article 138.
2. Animal health certificates shall:
 - (a) be verified and signed by the official veterinarian;
 - (b) remain valid for the period of time, provided for in the rules adopted pursuant to paragraph 4(c), during which the kept terrestrial animals covered by it, continue to comply with the animal health guarantees contained in it.
3. The official veterinarian shall, before signing an animal health certificate, verify that the kept terrestrial animals covered by it comply with the requirements of this Chapter by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 laying down rules for:
 - (a) the types of documentary, identity and physical checks for different species and categories of kept terrestrial animals that must be carried out by the official veterinarian in accordance with paragraph 3 of this Article to verify compliance with the requirements of this Chapter;
 - (b) the timeframes for the carrying out of such documentary, identity and physical checks and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of kept terrestrial animals;
 - (c) the duration of the validity of animal health certificates.

Article 147

Electronic animal health certificates

Electronic animal health certificates, produced, handled and transmitted by means of IMSOC, may replace accompanying animal health certificates provided for in Article 146(1) where:

- (a) such electronic animal health certificates contain all the information that the model form of animal health certificate is required to contain in accordance with Article 142 and rules adopted pursuant to Article 143;
- (b) the traceability of the kept terrestrial animals and the link between those animals and the electronic animal health certificate is ensured.

Article 148

Self-declaration by operators for movements to other Member States

1. Operators at the place of origin, shall issue a self-declaration document for movements of kept terrestrial animals from their place of origin in one Member State to their place of destination in another Member State and ensure that it accompanies such animals, where they are not required to be accompanied by an animal health certificate provided for in Article 140(1) and (2).

Tuesday 15 April 2014

2. The self-declaration document provided for in paragraph 1 shall contain the following information concerning the kept terrestrial animals:

- (a) their place of origin, their place of destination and when relevant any places of assembly or rest;
- (b) a description of the kept terrestrial animals, their species, category and quantity;
- (c) identification and registration where required in accordance with Articles 106, 107, 109 and 110, and Article 113(a) and rules adopted pursuant to Articles 114 and 117;
- (d) information needed to demonstrate that the kept terrestrial animals comply with the animal health requirements for movements provided for in Sections 1 to 6.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) detailed rules on the content of the self-declaration document provided for in paragraph 2 of this Article for different categories and species of animals;
- (b) information to be contained in the self-declaration document in addition to that provided for in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down rules for the model forms of the self-declaration documents provided for in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Section 8

Notification of movements of kept terrestrial animals to other Member States

Article 149

Obligation of operators concerning the notification of movements of kept terrestrial animals to other Member States

Operators shall notify the competent authority in their Member State of origin in advance of intended movements of kept terrestrial animals from that Member State to another Member State where:

- (a) the animals must be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 146 and 147 and rules adopted pursuant to Article 146(4);
- (b) the animals must be accompanied by an animal health certificate for kept terrestrial animals where they are being moved from a restricted zone and are subject to disease control measures as referred to in Article 140(2);
- (c) notification is required in accordance with delegated acts adopted pursuant to Article 151(1).

For the purposes of the first paragraph of this Article, operators shall provide the competent authority of their Member State of origin with all the necessary information to enable it to notify the movements of the kept terrestrial animals to the competent authority of the Member State of destination in accordance with Article 150(1).

Article 150

Competent authority responsibility for notification of movements to other Member States

1. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of kept terrestrial animals as referred to in Article 149.

Tuesday 15 April 2014

2. The notification referred to in paragraph 1 shall be carried out, whenever possible, through IMSOC.
3. Member States shall designate regions for the management of notifications of movements as provided for in paragraph 1.
4. By way of derogation from paragraph 1, the competent authority of the Member State of origin may authorise the operator to notify partially or completely movements of kept terrestrial animals through IMSOC to the competent authority of the Member State of destination.

Article 151

Delegation of power and implementing acts for the notification of movements by operators and the competent authority

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) the requirement for advance notification by operators of movement of kept terrestrial animals between Member States in accordance with Article 149 of categories or species of animals other than those referred to in points (a) and (b) of that Article, where traceability of such movements of those species or categories is necessary to ensure compliance with the animal health requirements for movements laid down in Sections 1 to 6;
 - (b) the information necessary to notify movements of kept terrestrial animals as provided for in Articles 149 and 150;
 - (c) the emergency procedures for the notification of movements of kept terrestrial animals in the case of power cuts and other disturbances of IMSOC;
 - (d) the requirements for the designation of regions by Member States for the management of notification of movements provided for in Article 150(3).
2. The Commission may, by means of implementing acts lay down rules concerning:
 - (a) the format of notifications of movements of kept terrestrial animals by:
 - (i) operators to the competent authority of their Member State of origin in accordance with Article 149;
 - (ii) the competent authority of the Member State of origin to the Member State of destination in accordance with Article 150;
 - (b) the deadlines for:
 - (i) the necessary information referred to in Article 149 to be provided by the operator to the competent authority of the Member State of origin;
 - (ii) the notification of movements of movements of kept terrestrial animals by the competent authority of the Member State of origin referred to in Article 150(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 4

Movements within the Union of terrestrial pet animals

Article 152

Non-commercial movements of terrestrial pet animals and delegated and implementing acts

1. Pet keepers shall only carry out non-commercial movements of terrestrial pet animals of the species listed in Annex I from one Member State to another Member State ~~where~~ **in accordance with the provisions of Regulation (EU) No 576/2013. [Am. 263]**

Tuesday 15 April 2014

~~(a) those terrestrial pet animals are identified and accompanied with an identification document when required in accordance with Article 112 or rules adopted pursuant to Article 114(c) and Article 117; [Am. 264]~~

~~(b) appropriate prevention and disease control measures have been taken during that movement, to ensure that the terrestrial pet animals do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) and emerging diseases to kept terrestrial animals at the place of destination and during transport. [Am. 265]~~

2. The Commission shall, **without prejudice to the provisions laid down in Regulation (EU) No 576/2013**, be empowered to adopt delegated acts in accordance with Article 253 concerning the prevention and disease control measures referred to in paragraph 1(b) of this Article to ensure that the terrestrial pet animals do not pose a significant risk for the spread of diseases referred to in Article 8(1)(d) and emerging diseases to animals during transport and at the place of destination and when relevant taking into account the health status of the place of destination. [Am. 266]

3. **Without prejudice to Regulation (EU) No 576/2013**, the Commission may, by means of implementing acts lay down rules concerning the prevention and disease control measures provided for in paragraph 1 of this Article ~~and the rules adopted pursuant to paragraph 2 thereof.~~ [Am. 267]

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 254(2).

Chapter 5

Movement of wild terrestrial animals

Article 153

Wild terrestrial animals

1. Operators shall only move wild animals from a habitat in one Member State to a habitat or to an establishment in another Member State where:

(a) the movements of the wild animals from their habitat are carried out in such a way that they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) or emerging diseases en route or at the place of destination;

(b) the wild animals do not come from a habitat in a restricted zone subject to movement restrictions due to the occurrence of a listed disease referred to in Article 8(1)(d) or an emerging disease for the listed species provided for in Article 70(2) (c), Article 80(1) and (2) and rules adopted pursuant to Articles 70(3)(b) and Articles 71(3), 80(4) and Article 81(3) or the emergency measures provided for in Articles 245 and 246 and rules adopted pursuant to Article 248 unless derogations have been granted in accordance to those rules;

(c) the wild animals are accompanied by an animal health certificate or other documents where animal health certification is necessary to ensure compliance with the animal health requirements for movements provided for in points (a) and (b) of this paragraph and the rules adopted pursuant to Article 154(1)(c) and (d) are complied with;

(d) the movement is notified by the competent authority of the Member State of origin to the competent authority of the Member State of destination, when animal health certificate is required by the rules adopted pursuant to Article 154(1) (c) .

2. When animal health certification is required by the rules adopted pursuant to Article 154(1)(c) the requirements provided for in Articles 142 and 145, Article 146(1),(2) and (3), Article 147 and the rules adopted pursuant to Articles 143 and 144 and Article 146(4), shall apply to movements of wild terrestrial animals.

Tuesday 15 April 2014

3. When notification of movements is required in accordance with paragraph 1(d) of this Article, the requirements provided for in Articles 149, 150 and the rules adopted pursuant to delegated acts laid down in Article 151 shall apply to movements of wild terrestrial animals.

Article 154

Empowerments concerning the movement of wild terrestrial animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) the animal health requirements for movements of wild terrestrial animals provided for in Article 153(1)(a) and (b);
- (b) the animal health requirements for the introduction of wild terrestrial animals when moved from the wild:
 - (i) into establishments;
 - (ii) for keeping as pet animals;
- (c) the types of movements of wild terrestrial animals for which, or the situations in which, an animal health certificate or other document is required to accompany such movements and the requirements concerning the contents of such certificates or other documents;
- (d) the notification by the competent authority of the Member State of origin to the competent authority of the Member State of destination in the case of movements of wild terrestrial animals between Member States and the information to be included in such notification.

2. The Commission may, by means of implementing acts, lay down rules specifying the requirements provided for in Article 153 and the delegated rules adopted pursuant to paragraph 1 concerning:

- (a) model forms of animal health certificates and other documents which are required to accompany movements of the wild terrestrial animals, when provided for in delegated acts adopted pursuant to paragraph 1(c);
- (b) the format of the notification by the competent authority of the Member State of origin and the deadlines for such notifications, when provided for in rules adopted pursuant to paragraph 1(d).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 6

Movements within the Union of germinal products

Section 1

General requirements

Article 155

General requirements for movement of germinal products

1. Operators shall take appropriate preventive measures to ensure that the movement of germinal products does not jeopardise the health status of kept terrestrial animals at the place of destination with regard to:

- (a) the listed diseases referred to in Article 8(1)(d);
- (b) emerging diseases.

Tuesday 15 April 2014

2. Operators shall only move germinal products from their establishments, and receive such germinal products if they comply with the following conditions:
 - (a) they come from establishments that have been:
 - (i) entered in the register of establishments by the competent authority in accordance with Article 88(a) and no derogation has been granted by the Member State of origin in accordance with Article 83;
 - (ii) approved by the competent authority in accordance with Article 92(1), when required by Article 89(1) or Article 90;
 - (b) they comply with the traceability requirements of Article 118(1) and rules adopted pursuant to Article 119(1).
3. Operators shall comply with the requirements of Article 122 for the transport of germinal products of kept terrestrial animals.
4. Operators shall not move germinal products from an establishment in one Member State to an establishment in another Member State, unless the competent authority of the Member State of destination gives its express authorisation for such movement, where those germinal products are required to be destroyed for disease eradication purposes as a part of an eradication programme provided for in Article 30(1) or (2).

Article 156

Obligations for operators at the place of destination

1. Operators of establishments at the place of destination receiving germinal products from an establishment in another Member State shall:
 - (a) check for the presence of:
 - (i) identification marks in accordance with Article 118 and rules adopted pursuant to Article 119;
 - (ii) animal health certificates as provided for in Article 159;
 - (b) inform the competent authority of any irregularity with regard to:
 - (i) the germinal products received;
 - (ii) the presence of the means of identification referred to in point (a)(i);
 - (iii) the presence of animal health certificates referred to in point (a)(ii).
2. In the event of an irregularity as referred to in paragraph 1(b), the operator shall keep the germinal products under its supervision until the competent authority has taken a decision regarding them.

Section 2

Movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry

Article 157

Operators obligations for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to other Member States

1. Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to another Member State if those germinal products comply with the following conditions:
 - (a) they are collected, produced, processed and stored in germinal product establishments approved for that purpose in accordance with Article 92(1) and Article 94;

Tuesday 15 April 2014

- (b) they fulfil the traceability requirements for the type of germinal product in accordance with Article 118 and rules adopted pursuant to Article 119;
 - (c) they have been collected from the donor animals which comply with the necessary animal health requirements to ensure that the germinal products do not spread listed diseases;
 - (d) they have been collected, produced, processed, stored and transported in a manner to ensure that they do not spread listed diseases.
2. Operators shall not move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry from a germinal product establishment which is subject to movement restrictions affecting the listed species in accordance with:
- (a) Article 55(1)(a), (c), (e) and Article 55(1)(f)(ii), Article 56 and Article 61(1)(a), Article 62(1), Article 65(1)(c) and Articles 74(1), 78(1) and (2);
 - (b) rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3) and 74(3), Article 79 and Article 81(2); and
 - (c) emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248 unless derogations have been provided for in rules adopted pursuant to Article 247.

Article 158

Delegation of power for movements of germinal products of kept animals of the bovine, porcine, ovine, caprine and equine species and of poultry to other Member States

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to other Member States provided for in Article 157, specifying:

- (a) rules for the collection, production, processing and storage of germinal products of those kept animals in approved establishments as referred to in Article 157(1)(a);
- (b) animal health requirements provided for in Article 157(1)(c):
 - (i) for kept animals from which germinal products were collected;
 - (ii) isolation or quarantine for the kept donor animals referred to in (i);
- (c) laboratory and other tests on kept donor animals and germinal products;
- (d) animal health requirements for the collection, production, processing, storage or other procedures and transport provided for in Article 157(1)(d);
- (e) derogations for operators from the rules provided for in Article 157, taking into account the risks of such germinal products and any risk mitigating measures in place.

Section 3

Animal health certification and notification of movements

Article 159

Operators' obligations concerning animal health certification for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry and delegated acts

1. Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry where they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3 when they are moved:

- (a) to another Member State;

Tuesday 15 April 2014

- (b) within a Member State or to another Member State, where:
- (i) the germinal products of kept animals are allowed to leave a restricted zone subject to disease control measures provided for in Article 55(1)(f)(ii) and Articles 56, 64 and 65, Article 74(1) and Article 78 and rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(3), Article 79 and Article 81(2) or the emergency measures provided for in Articles 246 and 247 and the rules adopted pursuant to Article 248 unless derogations have been granted from the animal health certification requirement in accordance with the rules referred in this point; and
 - (ii) the germinal products of kept animals are of species subject to those disease control or emergency measures referred in point (i).
2. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the germinal products from their place of origin to their place of destination.
3. The competent authority shall upon request by the operator issue an animal health certificate for the movements of germinal products referred to in paragraph 1.
4. Articles 142, 145, 146 and 147 and the rules adopted pursuant to Articles 143 and 144 and Article 146(4), shall apply to the animal health certification of the germinal products referred to in paragraph 1 of this Article, and Article 148 (1) and the rules adopted pursuant to Article 148(2) shall apply to the for self-declaration of movements of germinal products.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the animal health certificate requirements provided for in paragraph 1 of this Article for the movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry, which do not pose a significant risk for the spread of listed diseases due to the following:
- (a) the nature of the germinal products or the species of animal that those products come from;
 - (b) the methods of production and processing at the germinal product establishment;
 - (c) the intended use of the germinal products;
 - (d) alternative risk mitigating measures in place for the type and category of germinal products and the germinal product establishment.

Article 160

Content of animal health certificates

1. The animal health certificate for the germinal products provided for in Article 159 shall contain at least the following information:
- (a) the germinal product establishment of origin and the establishment or place of destination;
 - (b) the type of the germinal products and the species of kept donor animals;
 - (c) the volume of the germinal products;
 - (d) the marking of the germinal products, when required by Articles 118(1) and by rules adopted pursuant to Article 119 (1);
 - (e) information needed to demonstrate that the germinal products of the consignment comply with the movement requirements for the relevant species provided for in Articles 155 and 157 and rules adopted pursuant to Article 158.
2. The animal health certificate for the germinal products provided for in Article 159 may include other information required under other Union legislation.

Tuesday 15 April 2014

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) the information to be contained in the animal health certificate pursuant to paragraph 1 of this Article;
 - (b) animal health certification for different types of germinal products and of different animal species.
4. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for germinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 161

Notification of movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to other Member States

1. Operators shall:
 - (a) inform the competent authority in their Member State of origin in advance of the intended movement of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry to another Member State when:
 - (i) the germinal products are required to be accompanied by an animal health certificate in accordance with Article 159(1);
 - (ii) notification of movement is required in accordance with delegated acts adopted pursuant to Article 151(1) for germinal products, taking into account paragraph 3 of this Article;
 - (b) provide all the necessary information to enable the competent authority of the Member State of origin to notify the movement of the germinal products to the competent authority of the Member State of destination in accordance with paragraph 2.
2. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and of poultry in accordance with the rules adopted pursuant to Article 151.
3. Articles 149 and 150 and rules adopted pursuant to Article 151 shall be applicable to the notification of germinal products.

Section 4

Movements to other Member States of germinal products of kept terrestrial animals of species other than bovine, ovine, caprine, porcine and equine species and of poultry

Article 162

Germinal products of kept terrestrial animals other than those of the bovine, ovine, caprine, porcine and equine species and of poultry

1. Operators shall only move germinal products of kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and of poultry to another Member State if they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) to listed species at the place of destination, taking into account the health status at the place of destination.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning animal health requirements, animal health certification and notification requirements for movements of germinal products of kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and of poultry taking into account the following matters:
 - (a) listed diseases referred to in Article 8(1)(d) for the listed species;

Tuesday 15 April 2014

- (b) the species of animals from which the germinal product have been collected and type of germinal product;
- (c) the health status at the places of origin and of destination;
- (d) the type of collection, production, processing and storage;
- (e) other epidemiological factors.

3. Where animal health certification and the notification of movements of the germinal products are required in accordance with paragraph 2 of this Article:

- (a) the rules provided for in Articles 159, 160 and Article 161 and the rules adopted pursuant to Articles 159(5) and 160(3) shall apply for such certification;
- (b) the rules provided for in Article 161(1) and (2) shall apply for movement notification.

Section 5

Derogations

Article 163

Germinal products intended for scientific purposes and delegated acts

1. By way of derogation from Sections 1 to 4, the competent authority of the place of destination may authorise movements of germinal products for scientific purposes, which do not comply with the requirements of those Sections, with the exception of Article 155(1), Article 155(2)(c), Article 155(3) and Article 156, subject to compliance with the following conditions:

- (a) prior to granting such authorisation the competent authority of the place of destination must take the necessary risk mitigating measures to ensure that the movements of those germinal products do not jeopardise the health status en route and of the places of destination with regard to the listed diseases referred to in Article 8(1)(d);
- (b) the movements of those germinal products take place under the supervision of the competent authority of the place of destination.

2. When granting a derogation in accordance with paragraph 1, the competent authority of the place of destination shall notify the Member States of origin and the Member States of passage of the derogation granted and the conditions under which it has been granted.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning conditions for derogations by the competent authority of the place of destination, as provided for in paragraph 1 of this Article.

Chapter 7

Production, processing and distribution within the Union of products of animal origin

Article 164

General animal health obligations for operators and delegated acts

1. Operators shall take appropriate preventive measures to ensure that at all stages of the production, processing and distribution of products of animal origin in the Union, such products do not cause the spread of:

- (a) listed diseases referred to in Article 8(1)(d) taking into account the health status of the place of production, processing or destination;

Tuesday 15 April 2014

(b) emerging diseases.

2. Operators shall ensure that products of animal origin do not come from establishments or food business establishments or are obtained from animals which come from establishments subject to:

(a) emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248 unless derogations from the requirement provided for in paragraph 1 are provided for in rules adopted pursuant to Article 248;

(b) movement restrictions applicable to kept terrestrial animals and products of animal origin, as provided for in Articles 31(1), Article 55(1)(e), Article 56, Article 61(1)(a), Article 62(1), Article 65(1)(c), Article 70(1)(b), Article 74(1)(a), Article 78(1) and (2) and the rules adopted pursuant to Articles 55(2), Articles 63 and 66, Article 71(3), Article 74(3) and Articles 79 and Article 81(2) unless derogations from those movement restrictions are provided for in those rules.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed requirements amending and supplementing the requirements of paragraph 2 of this Article for the movement of products of animal origin, taking into account:

(a) the listed disease referred to in Article 8(1)(d) and species concerned by it and

(b) the risks involved.

Article 165

Animal health certificates obligations on operators and delegated acts

1. Operators shall only move the following products of animal origin within a Member State or to another Member State where they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3:

(a) products of animal origin that:

(i) are allowed to be moved from a restricted zone subject to emergency measures provided for in rules adopted pursuant to Article 248;

(ii) originate from animals of species subject to those emergency measures;

(b) products of animal origin that:

(i) are allowed to be moved from restricted zone subject to disease control measures in accordance with Article 31(1), Article 55(1)(f)(ii), Article 56, Article 61(1)(a), Article 62(1), Article 64, Articles 65(1)(c), 70(1)(b) and 74(1)(a) and Article 78(1) and (2) and rules adopted pursuant to Articles 55(2), Articles 63 and 67, Article 71(3) and 74(3), Article 79 and Article 81(2),

(ii) originate from animals of species subject to those disease control measures.

2. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the products of animal origin from their place of origin to their place of destination.

3. The competent authority shall upon request by the operator issue an animal health certificate for the movements of products of animal origin referred to in paragraph 1.

4. Articles 145, 146 and 147 and the rules adopted pursuant to Articles 143 and 144 and Article 146(4) shall apply to the animal health certification of the movements of the products of animal origin referred to in paragraph 1 of this Article.

Tuesday 15 April 2014

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the animal health certificate requirements provided for in paragraph 1 of this Article and the conditions for such derogations, for movements of products of animal origin which do not pose a significant risk for the spread of diseases due to:

- (a) the types of products of animal origin;
- (b) the risk mitigating measures applied to the products of animal origin, thereby reducing the risks of the spread of diseases;
- (c) the intended use of the products of animal origin;
- (d) the place of destination of the products of animal origin.

Article 166

Content of animal health certificates and delegated and implementing acts

1. The animal health certificate for products of animal origin provided for in Article 165(1) shall contain at least the following information:

- (a) the establishment or place of origin and the establishment or place of destination;
- (b) a description of the products of animal origin;
- (c) the quantity of the products of animal origin;
- (d) the identification of the products of animal origin, when required by Article 65 (1)(h) or rules adopted pursuant to Article 67(a);
- (e) information needed to demonstrate that the products of animal origin comply with the movement restriction requirements provided for in Article 164(2) and rules adopted pursuant to Article 164(3).

2. The animal health certificate for products of animal origin referred to in paragraph 1 may include other information required under other Union legislation.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the information to be contained in the animal health certificate as provided for in paragraph 1 of this Article.

4. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for products of animal origin referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 167

Notification of movements of products of animal origin to other Member States

1. Operators shall:

- (a) inform the competent authority in their Member State of origin in advance of the intended movement of the products of animal origin when the consignments are required to be accompanied by an animal health certificate in accordance with Article 165(1);
- (b) provide all necessary information to enable the competent authority of the Member State of origin to notify the movement of the products of animal origin to the Member State of destination in accordance with paragraph 2.

2. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of products of animal origin in accordance with Article 150 and the rules adopted pursuant to Article 151.

3. Articles 149 and 150 and rules adopted pursuant to Article 151 shall be applicable to the notification of products of animal origin.

Tuesday 15 April 2014

Chapter 8
Scope of national measures

Article 168

National measures concerning movements of animals and germinal products

1. Member States shall remain free to take national measures concerning the movement of kept terrestrial animals and germinal products thereof within their own territories.
2. Those national measures shall:
 - (a) take account of the rules on movement of animals and germinal products laid down in Chapters 3, 4, 5 and 6 and not be in contradiction with those rules;
 - (b) not hinder the movement of animals and products between Member States;
 - (c) not exceed the limits of what is appropriate and necessary to prevent the introduction and spread of the listed diseases referred to in Article 8(1)(d).

Article 169

National measures for limiting the impact of diseases other than listed diseases

Where a disease other than listed diseases constitutes a significant risk for the animal health situation of kept terrestrial animals in a Member State, the Member State concerned may take national measures to ~~control~~ **prevent the introduction or spread of** that disease, provided those measures ~~do not~~:

- (a) **only** hinder the movement of animals and products between Member States **when this is scientifically justified on the grounds of controlling infectious disease;**
- (b) **are proportionate in relation to the risk and do not** exceed the limits of what is appropriate and necessary to control that disease.

Member States shall notify the Commission in advance of any proposed national measures referred to in the first subparagraph that may affect movements between Member States.

Where the conditions laid down in the first paragraph are not fulfilled, the Commission may object to or amend the national measures referred to in the second paragraph by means of implementing acts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2) and shall enter into force with immediate effect. [Am. 268]

TITLE II

Aquatic animals and products of animal origin from aquatic animals

Chapter 1

Registration, approval, record keeping and registers

Section 1

Registration of aquaculture establishments

Article 170

Obligation of operators to register aquaculture establishments

1. Operators of aquaculture establishments shall, in order to be registered in accordance with Article 171, before they commence such activities:
 - (a) inform the competent authority of any aquaculture establishment under their responsibility;

Tuesday 15 April 2014

- (b) provide the competent authority with information on:
- (i) the name and address of the operator;
 - (ii) the location and a description of the facilities;
 - (iii) the categories, species and numbers of aquaculture animals on the aquaculture establishment and the capacity of the aquaculture establishment;
 - (iv) the type of aquaculture establishment;
 - (v) other aspects of the establishment which are relevant in determining the risk posed by it.
2. Operators of aquaculture establishments referred to in paragraph 1 shall inform the competent authority of any:
- (a) significant changes in the aquaculture establishments concerning the matters referred to in paragraph 1(b);
 - (b) cessation of activity in the aquaculture establishment.
3. Aquaculture establishments which are subject to approval in accordance with Article 174(1) shall not be required to provide the information referred to in paragraph 1 of this Article.
4. An operator may apply for a registration provided for in paragraph 1 to cover a group of aquaculture establishments provided that they comply with the conditions laid down in either points (a) or (b):
- (a) they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system;
 - (b) they are under the responsibility of the same operator, and
 - (i) under a common biosecurity system; and
 - (ii) located in geographical proximity.

Where an application for registration covers a group of establishments, the rules laid down in paragraphs 1 to 3 of this Article and Article 171(2) and the rules adopted pursuant to Article 173, which are applicable to a single aquaculture establishment, shall be applicable to the whole group of aquaculture establishments.

Article 171

Obligations of the competent authority concerning the registration of aquaculture establishments

The competent authority shall register:

- (a) aquaculture establishments in the register of aquaculture establishments provided for in Article 183(1), where the operator has provided the information required in accordance with Article 170(1);
- (b) groups of aquaculture establishment in that register of aquaculture establishments provided that the criteria laid down in Article 170(4) are complied with.

Article 172

Derogations from the obligation of operators to register aquaculture establishments

By way of derogation from Article 170(1), Member States may exempt certain categories of aquaculture establishments from the registration requirement taking into account the following criteria:

- (a) the categories, species and number or volume of aquaculture animals on the aquaculture establishment and the capacity of the aquaculture establishment;
- (b) the type of aquaculture establishment;

Tuesday 15 April 2014

- (c) the movements of aquaculture animals into and out of the aquaculture establishment.

Article 173

Implementing powers concerning derogations from the obligation to register aquaculture establishments

The Commission may, by means of implementing acts lay down rules concerning:

- (a) the information to be provided by operators for the purpose of the registration of the aquaculture establishment as provided for in Article 170(1);
- (b) the types of aquaculture establishments for which the derogations from the registration requirement may be granted by Member States as provided for in Article 172, provided that they pose an insignificant risk and taking into account the criteria provided for Article 172.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Section 2

Approval of certain types of aquaculture establishments

Article 174

Approval of certain aquaculture establishments and delegated acts

1. Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 178(1) and they shall not commence their activities until their aquaculture establishment has been approved in accordance with Article 179(1):

- (a) aquaculture establishments where aquaculture animals are kept with the view to their being moved from that aquaculture establishment either alive or as products of aquaculture animal origin, ~~however, such application shall not be required where they are solely moved either for:~~ [Am. 269]

~~(i) for a direct supply for human consumption of small quantities to the final consumer; or [Am. 270]~~

~~(ii) to local retail establishments directly supplying the final consumer. [Am. 271]~~

- (b) other aquaculture establishments which pose a high risk due to:

- (i) the categories, species and number of aquaculture animals on the aquaculture establishment;
- (ii) the type of aquaculture establishment;
- (iii) movements of aquaculture animals into and out of the aquaculture establishment.

1a. By way of derogation from paragraph 1, the competent authority may exempt from the obligation to apply for approval operators of aquaculture establishments where aquaculture animals are solely moved either:

- (i) for a direct supply for human consumption of small quantities to the final consumer; or**
- (ii) to local retail establishments directly supplying the final consumer,**

provided that such movements do not pose a significant risk. [Am. 272]

2. Operators shall cease activity at an aquaculture establishment referred to in paragraph 1 where:

- (a) the competent authority withdraws or suspends its approval in accordance with Article 182(2); or

Tuesday 15 April 2014

(b) in the event of conditional approval, granted in accordance with Article 181(3), the aquaculture establishment fails to comply with the outstanding requirements referred to in Article 181(3) and does not obtain a final approval in accordance with Article 182(4).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning supplementing and amending the rules for the approval of aquaculture establishments provided for in paragraph 1 of this Article concerning:

(a) derogations from the requirement for operators to apply to the competent authority for approval of the types of aquaculture establishments referred to in paragraph 1(a);

(b) the types of aquaculture establishments that must be approved in accordance with paragraph 1(b).

4. The Commission shall take the following criteria into account, when adopting delegated acts provided for in paragraph 3:

(a) the species and categories of aquaculture animals kept in an aquaculture establishment;

(b) the type of aquaculture establishment and the type of production;

(c) typical movement patterns of the type of aquaculture establishment and concerned species or category of aquaculture animals.

5. An operator may apply for an approval of group of aquaculture establishments provided that the requirements provided for in Article 175(a) and (b) are complied with.

Article 175

Approval by the competent authority of group of aquaculture establishments

The competent authority may grant approval as provided for in Article 179(1) covering a group of aquaculture establishments, provided that they comply with the conditions laid down in either point (a) or point (b):

(a) they are located in an epidemiologically linked area and all operators operate under a common biosecurity system; however, dispatch centres, purification centres and similar establishments located inside such an epidemiologically linked area must be approved individually;

(b) they are under the responsibility of the same operator; and

(i) under a common biosecurity system; and

(ii) located in geographical proximity.

When a single approval is granted for a group of aquaculture establishments, the rules laid down in Article 176 and Articles 178 to 182 and the rules adopted pursuant to Articles 178(2) and 179(2) which are applicable to a single aquaculture establishment shall be applicable to the group of aquaculture establishments.

Article 176

Approval of status of confined aquaculture establishments

Operators of aquaculture establishments, who want to obtain the status of confined establishment shall:

(a) apply to the competent authority for approval in accordance with Article 178(1);

Tuesday 15 April 2014

- (b) not move aquaculture animals to a confined aquaculture establishment in accordance with the requirements provided for in Article 203(1) and any delegated acts adopted in accordance with Article 203(2) until their establishment obtains an approval of that status by the competent authority in accordance with Article 179 or Article 181.

Article 177

Approval of **processing establishments and** disease control aquatic food establishments [Am. 273]

~~Operators of~~ **Natural and legal persons intending to operate processing establishments and** disease control aquatic food establishments shall ensure that their establishments are approved by the competent authority to slaughter aquatic animals for disease control purposes in accordance with Article 61(1)(b), Article 62 and Articles 68(1), 78(1) and (2) and the rules adopted pursuant to Article 63 and Articles 70(3), 71(3) and 78(3). [Ams 274 and 275]

Article 178

Information obligation of operators in view to obtain approval and implementing acts

1. **Intending** operators shall, for the purposes of their application for the approval of their establishment provided for in Article 174(1), Article 175, Article 176(a) and Article 177 provide the competent authority with the information on: [Am. 276]

- (a) the name and address of the operator;
- (b) the location of the establishment and a description of facilities;
- (c) the categories, species and numbers of aquaculture animals **intended to be kept** on the establishment; [Am. 277]
- (d) the type of establishment;
- (e) where relevant, the details of the approval of a group of aquaculture establishments in accordance with Article 175;
- (f) other aspects of the aquaculture establishment, which are relevant in determining the risk posed by it;

(fa) the water supply and discharge of the establishment. [Am. 278]

2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of any:

- (a) significant changes in the establishments concerning the matters referred to in paragraph 1(c);
- (b) cessation of activity in the establishment.

3. The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in the application for the approval of their establishment, in accordance with paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 179

Granting of approval and conditions for approval and delegated acts

1. The competent authority shall only grant approvals of aquaculture establishment referred to in Article 174(1) and, Article 176(a), group of aquaculture establishments referred to in Article 175 and disease control aquatic food establishments referred to in Article 177 where such establishments:

(a) comply with the following requirements, where appropriate on:

- (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in Article 9(1)(b) and rules adopted pursuant to Article 9(2);

Tuesday 15 April 2014

- (ii) surveillance requirements provided for in Article 22 and where relevant for the type of establishment and the risk involved, in Article 23, and the rules adopted pursuant to Article 24;
 - (iii) record keeping provided for in Articles 185 to 187 and the rules adopted pursuant to Articles 188 and 189;
- (b) have facilities and equipment that are:
- (i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment;
 - (ii) of adequate capacity for the quantity of aquatic animals;
- (c) do not lead to an unacceptable risk for the spread of disease, taking into account the risk mitigating measures in place;
- (d) have a system in place which enables the operator to demonstrate to the competent authority that the requirements laid down in points (a), (b) and (c) are fulfilled.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the requirements provided for in paragraph 1 of this Article as regards:
- (a) quarantine, isolation and other biosecurity measures referred to in paragraph 1(a)(i);
 - (b) surveillance referred to in paragraph 1(a)(ii);
 - (c) facilities and equipment referred to in paragraph 1(b).
3. The Commission shall take into account the following matters when establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2:
- (a) the risks posed by each type of establishment;
 - (b) the species and categories of aquaculture or aquatic animals;
 - (c) the type of production;
 - (d) typical movement patterns of the type of aquaculture establishment and species and categories of animals kept in those establishments.

Article 180

Scope of the approval of establishments

The competent authority shall expressly specify in approvals of aquaculture establishment or a disease control aquatic food establishment granted pursuant to Article 179(1):

- (a) for which of the types of aquaculture establishments referred to in Article 174(1), Article 176(a), groups of aquaculture establishments referred to in Article 175 and disease control aquatic food establishments referred to in Article 177, and rules adopted pursuant to Article 174(3)(b) the approval applies;
- (b) for which species and categories of aquaculture animals the approval applies.

Article 181

Procedures for granting the approval by the competent authority

1. The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 174(1) and Articles 176 and 177.

Tuesday 15 April 2014

2. Upon receipt of an application for approval from an operator in accordance with Article 174(1), Article 176 and Article 177, the competent authority shall make an on-site visit.

3. The competent authority may grant conditional approval of an establishment where it appears, based on the application of the operator and the subsequent on-site visit of the establishment by the competent authority as provided for in paragraph 1 of this Article, that it meets all the main requirements that provide sufficient guarantees that such an establishment does not represent a significant risk, with a view to ensuring the compliance with the outstanding requirements for approval provided for in Article 179(1) and the rules adopted pursuant to Article 179(2).

4. Where conditional approval has been granted by the competent authority in accordance with paragraph 3 of this Article, it shall grant full approval only where it appears from another on-site visit of the establishment, carried out within three months from the date of granting conditional approval, that the establishment meets all the requirements for approval provided for in Article 179(1) and the rules adopted pursuant to Article 179(2).

Where that on-site visit shows that clear progress has been made but the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not exceed a total period of six months.

Article 182

Review, suspension and withdrawal of approvals by the competent authority

1. The competent authority shall keep the approvals of establishments granted in accordance with Article 179(1) under review. **The competent authority, based on the risk factor, shall define review frequency or minimum and maximum review deadlines, as well as those instances in which such deadlines cannot be met.** [Am. 279]

2. Where the competent authority identifies serious deficiencies in the establishment as regards compliance with the requirements laid down in Article 179(1) and the rules adopted pursuant to Article 179(2) and the operator is not able to provide adequate guarantees that those deficiencies will be resolved, the competent authority shall initiate procedures to withdraw the establishment's approval.

However, the competent authority may suspend an establishment's approval where the operator can guarantee that it will resolve deficiencies within a reasonable period of time.

3. Approval shall only be restored after withdrawal or suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation, appropriate for that type of establishment.

Section 3

Register of the competent authority of aquaculture establishments, **processing establishments** and disease control aquatic food establishments [Am. 280]

Article 183

Register of aquaculture establishments, **processing establishments** and disease control aquatic food establishments [Am. 281]

1. The competent authority shall establish and keep up-to-date a register of:

(a) all aquaculture establishments registered in accordance with Article 171;

(b) all aquaculture establishments approved in accordance with Articles 179(1);

(c) all **processing establishments and** disease control aquatic food establishments approved in accordance with Article 179(1). [Am. 282]

2. The register of aquaculture establishments provided for in paragraph 1 shall contain information on:

(a) the name and address of the operator and its registration number;

Tuesday 15 April 2014

- (b) the geographical position of the aquaculture establishment or when applicable, the group of aquaculture establishments;
 - (c) the type of production at the establishment;
 - (d) the water supply and discharge of the establishment, when relevant;
 - (e) the species of aquaculture animals kept at the establishment;
 - (f) up-to-date information on the health status of the registered aquaculture establishment, or when applicable, the group of establishments, as regards the listed diseases referred to in Article 8(1)(d).
3. For establishments approved in accordance with Article 179(1), the competent authority shall make publicly available by electronic means at least the information referred to in paragraph 2(a), (c), (e) and (f) of this Article.
4. Where appropriate and relevant, the competent authority may combine the registration provided for in paragraph 1 with registration for other purposes.

Article 184

Delegation of powers and implementing acts concerning the register of aquaculture establishments

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 254 concerning:
- (a) the information to be included in the register of aquaculture establishments provided for in Article 183(1);
 - (b) the public availability of that register of establishments.
2. The Commission may, by means of implementing acts, lay down rules on the format of and procedures for the register of establishments provided for in Article 183(1) and (3).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Section 4

Record keeping and traceability

Article 185

Record keeping obligations of operators of aquaculture establishments

1. Operators of aquaculture establishments subject to registration in accordance with Article 171 or approval in accordance with Article 179(1) shall keep up-to-date records containing at least the following information:
- (a) all movements of aquaculture animals and products of animal origin obtained from those animals into and out of the aquaculture establishment, stating as appropriate:
 - (i) their place of origin or destination;
 - (ii) the date of such movements;
 - (b) the animal health certificates in paper or electronic form required to accompany movements of aquaculture animals arriving at the aquaculture establishment in accordance with Article 208 and the rules adopted pursuant to Articles 211 (b) and (c) and Article 213(2);
 - (c) the mortality in each epidemiological unit and other disease problems at the aquaculture establishment as relevant for the type of production;
 - (d) biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:
 - (i) the category and species of the aquaculture animals on the establishment;

Tuesday 15 April 2014

- (ii) the type of production at the aquaculture establishment;
 - (iii) the type of aquaculture establishment;
 - (e) the results of the animal health visits, when required in accordance with Article 23(1) and the rules adopted pursuant to Article 24.
2. Operators of aquaculture establishments shall:
- (a) record the information provided for in paragraph 1(a) in such a way that the tracing of the place of origin and destination of aquatic animals can be guaranteed;
 - (b) keep the information provided for in paragraph 1 on the aquaculture establishment and, made it available to the competent authority on request;
 - (c) retain the information provided for in paragraph 1 for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Article 186

Record keeping obligation for **processing establishments and** disease control aquatic food establishments [Am. 283]

1. Operators of **processing establishments and** disease control aquatic food establishments subject to approval in accordance with Article 177 shall keep up-to-date records of all movement of aquaculture animals and products of animal origin obtained from such animals into and out of such establishments. [Am. 284]
2. Operators of **processing establishments and** disease control aquatic food establishments shall: [Am. 285]
- (a) keep the records provided for in paragraph 1 on the disease control aquatic food establishment and make them available to the competent authority on request;
 - (b) retain the records provided for in paragraph 1 for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Article 187

Record keeping obligation for transporters

1. Transporters of aquaculture animals and wild aquatic animals intended for aquaculture **or for release in a natural environment in order to replenish wild stocks** shall keep up-to date records on: [Am. 286]
- (a) mortality rates of the aquaculture animals and wild aquatic animals during transport, as practicable for the type of transport and the species of aquaculture animals and wild aquatic animals transported;
 - (b) aquaculture establishments and disease control aquatic food establishments visited by the means of transport;
 - (c) any exchange of water that took place during transport, specifying the sources of new water and sites of release of water.
2. Transporters shall:
- (a) keep the records provided for in paragraph 1 and make them available to the competent authority on request;
 - (b) retain the records provided for in paragraph 1 for a minimum period to be determined by the competent authority, but which may not be less than a period of three years.

Tuesday 15 April 2014

Article 188

Delegation of powers concerning record keeping

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules supplementing the record keeping requirements provided for in Articles 185, 186 and 187 laying down rules on:

- (a) derogations from the record keeping requirements for:
 - (i) operators of certain categories of aquaculture establishments and transporters;
 - (ii) aquaculture establishments keeping a small number of animals or transporters transporting a small number of animals;
 - (iii) certain categories or species of animals;
- (b) information to be recorded by operators in addition to that provided for in Articles 185(1), 186(1) and 187(1);
- (c) the minimum period of time during which records provided for in Articles 185, 186 and 187 are required must be kept.

2. The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 1:

- (a) the risks posed by each type of aquaculture establishment;
- (b) the categories or species of aquaculture animals on the aquaculture establishment;
- (c) the type of production of the establishment;
- (d) typical movement patterns for the type of aquaculture establishment or disease control aquatic food establishment;
- (e) the number or volume of aquaculture animals at the establishment or being transported.

Article 189

Implementing powers concerning record keeping

The Commission may, by means of implementing acts, lay down rules concerning:

- (a) the format of records to be kept in accordance with Articles 185, 186 and 187;
- (b) electronic keeping of those records;
- (c) operational specifications for record-keeping.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 2

Movements within the Union of aquatic animals other than aquatic pet animals

Section 1

General Requirements

Article 190

General requirements for movement of aquatic animals

1. Operators shall take appropriate measures to ensure that the movement of aquatic animals does not jeopardise the health status at the place of destination with regard to:

- (a) the listed diseases referred to in Article 8(1)(d);

Tuesday 15 April 2014

(b) emerging diseases.

2. Operators shall not move aquatic animals into an aquaculture establishment or for human consumption or release them into the wild, where such aquatic animals are subject to:

(a) movement restrictions affecting the category and species concerned in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, Article 70(1) and (2), Articles 74(1), 78(1) and (2), 80(1) and (2) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 70(3), 71(3 and 74(3), Article 79, and Articles 80(4) and 81(2); or

(b) the emergency measures laid down in Articles 244 and 247 and the rules adopted pursuant to Article 248.

However, operators may move those aquatic animals where derogations from the movement restrictions for such movements or release are provided for in Title II of Part III or derogations from emergency measures in rules adopted pursuant to Article 248.

3. Operators shall take all necessary measures to ensure that aquatic animals, after leaving their place of origin, are consigned without delay to the final place of destination.

Article 191

Disease preventive measures in relation to transport and delegated acts

1. Operators shall take the appropriate and necessary disease preventive measures to ensure that:

(a) the health status of aquatic animals is not jeopardised during transport;

(b) transport operations of aquatic animals do not cause the potential spread of listed diseases referred to in Article 8(1)(d) to humans or animals en route, and at places of destination;

(c) cleaning, disinfection and disinfestations of equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport;

(d) any exchanges of water during the transport of aquatic animals intended for aquaculture are carried out at places and under conditions which do not jeopardise the health status with regard to the listed diseases referred to in Article 8(1)(d) of:

(i) the aquatic animals being transported;

(ii) any aquatic animals en-route to the place of destination;

(iii) aquatic animals at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) the cleaning, disinfection and disinfestations of equipment and means of transport in accordance with paragraph 1(c) and the use of biocidal products for such purposes;

(b) other appropriate biosecurity measures during transport as provided for in paragraph 1(c);

(c) water exchanges during transport as provided for in paragraph 1(d).

Article 192

Change of intended use

1. Aquatic animals which are moved for destruction or slaughter in accordance with the measures referred to in point (a) or (b) shall not be used for any other purpose:

(a) disease control measures provided for in Articles 31(1) and 55(1), Articles 56, 61, 62, 64, 65, 67 and 70, Article 74(1) and Articles 78 and 80 and the rules adopted pursuant to Article 55(2), Articles 63 and 66, Articles 70(3), 71(3) and 74(3), Article 79, and Articles 80(3) and 81(2);

Tuesday 15 April 2014

(b) emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248.

2. Aquatic animals moved for human consumption, aquaculture, release into the wild or any other specific purpose, shall not be used for any purpose other than the intended one.

Article 193

Obligations for operators at the place of destination

1. Operators of establishments and food business establishments receiving aquaculture ~~aquaculture~~ **aquatic** animals shall, **before the aquatic animals are unloaded**: [Am. 287]

(a) check that one of the following documents are present:

(i) the animal health certificates provided for in Article 208(1), Article 209 and Article 224(1) and the rules adopted pursuant to Articles 188, 211 and 213 are present;

(ii) the self-declaration documents provided for in Article 218(1) and the rules adopted pursuant to Article 218(3) and (4) are present;

(aa) inspect the consignment for any irregularity; [Am. 288]

(b) inform the competent authority of any irregularity with regard to:

(i) the ~~aquaculture~~ **aquatic** animals received; [Am. 289]

(ii) the presence of the documents referred to in point (a) (i) and (ii).

2. In the event of any irregularity as referred to in paragraph 1(b), the operator shall ~~isolate~~ **not permit** the aquaculture animals concerned by that irregularity **to be unloaded** until the competent authority has taken a decision regarding them. [Am. 290]

Article 194

General requirements for movements of aquaculture animals passing through Member States but intended for export from the Union to third countries or territories

Operators shall ensure that aquaculture animals intended for export to a third country or territory and passing through the territory of other Member States fulfil the requirements laid down in Articles 190, 191 and 192.

Section 2

Aquatic animals intended for aquaculture establishments or to be released into the wild

Article 195

Abnormal mortalities or other serious disease symptoms

1. Operators shall not move aquatic animals from an aquaculture establishment or from the wild to another aquaculture establishment or release them into the wild if they originate from an aquaculture establishment or environment where there are:

(a) abnormal mortalities; or

(b) other serious disease symptoms with an undetermined cause.

2. By way of derogation from paragraph 1, the competent authority may authorise such movement or release of aquatic animals, based on an evaluation of risks, provided that the aquatic animals originate from a part of the aquaculture establishment or from the wild that is independent of the epidemiological unit where the abnormal mortalities or other disease symptoms have occurred.

Tuesday 15 April 2014

Article 196

Movement of ~~aquaculture~~ **kept aquatic** animals intended for Member States, zones or compartments which have been declared disease free or which are subject to an eradication programme and delegated acts [Am. 291]

1. Operators shall only move ~~aquaculture animals~~ **kept aquatic animals** from an ~~aquaculture~~ establishment for the purposes referred to in ~~point points~~ (a) ~~or~~ and (b) of this Article, if those ~~aquaculture~~ animals originate from a Member State, or zone or compartment thereof, which has been declared disease-free in accordance with Article 36(3) or 37(4) for listed diseases referred to in Article 8(1)(b) or (c) when they are of listed species for those listed diseases and the ~~aquaculture~~ **kept aquatic** animals are: [Am. 292]

(a) to be introduced into a Member State, or zone or compartment thereof which is:

(i) has been declared disease free in accordance with Article 36(3) or Article 37(4); or

(ii) subject to a eradication programme as provided for in Article 30(1) and (2) as regards one or more of the listed diseases referred to in Article 8(1)(b) and (c);

~~(b) intended for:~~

~~(i) an aquaculture establishment subject to:~~

~~— registration in accordance with Article 171; or~~

~~— approval in accordance with Articles 174, 175, 176 and Article 177; or~~

~~(ii) release into the wild. [Am. 293]~~

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the movement or release requirements of paragraph 1 of this Article, which do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) due to:

(a) the species, categories, and life stage of the ~~aquaculture~~ **kept aquatic** animals; [Am. 294]

(b) the type of establishment of origin and of destination;

(c) the intended use of the ~~aquaculture~~ **kept aquatic** animals; [Am. 295]

(d) the place of destination of the ~~aquaculture~~ **kept aquatic** animals; [Am. 296]

(e) treatments, processing methods and other special risk mitigating measures applied at places of origin or destination.

Article 197

Derogations by Member States concerning the obligation of operators for movement of aquaculture animals between Member States, zones or compartments which are subject to an eradication programme

By way of derogation from Article 196(1), Member States may authorise operators to move aquaculture animals into a zone or compartment ~~in another Member State~~ **within their territory** for which an eradication programme has been established in accordance with Article 30(1) and (2) as regards the listed diseases referred to in Article 8(1)(b) and (c), from ~~another a~~ zone or compartment **in another Member State** for which such a programme has also been established for the same listed diseases, provided that such movement will not jeopardise the health status of the Member State, zone or compartment of destination. [Am. 297]

Tuesday 15 April 2014

Article 198

Member States' measures concerning the release of aquaculture animals into the wild

Member States may require that ~~aquaculture~~ **aquatic** animals shall only be released into the wild if they originate from a Member State, or zone or compartment declared disease-free in accordance with Article 36(1) or Article 37(1) as regards the listed diseases referred to in Article 8(1)(b) and (c) for which the species of ~~aquaculture~~ **aquatic** animals to be moved is a listed species, regardless of the health status of the area where the ~~aquaculture~~ **aquatic** animals are to be released. [Am. 298]

Article 199

Movement of wild aquatic animals intended for Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme and delegated acts

1. Articles 196 and 197 shall also apply to movements of wild aquatic animals intended for an aquaculture establishment, **processing establishment** or disease control aquatic food establishment subject to: [Am. 299]

(a) registration in accordance with Article 171; or

(b) approval in accordance with Articles 174 to 177.

2. Operators shall take disease preventive measures when moving wild aquatic animals between habitats so that such movements do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) to aquatic animals at the place of destination.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the disease preventive measures to be taken by operators as provided for in paragraph 2 of this Article.

Section 3

Aquatic animals intended for human consumption

Article 200

Movement of ~~aquaculture~~ **kept aquatic** animals intended for **human consumption in** Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme and delegated acts [Am. 300]

1. Operators shall only move ~~aquaculture~~ **kept aquatic** animals **intended for human consumption** from an aquaculture establishment for the purposes referred to in point (a) or (b) of this paragraph, if those ~~aquaculture~~ animals originate from a Member State, or zone or compartment thereof, which has been declared disease-free in accordance with Article 36(3) or 37(4) for listed diseases referred to in Article 8(1)(b) or (c) when they are of listed species for those listed diseases and they are: [Am. 301]

(a) to be introduced into a Member State, or zone or compartment thereof which has been declared disease free in accordance with Articles 36(3) or 37(4) or for which an eradication programme has been established in accordance with Article 30(1) or (2) as regards one or more of the listed diseases referred to in Article 8(1)(b) and (c);

(b) intended for human consumption.

2. By way of derogation from paragraph 1 of this Article Member States may authorise operators to introduce ~~aquaculture~~ **kept aquatic** animals into a zone or compartment for which an eradication programme has been established in accordance with Article 30(1) or (2) as regards the listed diseases referred to in Article 8(1)(b) and (c), from another zone or compartment for which such a programme has also been established as regards the same diseases within that Member State, provided that such movement will not jeopardise the health status of the Member State, or zone or compartment thereof. [Am. 302]

Tuesday 15 April 2014

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the derogations from movement requirements provided for in paragraph 2 of this Article for those movements of ~~aquaculture~~ **kept aquatic** animals which do not pose significant risk of spreading of diseases due to: [**Am. 303**]

(a) the species, categories, and live stage of the ~~aquaculture~~ **kept aquatic** animals; [**Am. 304**]

(b) the methods of keeping the ~~aquaculture~~ **aquatic** animals and type of production in the ~~aquaculture~~ establishments of origin and of destination; [**Am. 305**]

(c) the intended use of the ~~aquaculture~~ **kept aquatic** animals; [**Am. 306**]

(d) the place of destination of the ~~aquaculture~~ **kept aquatic** animals; [**Am. 307**]

(e) treatments, processing methods and other special risk mitigating measures applied at place of origin or place of destination.

Article 201

Movement of wild aquatic animals intended for Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme and delegated acts

1. Article 200(1) and (2) and the rules adopted pursuant to Article 200(3) shall also apply to movements of wild aquatic animals intended for human consumption and which are intended for Member States, or zones or compartments thereof, which have been declared disease-free in accordance with Articles 36(3) or 37(4) or are subject to an eradication programme in accordance with Article 30(1) or (2), where such measures are necessary to ensure that those wild aquatic animals do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) to aquatic animals at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning movement requirements for wild aquatic animals intended for human consumption supplementing paragraph 1 of this Article.

Section 4

Aquatic animals not intended for establishments, release into the wild or for human consumption

Article 202

Movement of aquatic animals not intended for establishments, release into the wild or for human consumption and delegated acts

1. Operators shall take the necessary preventive measures to ensure that movements of aquatic animals not intended for establishments, release into the wild or for human consumption do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) to aquatic animals at the place of destination.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the preventive measures provided for in paragraph 1 of this Article to ensure that the aquatic animals do not spread the listed diseases referred to in Article 8(1)(d), whilst taking into account the matters referred to in paragraph 3 of this Article.

3. The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 2:

(a) the listed diseases referred to in Article 8(1)(d) relevant for the listed species or category of aquatic animals;

Tuesday 15 April 2014

- (b) the health status as regards listed diseases referred to in Article 8(1)(d) at the compartments, zones or Member States of origin and destination;
- (c) the places of origin and of destination;
- (d) the type of movements of the aquatic animals;
- (e) the species and categories of the aquatic animals;
- (f) the age of the aquatic animals;
- (g) other epidemiological factors.

Section 5

Derogations from sections 1 to 4 and additional risk mitigation measures

Article 203

Aquatic animals intended for confined aquaculture establishments and delegated acts

1. Operators shall only move aquatic animals to a confined aquaculture establishment if they comply with the following conditions:
 - (a) they originate from another confined aquaculture establishment;
 - (b) they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) to listed species of animals at the confined aquaculture establishment of destination except where such movement is authorised for the scientific purposes.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) detailed requirements for movements of aquaculture animals to confined aquaculture establishments in addition to those provided for in paragraph 1 of this Article;
 - (b) specific rules for movements of aquaculture animals to confined aquaculture establishments where the risk mitigating measures in place guarantee that such movements do not pose a significant risk for the health of aquaculture animals within that confined aquaculture establishment and surrounding establishments.

Article 204

Derogation for movements of aquatic animals for scientific purposes and delegated acts

1. The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements into their territory of aquatic animals for scientific purposes, which do not comply with the requirements of Sections 1 to 4, with the exception of Articles 190(1) and (3), and Articles 191, 192 and Article 193.
2. The competent authorities shall only grant derogations for movements of aquatic animals for scientific purposes, as provided for in paragraph 1 under the following conditions:
 - (a) the competent authorities of the place of destination and of the place of origin:
 - (i) have agreed on the conditions for such movements;

Tuesday 15 April 2014

- (ii) have taken the necessary risk mitigating measures to ensure that the movements of those aquatic animals do not jeopardise the health status en route and of the places of destination with regard to the listed diseases referred to in Article 8(1)(d);
 - (iii) have notified, where relevant, the competent authority of Member States of passage of the derogation granted and the conditions under which this authorisation is granted;
- (b) the movements of those aquatic animals take place under the supervision of the competent authorities of the place of origin, the place of destination, and where relevant, the competent authority of the Member State of passage.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amending and supplementing the rules for derogations by the competent authorities provided for in paragraphs 1 and 2 of this Article.

Article 205

Delegation of power concerning specific requirements and derogations for exhibition, zoos, pet shops, garden ponds, commercial aquaria and wholesalers

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) specific requirement supplementing the rules laid down in from Sections 1 to 4 and for the movements of aquatic animals for the following purposes:
 - (i) zoos, pet shops and wholesalers;
 - (ii) exhibitions and for sporting, cultural and similar events; or
 - (iii) intended for commercial aquaria;
- (b) derogations from Sections 1 to 4 with the exception of Article 190(1) and (3) and Articles 191, 192 and 193 for the movements of aquatic animals referred to in point (a), **provided that adequate biosecurity provisions are in place to ensure that those movements do not pose a significant risk to the health status of the place of destination.** [Am. 308]

Article 206

Implementing power for temporary derogations for movements of specific species or categories of aquatic animals

The Commission shall, by means of implementing acts lay down rules concerning temporary derogations from the rules laid down in this Chapter for movements of specific species or categories of aquatic animals where:

- (a) the movement requirements provided for in Article 195, Article 196(1), Articles 197 and 198, Article 199(1) and (2), Article 200 and Articles 201(1), 202(1), 203(1), 204(1) and (2) and the rules adopted pursuant to Articles 196(2), 199(3), 201(2), 202(2), 203(2) and 204(3) and Article 205 are not efficiently mitigating the risks posed by certain movements of those aquatic animals; or
- (b) the listed disease referred to in Article 8(1)(d) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

On duly justified imperative grounds of urgency relating to a listed disease representing a risk of highly significant impact and taking into account the matters referred to in Article 205 the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 255(3).

Tuesday 15 April 2014

Article 207

Matters to be taken into account when adopting delegated and implementing acts provided for in this Section

The Commission shall take the following matters into account, when establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 203(2), 204(3) and Articles 205 and 206:

- (a) the risks involved with the movement;
- (b) the health status as regards the listed diseases referred to in Article 8(1)(d) at the places of origin and destination;
- (c) listed aquatic animal species for the listed diseases referred to in Article 8(1)(d);
- (d) biosecurity measures in place;
- (e) any specific conditions under which the ~~aquaculture~~ **aquatic** animals are kept; **[Am. 309]**
- (f) specific movement patterns of the type of ~~aquaculture~~ establishment and concerned species or category of ~~aquaculture~~ **aquatic** animals; **[Am. 310]**
- (g) other epidemiological factors.

Section 6

Animal health certification

Article 208

Obligation of operators to ensure that aquaculture animals are accompanied by an animal health certificate

1. Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority at the place of origin in accordance with Article 216(1) when they are of listed species for the listed diseases referred to in point (a) and they are being moved or one of following purposes:

- (a) they are intended for introduction into a Member State, or zone or compartment thereof which has been declared disease-free in accordance with Articles 36(3) and 37(4) or for which an eradication programme has been established as provided for in Article 30(1) or (2) as regards one or more of the listed diseases referred to in Article 8(1)(b) and (c); and
- (b) they are intended for one of the following purposes:
 - (i) an aquaculture establishment;
 - (ii) release into the wild;
 - (iii) human consumption.

2. Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority at the place of origin in accordance with Article 216(1) when they are of listed species for the relevant disease(s) referred to in point (a) and they are being moved or one of following reasons:

- (a) they are allowed to leave a restricted zone subject to disease control measures provided for in Article 55(1)(f)(ii), Articles 56 and 64, Articles 65(1), 74(1), 78(1) and (2) or the rules adopted pursuant to Article 55(2), Articles 67 and 68, Articles 71(3) and 74(3), Article 79, Article 81(2) and Article 248 for one or more of listed diseases referred to in Article 8(1)(a) and (b);

Tuesday 15 April 2014

(b) they are intended for one of the following uses:

- (i) an aquaculture establishment;
- (ii) released into the wild;
- (iii) human consumption.

3. Operators shall take all necessary measures to ensure that the animal health certificate accompanies the aquaculture animals from their place of origin to their place of destination, unless specific measures are provided for in rules adopted pursuant to Article 214.

Article 209

Obligation of operators to ensure that other aquatic animals are accompanied by an animal health certificate and implementing power

1. Operators shall only move aquatic animals other than aquaculture animals referred to in Article 208(1) and (2) if they are accompanied by an animal health certificate issued by the competent authority at the place of origin in accordance with Article 216(1) where, due to the risk involved with the movement of those aquatic animals, animal health certification is necessary to ensure compliance with the following movement requirements for the listed species of animals:

- (a) the requirements provided for in Sections 1 to 5 and the rules adopted pursuant to those Sections;
- (b) disease control measures provided for in Article 55(1), Article 56, Article 61(1), Articles 62 and 64, Articles 65(1), 74(1) and 78(1) and (2) or the rules adopted pursuant to Article 55(2), Articles 63, 67 and 68, Articles 71(3) and 74(3), Article 79 and Article 81(2);
- (c) emergency measures provided for in the rules adopted pursuant to Article 248.

2. Article 208 shall also apply to wild aquatic animals intended for an aquaculture establishment, unless the competent authority of origin concludes that the certification is not feasible due to the nature of the place of origin of those wild aquatic animals.

3. The Commission shall, by means of implementing acts, lay down rules concerning the obligation of operators, provided for in paragraph 2 of this Article, to ensure that wild aquatic animals intended for an aquaculture establishment are accompanied by an animal health certificate.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 210

Member States' derogation for national animal health certification

By way of derogation from the animal health certification requirements of Articles 208 and 209 Member States may grant derogations for movements of certain consignments of aquatic animals without an animal health certificate within their territories provided that they have an alternative system in place to ensure that such consignments are traceable and they comply with the animal health requirements for such movement provided for in Sections 1 to 5.

Article 211

Delegation of powers concerning animal health certification for aquatic animals

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) derogations from the animal health certificate requirements provided for in Articles 208 and 209 and the conditions for such derogations, for movements of aquatic animals which do not pose significant risk of the spread of diseases due to:
 - (i) the categories, live stage or species of the aquatic animals;

Tuesday 15 April 2014

- (ii) the methods of keeping and the type of production of those species and categories of aquaculture animals;
 - (iii) the intended use of the aquatic animals;
 - (iv) the place of destination of the aquatic animals;
- (b) special rules for animal health certification provided for in Articles 208 and 209 where alternative risk mitigating measures taken by the competent authority, ensure:
- (i) the traceability of the aquatic animals;
 - (ii) that the aquatic animals being moved comply with required animal health conditions provided for in Sections 1 to 5.
- (c) detailed rules on the animal health certificates required to accompany movements of aquatic animals for scientific purposes referred to in Article 204(1).

Article 212

Contents of animal health certificates

1. The animal health certificate shall contain at least the following information:
 - (a) the establishment or place of origin, the establishment or place of destination and where relevant for the spread of diseases, any establishment or place visited en route;
 - (b) a description of the aquatic animals;
 - (c) the number, volume or weight of aquatic animals;
 - (d) the necessary information needed to demonstrate that the animals comply with the movement requirements provided for in Sections 1 to 5.
2. The animal health certificate may include other information required under other Union legislation.

Article 213

Delegation of powers and implementing acts concerning the content of animal health certificates

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the content of animal health certificates provided for in Article 212(1):
 - (a) detailed rules on the content of those animal health certificates provided for in Article 212(1) for different categories and species of aquatic animals;
 - (b) additional information to be contained in the animal health certificate provided for in Article 212(1).
2. The Commission may, by means of implementing acts, lay down rules concerning the model forms for the animal health certificates.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 214

Operators obligation to ensure that animal health certificates accompany the aquatic animals to the place of destination and delegated acts

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning specific measures supplementing the requirements for animal health certification provided for in Article 208 for the following types of movements of aquatic animals:

- (a) movements of aquatic animals, which may not continue their route to their final place of destination and are required to return to their place of origin or be moved to a different destination, for one or more of the following reasons:

Tuesday 15 April 2014

- (i) their intended route was unexpectedly interrupted for animal welfare reasons;
 - (ii) unpredicted accidents or events on the route;
 - (iii) the aquatic animals were rejected at the place of the destination in another Member State or at the external border of the Union;
 - (iv) the aquatic animals were rejected in a third country;
- (b) movements of aquaculture animals intended for exhibitions and sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 215

Operators obligation to cooperate with the competent authorities for animal health certification purposes

Operators shall:

- (a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Articles 208 and 209 and the rules adopted pursuant to Articles 211, 213 and 214;
- (b) where necessary, subject the aquatic animals to identity, physical and documentary checks as provided for in Article 216 (3) and the rules adopted pursuant to Article 216(4).

Article 216

Competent authority responsibility for animal health certification and delegated acts

1. The competent authority shall, upon request by the operator, issue an animal health certificate for the movement of aquatic animals, where required by Articles 208 and 209, or by rules adopted pursuant to that Articles 211 and Article 214 provided that the following animal health requirements have been complied with, as relevant:

- (a) those provided in Article 190, Article 191(1), Articles 192, 194 and 195, Article 196(1), Articles 197 and 198, Article 199(1) and (2), Article 200, Articles 202(1), 203(1) and 204(1) and (2);
- (b) those provided in delegated acts adopted pursuant to Articles 191(2), 196(2), 199(3), 200(3), 201(2), 202(2), 203(2) and 204(3) and Article 205;
- (c) those provided for in implementing acts adopted pursuant to Article 206.

2. Animal health certificates shall:

- (a) be verified and signed by the official veterinarian;
- (b) remain valid for a period of time, provided for in the rules adopted pursuant to paragraph 4(b), during which time the aquaculture animals covered by it, must continue to comply with the animal health guarantees contained in it.

3. The official veterinarian shall, before signing an animal health certificate verify that the aquatic animals covered by it comply with the requirements of this Chapter by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4 where appropriate, taking into account the species and categories of aquatic animals concerned and the animal health requirements.

Tuesday 15 April 2014

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 laying down rules concerning:

- (a) the types of documentary, identity and physical checks and examinations for different species and categories of aquatic animals that must be carried out by the official veterinarian in accordance with paragraph 3 of this Article to verify compliance with the requirements of this Chapter;
- (b) the timeframes for the carrying out of such documentary, identity and physical checks, examination and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of aquatic animals.

Article 217

Electronic health certificates

Electronic animal health certificates, produced, handled and transmitted by means of IMSOC, may replace accompanying animal health certificates provided for in Article 208 where such electronic animal health certificates:

- (a) contain all the information that the model animal health certificate is required to contain in accordance with Article 212(1) and the rules adopted pursuant to Article 213;
- (b) ensure the traceability of the aquatic animals and the link between those animals and the electronic animal health certificate.

Article 218

Self- declaration by operators for movements of ~~aquaculture~~ **aquatic animals** to other Member States and delegated acts
[Am. 311]

1. Operators at the place of origin, shall issue a self-declaration document for movements of ~~aquaculture~~ **aquatic** animals from their place of origin in one Member State to the place of destination in another Member State and ensure that it accompanies such ~~aquaculture~~ **aquatic** animals, where they are not required to be accompanied by an animal health certificate provided for in Articles 208 and 209 or rules adopted pursuant to that Articles 211 and Article 214. [Am. 312]

2. The self-declaration document provided for in paragraph 1 shall contain at least the following information concerning the ~~aquaculture~~ **aquatic** animals: [Am. 313]

- (a) their places of origin and destination, and when relevant any places en route;
- (b) a description of the ~~aquaculture~~ **aquatic** animals, the species, their quantity, weight or volume as relevant for the animals concerned; [Am. 314]
- (c) the information needed to demonstrate that the ~~aquaculture~~ **aquatic** animals comply with the movement requirements provided for in Sections 1 to 5. [Am. 315]

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

- (a) detailed rules on the content of the self-declaration document provided for in paragraph 2 of this Article for different species and categories of ~~aquaculture~~ **aquatic** animals; [Am. 316]
- (b) additional information to be contained in the self-declaration document to the one provided for in paragraph 2 of this Article.

4. The Commission may, by means of implementing acts, lay down rules for a model form of the self-declaration document provided for in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Tuesday 15 April 2014

Section 7

Notification of movements of aquatic animals to other Member States

Article 219

Obligation of operators concerning the notification of movements of aquatic animals between Member States

Operators shall notify the competent authority in their Member State of origin in advance of the intended movement of aquatic animals from one Member State to another Member State where:

- (a) the aquatic animals are required to be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 208 and 209 or rules adopted pursuant to Article 211 and Article 214(2);
- (b) the aquatic animals are required to be accompanied by an animal health certificate for aquatic animals when they are being moved from a restricted zone as referred to in Article 208(2)(a);
- (c) the aquaculture animals and wild aquatic animals being moved are intended for:
 - (i) an establishment subject to registration in accordance with Article 171 or approval in accordance with Articles 174 to 177;
 - (ii) for release into the wild;
- (d) notification is required in accordance with the delegated acts adopted pursuant to Article 221.

For the purposes of the notification provided for in the first paragraph of this Article, the operators shall provide the competent authority of the Member State of origin with all the necessary information to enable it to notify the movement to the competent authority of the Member State of destination in accordance with Article 220(1).

Article 220

The responsibility of the competent authority for the notification of movements of aquatic animals to other Member States

1. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of aquatic animals as referred to in Article 219(1), unless a derogation has been granted in accordance with Article 221(1)(c) for such notification.
2. The notification referred to in paragraph 1 of this Article shall be carried out whenever possible, through IMSOC.
3. Member States shall designate regions for the management of notifications of movements by the competent authority as provided for in paragraph 1 of this Article.
4. By way of derogation from paragraph 1, the competent authority of Member State of origin may authorise the operator to notify partially or completely movements of aquatic animals through IMSOC to the competent authority of the Member State of destination.

Article 221

Delegation of powers and implementing acts for the notification of movements of aquatic animals by the competent authority

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) the requirement for notification by operators in accordance with Article 219(1) of movements between Member States of aquatic animals of categories or species other than those referred to in Article 219(1)(a), (b) and (c) where traceability of such movements is necessary to ensure compliance with the animal health requirements laid down in this Chapter;

Tuesday 15 April 2014

- (b) the information necessary to notify movements of aquatic animals by operators and the competent authority as provided for in Articles 219(1) and 220(1);
 - (c) derogations from the notification requirements provided for in Article 219(1)(c) for categories or species of aquatic animals or types of movements which pose an insignificant risk;
 - (d) the emergency procedures for notification of movements of aquatic animals in the case of power cuts or other disturbances of the IMSOC system;
 - (e) the requirements for the designation of regions by Member States provided for in Article 220(3).
2. The Commission may, by means of implementing acts, lay down rules concerning:
- (a) the format of notifications by:
 - (i) operators to the competent authority of the Member State of origin of movements of aquatic animals in accordance with Article 219(1);
 - (ii) the competent authority of the Member State of origin to the Member State of destination of movements of aquatic animals in accordance with Article 220(1);
 - (b) the deadlines for:
 - (i) the necessary information to be provided to the competent authority of the Member State of origin by operators referred to in Article 219(1);
 - (ii) the notification of movements by the competent authority of the Member State of origin referred to in Article 220(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 3

Movements within the Union of aquatic pet animals

Article 222

Non-commercial movements of aquatic pet animals and delegated and implementing acts

1. Pet keepers shall only carry out non-commercial movements of aquatic pet animals of the species listed in Annex I if appropriate disease prevention and control measures have been taken to ensure that they do not pose a significant risk for the spread of listed diseases referred to in Article 8(1)(d) and emerging diseases to animals at the place of destination and during transport.
2. Article 112 and the rules laid down in delegated acts pursuant to Article 114(f) and in implementing acts adopted pursuant to Article 117 shall apply for the identification, registration and traceability of aquatic pet animals.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the disease prevention and control measures referred to in paragraph 1 of this Article to ensure that the aquatic pet animals do not pose a significant risk for the spread of diseases referred to in Article 8(1)(d) and emerging diseases to animals during transport and at the place of destination, when relevant taking into account the health status of the place of destination.
4. The Commission may, by means of implementing acts lay down rules concerning the disease prevention and control measures provided for in paragraph 1 of this Article and the rules adopted pursuant to paragraph 2 thereof.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Tuesday 15 April 2014

Chapter 4

Production, processing and distribution within the Union of products of animal origin from aquatic animals, other than live aquatic animals

Article 223

General animal health obligations for operators and delegated acts

1. Operators shall take appropriate preventive measures to ensure that during all stages of the production, processing and distribution of products of animal origin from aquatic animals, other than live aquatic animals in the Union, those products do not cause the spread of:

(a) listed diseases referred to in Article 8(1)(d) taking into account the health status of the place of production, processing and destination;

(b) emerging diseases.

2. Operators shall ensure that products of animal origin from aquatic animals, other than live aquatic animals do not come from either establishments or food business establishments or are obtained from animals, which come from either establishments food business establishments subject to:

(a) emergency measures provided for in Articles 246 and 247 and rules adopted pursuant to Article 248 unless derogations have been provided for those rules in Part VI;

(b) movement restrictions applicable to the aquatic animals and products of animal origin from aquatic animals, as provided for in Articles 31(1) and 55(1), Article 56, Article 61(1)(a), Article 62(1), Articles 65(1)(c), 70(1)(b) and 74(1)(a), Articles 78(1) and (2), and 80(1) and (2) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3) and 74(3) and Article 79 and Article 80(3) and 81(2) unless derogation have been provided for in those rules.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning detailed requirements supplementing paragraph 2 of this Article for movements of products of animal origin from aquatic animals other than live aquatic animals, taking into account:

(a) the diseases and species of aquatic animals concerned by the disease, for which emergency measures or movement restrictions referred to in paragraph 2 apply;

(b) the types of products of animal origin from aquatic animals;

(c) the risk mitigating measures applied to the products of animal origin from aquatic animals at the places of origin and destination;

(d) the intended use of the products of animal origin from aquatic animals;

(e) the place of destination of the products of animal origin from aquatic animals.

Article 224

Animal health certificates and delegated acts

1. Operators shall only move the following products of animal origin from aquatic animals other than live aquatic animals where they are accompanied by an animal health certificate issued by the competent authority at the place of origin in accordance with paragraph 3:

(a) products of animal origin from aquatic animals that are allowed to leave a restricted zone subject to emergency measures provided for in rules adopted pursuant to Article 248 and such products of animal origin originate from aquatic animals of species subject to those emergency measures;

Tuesday 15 April 2014

- (b) products of animal origin from aquatic animals that are allowed to leave a restricted zone subject to disease control measures in accordance with the Articles 31(1), Article 55(1)(c), Article 56, Article 61(1)(a), Articles 62(1) and 63(1), Article 65(1)(c), 70(1)(b) and 74(1)(a), Articles 78(1) and (2), 80(1) and (2) and the rules adopted pursuant to Article 55 (2), Articles 63 and 67, Articles 71(3) and 74(3), Article 79 and Articles 80(3) and 81(2) and such products of animal origin originate from aquatic animals of species subject to those disease control measures.
2. Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the products of animal origin from their place of origin to their place of destination.
3. The competent authority shall upon request by the operator issue an animal health certificate for the movements of products of animal origin other than live aquatic animals referred to in paragraph 1.
4. Article 212 and Articles 214 to 217 and the rules adopted pursuant to Article 213 and Article 216(4) shall apply to the certification of movements of products of animal origin other than live aquatic animals, referred to in paragraph 1 of this Article.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning requirements and detailed rules on the animal health certificate to accompany products of animal origin other than live aquatic animals, referred to in paragraph 1 of this Article taking into account:
- (a) the types of products of animal origin;
 - (b) the risk mitigating measures applied to the products of animal origin which reduce the risks of the spread of diseases;
 - (c) the intended use of the products of animal origin;
 - (d) the place of destination of the products of animal origin.

Article 225

Content of animal health certificates and delegated and implementing acts

1. The animal health certificate for products of animal origin other than live aquatic animals shall contain at least the following information:
- (a) the establishment or the place of origin and the establishment or place of destination;
 - (b) a description of the products of animal origin;
 - (c) the quantity or the volume of the products of animal origin;
 - (d) the identification of the products of animal origin, when required by Article 65(1)(h) or rules adopted pursuant to Article 66;
 - (e) information needed to demonstrate that the products of animal origin of the consignment comply with the movement restriction requirements provided for in Article 223(2) and rules adopted pursuant to Article 223(3).
2. The animal health certificate for products of animal origin other than live aquatic animals may include other information required under other Union legislation.

Tuesday 15 April 2014

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amending and supplementing the information to be contained in the animal health certificate as provided for in paragraph 1 of this Article.
4. The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates provided for in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 226

Notification of movements of products of animal origin to other Member States

1. Operators shall:
 - (a) inform the competent authority in their Member State of origin in advance of the intended movement of products of animal origin, other than live aquatic animals, when the consignments are required to be accompanied with an animal health certificate in accordance with Article 224(1);
 - (b) provide all necessary information to enable the competent authority of the Member State of origin to notify the movement of products of animal origin, other than live aquatic animals, to the Member State of destination in accordance with paragraph 2.
2. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of products of animal origin, other than live aquatic animals, in accordance with Article 220(1).
3. Articles 219 and 220 and rules adopted pursuant to Article 221 shall be applicable to the notification of products of animal origin other than live aquatic animals.

Chapter 5

National measures

Article 227

National measures for limiting the impact of diseases other than listed disease

1. Where a disease other than a listed disease referred to in Article 8(1)(d) constitutes a significant risk for aquatic animals in a Member State, the Member State concerned may take national measures to prevent the introduction of or to control the spread of that disease.

Member States shall ensure that those national measures do not exceed the limits of what is appropriate and necessary to prevent the introduction of or to control the spread of the disease within the Member State.

2. Member States shall notify the Commission in advance of any proposed national measures referred to in paragraph 1 that may affect movements between Member States.
3. The Commission shall approve and if necessary amend the national measures referred to in paragraph 2 of this Article by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).
4. The approval referred to in paragraph 3 shall only be granted where the establishment of movement restrictions between Member States is necessary to prevent the introduction of or to control the spread of the disease referred to in paragraph 1, taking into account the overall impact of the disease and the measures taken on the Union.

Tuesday 15 April 2014

TITLE III

Animals of species other than those defined as terrestrial and aquatic animals, and germinal products and products of animal origin from such other animals

Article 228

Animal health requirements concerning other animals, and germinal products and products of animal origin of such other animals

Where other animals are listed species for a listed disease referred to in Art 8(1)(d), and those other animals, or their germinal products or products of animal origin represent a risk to public or animal health: the following animal health requirements shall apply:

- (a) the requirements concerning registration, approval, record keeping and registers for establishments and transporters provided for in Chapters 1 of Titles I and II;
- (b) the requirements concerning traceability provided for in Articles 102 to 105 and Articles 112 and 113 for other animals and Article 119 for germinal products;
- (c) movement requirements:
 - (i) for other animals mainly living in terrestrial environment or are normally affected by diseases of terrestrial animals, taking into account the criteria provided for in paragraph 3(d) and (e) of Article 229, provided for in Section 1 and Section 6 of Chapter 3 of Title I of Part IV, Chapters 4 and 5 of Title I of Part IV;
 - (ii) for other animals mainly living in aquatic environment or that are normally affected by diseases of aquatic animals, taking into account the criteria provided for in Article 229(3)(d) and (e), the requirements provided for in Sections 1 to 5 of Chapter 2 of Title II of Part IV and Chapter 2 of Title II;
 - (iii) for other pet animals, the requirements provided for in Articles 112 and 152;
 - (iv) for germinal products the general requirements for movements provided for in Articles 155 and 156 and the special requirements for movements to other Member States provided for in Articles 162 and 163;
 - (v) for products of animal origin, the general animal health obligations for operators for the production, processing and distribution within the Union of products of animal origin provided for in Articles 164 and 223;
- (d) the following animal health certification obligation for operators and the competent authority and self-declaration for operators:
 - (i) for other animals, pursuant to the rules provided for in Articles 140 to 148 or Articles 208 to 218;
 - (ii) for germinal products, pursuant to the rules provided for in Articles 159 and 160;
 - (iii) for products of animal origin, pursuant to the rules provided for in Articles 165 and 166 or Articles 224 and 225;
- (e) notification of movements by operators and by the competent authority, taking into account the requirements provided for in Articles 149, 150, 151, 161, 167 and in Articles 219 to 221 and 226.

Tuesday 15 April 2014

Article 229

Delegation of powers and implementing acts concerning animal health requirements for other animals, and germinal products and products of animal origin of other animals

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning supplementing and amending the requirements for other animals, and their germinal products or products of animal origin, as provided for in Article 228, which are necessary to mitigate the risk of the diseases referred to therein, concerning:

- (a) the requirements on registration, approval, record keeping and registers for establishments keeping or transporters transporting other animals, and their germinal products or products of animal origin, as provided for in Article 228(a);
- (b) traceability requirements for other animals and their germinal products, as provided for in Article 228(b);
- (c) movement requirements for other animals and their germinal products and products of animal origin, as provided for in Article 228(c);
- (d) requirements on animal health certification obligations by operators and the competent authority and self-declaration obligations by operators for other animals and their germinal products and products of animal origin, as provided for in Article 228(d);
- (e) requirements on notification of movement by operators and the competent authority for other animals and their germinal products and products of animal origin, as provided for in Article 228(e).

2. The Commission may adopt implementing acts concerning detailed rules for the implementation of the disease control and prevention measures provided for in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

3. The Commission shall take one or more of the following criteria into account when adopting the delegated acts and implementing acts provided for in paragraphs 1 and 2:

- (a) the species or categories of other animals are listed in accordance with Article 7(2) as listed species for one or more listed diseases, for which certain disease prevention and control measures provided for in this Regulation apply;
- (b) the profile of the listed disease, which concerns species and categories of other animals referred to in point (a);
- (c) the feasibility, availability and effectiveness of disease prevention and control measures for the listed species concerned by such measures;
- (d) the prevailing terrestrial or aquatic living environment of those other animals;
- (e) the type of diseases that are affecting such other animals, which can be either diseases normally affecting terrestrial or normally affecting aquatic animals, regardless of the prevailing living environment referred to in point (b).

Tuesday 15 April 2014

PART V
ENTRY INTO THE UNION AND EXPORT

Chapter 1

Entry into the Union of animals, germinal products and products of animal origin from third countries and territories

Section 1

Requirements for the entry into the Union

Article 230

Requirements for entry into the Union of animals, germinal products and products of animal origin

1. Member States shall only permit the entry into the Union of consignments of animals, germinal products and products of animal origin from third countries or territories if they comply with the following requirements:
 - (a) they come from a third country or territory, listed in accordance with Article 231 for the particular species and category of animals, or germinal products or products of animal origin, or zone or compartment thereof, unless they are covered by a derogation or additional rules adopted pursuant to Article 241(1);
 - (b) they come from establishments which are approved and listed where such approval and listing is required by Article 234 and rules adopted pursuant to Article 235;
 - (c) they comply with the animal health requirements for entry into the Union laid down in delegated acts adopted pursuant to Article 236(1), where such requirements are laid down for the animal, germinal product or product of animal origin of the consignment;
 - (d) they are accompanied by an animal health certificate, declarations and other documents where required by Article 239(1) or rules adopted pursuant to Article 239(4).
2. Operators shall present consignments of animals, germinal products and products of animal origin from third countries or territories for the purposes of official control provided for in Article 45 of Regulation (EU) No xxxx/xxxx (*) [official controls Regulation], unless derogation is provided for pursuant to that Regulation at the point of entry into the Union.

Section 2

Listing of third countries and territories

Article 231

Lists of third countries and territories from which the entry into the Union of animals, germinal products and products of animal origin is permitted and implementing and delegated acts

1. The Commission shall, by means of implementing acts, draw up lists of third countries and territories from which the entry into the Union of specific species and categories of animals, germinal products and products of animal origin shall be permitted, taking into account the following criteria:
 - (a) the animal health legislation of the third country or territory and the rules on the entry into that country or territory of animals, germinal products and products of animal origin from other third countries and territories;

(*) Reference number of 2013/0140(COD).

Tuesday 15 April 2014

- (b) the assurances provided by the competent authority of the third country or territory concerning the efficient implementation and control of the animal health legislation referred to in point (a);
- (c) the organisation, structure, resources and legal powers of the competent authority in the third country or territory;
- (d) the animal health certification procedures in the third country or territory;
- (e) the animal health status of the third country or territory, or zones and compartments thereof, with regard to:
 - (i) listed diseases and emerging diseases;
 - (ii) any aspects of animal and public health or the environmental situation in the third country or territory, or zone or compartment thereof, which may pose a risk to the animal or public health or the environmental status of the Union;
- (f) the guarantees which the competent authority of the third country or territory can provide regarding compliance or equivalence with the relevant animal health requirements applicable in the Union;
- (g) the regularity and speed with which the third country or territory supplies the information concerning infectious or contagious animal diseases in its territory to the World Organisation for Animal Health (OIE), in particular information concerning the diseases listed in the Aquatic or Terrestrial Animal Health Codes of the OIE;
- (h) the results of Commission controls carried out in the third country or territory;
- (i) any experience gathered from previous entries of animals, germinal products and products of animal origin from the third country or territory and the results of official controls carried out at the point of entry into the Union on such animals, germinal products and products of animal origin.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

2. Pending the adoption of the lists of third countries and territories provided for in paragraph 1, and provided that such lists have not been drawn up pursuant to the Union legislation referred to in Article 258(2), Member States shall determine from which third countries and territories specific species or categories of animals, germinal products or products of animal origin may enter the Union.

For the purposes of the first subparagraph, Member States shall take into account the criteria for inclusion in the lists of third countries and territories provided for in paragraph 1(a) to (i) of this Article.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from paragraph 2 of this Article, limiting the possibility for Member States to decide from which third countries and territories a specific species or category of animal, germinal product or product of animal origin may enter the Union, where necessary due to the risk posed by that specific species or category of animal, germinal product or product of animal origin.

Article 232

Information to be included in the lists of third countries and territories

The Commission shall specify the following information for each third country or territory in the lists provided for in Article 231(1):

- (a) the categories or species of animals, germinal products or products of animal origin that may enter the Union from that third country or territory;
- (b) whether the animals, germinal products or products of animal origin specified in accordance with point (a) may enter the Union from the whole territory of that third country or territory or only from one or more zones or compartments thereof.

Tuesday 15 April 2014

Article 233

Suspension and withdrawal from the list of third countries and territories and implementing acts

1. The Commission shall, by means of implementing acts, suspend or withdraw from the list provided for in Article 231 (1) a third country or territory, or zone or compartment thereof, for any of the following reasons:

- (a) the third country or territory, or one or more zones or compartments thereof, no longer complies with the criteria laid down in Article 231(1), where relevant for the entry into the Union of a particular species or category of animal, germinal product or product of animal origin;
- (b) the animal health situation in the third country or territory, or zone or compartment thereof is such that a suspension or withdrawal from that list is necessary to protect the animal health status of the Union;
- (c) in spite of a request of the Commission to the third country or territory for up-to-date information on the animal health situation and other matters referred to in Article 231(1), that third country or territory has not provided such information;
- (d) the third country or territory has refused to agree to Commission control being carried out on behalf of the Union in its territory.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

On duly justified imperative grounds of urgency relating to a serious risk for the introduction into the Union of a listed disease referred to in Article 8(1)(d), the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).

2. The Commission may, by means of implementing acts, reinsert a third country or territory, or zone or compartment thereof, that has been suspended or withdrawn from the list provided for in Article 231(1) for one of the following reasons:

- (a) for the reasons referred to in paragraph 1(a) or (c) of this Article, provided that the third country or territory demonstrates that it complies with the criteria for being listed provided for in Article 231(1);
- (b) for the reasons referred to in paragraph 1(b) of this Article, provided that the third country or territory provides appropriate guarantees that the animal health **or public health** situation that gave rise to that suspension or withdrawal from that list has been resolved or no longer represents a threat to the animal or public health of the Union; **[Am. 317]**
- (c) for the reasons referred to in paragraph 1(d) of this Article, provided that:
 - (i) the third country or territory agreed to a Commission control being carried out on behalf of the Union in its territory; and
 - (ii) the results of that Commission control shows that the third country or territory, and zones or compartments thereof comply with the criteria for being listed provided for in Article 231(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules amending and supplementing the criteria for suspension and withdrawal of a third country or territory, or zones or compartments thereof, from the list provided for in Article 231(1), as provided for in paragraph 1 of this Article.

Tuesday 15 April 2014

Section 3

Approval and listing of establishments in third countries and territories

Article 234

Approval and listing of establishments

1. Member States shall only permit the entry into the Union of terrestrial animals and germinal products thereof originating from a type of establishment for which approval is required in the Union in accordance with in Article 89(2) and the rules adopted pursuant to Article 89(3) and Article 90, if that establishment in the third country or territory:

(a) complies with animal health requirements in that third country or territory which are equivalent to the rules for that type of establishments applicable in the Union;

(b) is approved and listed by the competent authority of the third country or territory of dispatch.

2. The Commission shall collect the lists of approved establishments referred to in paragraph 1(b) received from the competent authorities of the third countries or territories.

3. The Commission shall provide to the Member States any new or updated lists of approved establishments received from the third countries or territories and shall make them publicly available.

Article 235

Delegation of powers for approval and listing of establishments

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning rules derogating from the requirements of Article 234(1)(b) where alternative risk mitigating measures in place in the third country or territory provide equivalent guarantees for the animal health within the Union.

Section 4

Entry into the Union of species and categories of animals, germinal products and products of animal origin

Article 236

Delegation of powers for animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the animal health requirements for:

(a) the entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries or territories;

(b) the movement within the Union and handling of those animals, germinal products and products of animal origin after their entry into the Union.

2. The animal health requirements provided for in paragraph 1(a) shall:

(a) be as stringent as the animal health requirements laid down in this Regulation and the rules adopted pursuant thereto applicable to the movement of the species and categories of animals, germinal products or products of animal origin in question within the Union; or

Tuesday 15 April 2014

(b) be equivalent to the animal health requirements applicable to the species and categories of animals, germinal products or products of animal origin provided for in Part IV of this Regulation.

3. Pending the adoption of delegated acts laying down animal health requirements as regards a particular species or category of animal, germinal product or product of animal origin, provided for in paragraph 1 of this Article and provided that such requirements have not already been laid down pursuant to the Union legislation referred to in Article 258(2), Member States may apply national rules, provided that those rules:

(a) comply with the requirements laid down in paragraph 2 of this Article and take the matters referred to in Articles 237 and 238 into account;

(b) are not less stringent than those which are laid down in Titles I and II of Part IV.

Article 237

Matters to be taken into account in delegated acts provided for in Article 236 with regard to entry into the Union of animals

The Commission shall take the following matters into account when laying down animal health requirements in delegated acts provided for in Article 236(1), for the entry into the Union of particular species and categories of animals:

(a) the listed diseases referred to in Article 8(1)(d) and emerging diseases;

(b) the health status of the Union concerning the listed diseases referred to in Article 8(1)(d) and emerging diseases;

(c) the listed species with regard to those listed diseases referred to in Article 8(1)(d) and emerging diseases;

(d) the age and sex of the animals;

(e) the origin of the animals;

(f) the type of establishment and the type of production at the places of origin and of destination;

(g) the intended place of destination;

(h) the intended use of the animals;

(i) any risk mitigating measures in place in the third countries or territories of origin or transit, or after the arrival into the territory of the Union;

(j) animal health requirements applicable to movements of those animals within the Union;

(k) other epidemiological factors;

(l) international animal health trade standards, relevant to the species and categories of those animals.

Article 238

Matters to be taken into account in delegated acts provided for in Article 236 with regard to the entry into the Union of germinal products and products of animal origin

The Commission shall take the following matters into account when laying down the animal health requirements, in delegated acts provided for in Article 236(1), for the entry into the Union of germinal products and products of animal origin;

(a) the listed diseases referred to in Article 8(1)(d) and emerging diseases;

(b) the health status of the animals from which the germinal products or products of animal origin originate and of the Union concerning the listed diseases referred to in Article 8(1)(d) and emerging diseases;

Tuesday 15 April 2014

- (c) the type and nature of particular germinal products or products of animal origin, treatments, processing methods and other risk mitigating measures that have been applied at the place of origin, dispatch of consignment or destination;
- (d) the type of establishment and the type of production at the places of origin and of destination;
- (e) the intended place of destination;
- (f) the intended use of the germinal products or products of animal origin;
- (g) animal health requirements applicable to movements of the germinal products and products of animal origin within the Union;
- (h) other epidemiological factors;
- (i) international animal health trade standards, relevant for the particular germinal products and products of animal origin.

Section 5

animal health certificates, declarations and other documents

Article 239

Animal health certificates, declarations and other documents for entry into the Union

1. Member States shall only permit the entry into the Union of consignments of animals, germinal products and products of animal origin provided they are accompanied by:
 - (a) an animal health certificate issued by the competent authority of the third country or territory of origin;
 - (b) declarations or other documents, where required by the rules adopted pursuant to paragraph 4(a).
2. Member States shall not permit the entry into the Union of consignments of animals, germinal products and products of animal origin unless the animal health certificate referred to in paragraph 1(a) has been verified and signed by an official veterinarian in a third country or territory in compliance with the certification requirements equivalent to those laid down in Articles 146(3) or 216(3) and rules adopted pursuant to Articles 146(4) or 216(4).
3. Member States shall permit electronic animal health certificates that are produced, handled and transmitted by means of IMSOC, to replace the accompanying animal health certificates referred to in paragraph 1, where such electronic animal health certificates:
 - (a) contain all the information that the animal health certificate referred to in paragraph 1(a) of this Article is required to contain in accordance with Article 240(1) and rules adopted pursuant to Article 240(3);
 - (b) ensure the traceability of the consignments of animals, germinal products and products of animal origin and links those consignments to the electronic animal health certificate.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) derogations from the animal health requirements provided for in paragraph 1(a), for consignments of animals, germinal products and products of animal origin and specific rules for the animal health certification of those consignments, that pose an insignificant risk to the animal health or public health within the Union, due to one or more of the following factors:
 - (i) the category or species of animals, germinal products or products of animal origin;

Tuesday 15 April 2014

- (ii) the methods of keeping and types of production of the animals, germinal products and products of animal origin;
 - (iii) their intended use;
 - (iv) alternative risk mitigating measures which are in place in the third countries or territories of origin or transit, or after the arrival into the territory of the Union, providing equivalent protection of the animal health and public health of the Union provided for in this Regulation;
 - (v) the provision by the third country or territory of guarantees that compliance with the requirements for entry into the Union is demonstrated by means other than an animal health certificate;
- (b) the requirements for consignments of animals, germinal products and products of animal origin entering into the Union to be accompanied by declarations or other documents needed to demonstrate that the animals, germinal products and products of animal origin entering into the Union meet the animal health requirements for entry into the Union laid down in rules adopted pursuant to Article 236(1).

Article 240

Content of animal health certificates

1. The animal health certificate referred to in Article 239(1)(a) shall contain at least the following information:
 - (a) the name and address of:
 - (i) the establishment or place of origin;
 - (ii) the establishment or place of destination;
 - (iii) where applicable, establishments for assembly operations or rest of the kept animals;
 - (b) a description of the animals, germinal products or products of animal origin;
 - (c) the number or volume of the animals, germinal products or products of animal origin;
 - (d) where applicable, the identification and registration of the animals or germinal products;
 - (e) the information needed to demonstrate that the animals, germinal products and products of animal origin in the consignment comply with the animal health requirements for entry into the Union provided for in Article 230 and Article 236(3) and the rules adopted pursuant to Article 236(1) and Article 241.
2. The animal health certificate referred to in Article 239(1)(a) may include other information required under other Union legislation.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:
 - (a) the information to be contained in the animal health certificate referred to in Article 239(1)(a) in addition to that referred to in paragraph 1 of this Article;
 - (b) the information to be contained in declarations or other documents referred to in Article 239(1)(b).
4. The Commission may, by means of implementing acts, lay down rules concerning model forms for the animal health certificates, declarations and other documents referred to in Article 239(1). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Tuesday 15 April 2014

5. Pending the establishment of rules in delegated and implementing acts adopted pursuant to paragraph 3 and 4 of this Article, as regards a particular species or categories of animals, germinal product or product of animal origin, and provided that such rules have not been laid down pursuant to the Union legislation referred to in Article 258(2), Member States may apply national rules, provided they comply with the conditions laid down in paragraph 1 of this Article.

Section 6

Derogations and additional requirements for certain categories of animals, germinal products and products of animal origin

Article 241

Derogations and additional requirements for certain categories of animals, germinal products and products of animal origin

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning derogations from the requirements provided for in Article 230(1) and Articles 234 and 239 and additional requirements for the entry into the Union of the following:

(a) animals:

- (i) intended for circuses, events, exhibitions, display, shows and confined establishments;
- (ii) which are pet animals;
- (iii) intended to be used for scientific purposes;
- (iv) for which the Union is not the final destination;
- (v) which originate in the Union and which are moved to a third country or territory, and then are moved back to the Union from that third country or territory;
- (vi) which originate in the Union and which are transported through a third country or territory en route to another part of the Union;
- (vii) which are intended for grazing purposes on a temporary basis, in the vicinity of the Union borders;
- (viii) which pose an insignificant risk to the animal health status within the Union;

(b) products of animal origin:

- (i) intended for personal use;
- (ii) for consumption on means of transport arriving from third countries or territories;

(c) germinal products and products of animal origin:

- (i) intended to be used as trade samples;
- (ii) intended to be used as research and diagnostic samples;
- (iii) for which the Union is not the final destination;
- (iv) which originate in the Union and are moved to a third country or territory, and then are moved back to the Union from that third country or territory;

Tuesday 15 April 2014

(v) which originate in the Union and are transported through a third country or territory en route to another part of the Union;

(vi) which pose an insignificant risk to the animal health status within the Union.

Those delegated acts shall take into account the matters referred to in Article 237 and 238.

2. The Commission may, by means of implementing acts, lay down rules:

(a) concerning model forms for the animal health certificates, declarations and other documents for the categories of animals, germinal products and products of animal origin referred to in paragraph 1;

(b) indicating, for the products referred to in paragraph 1 of this Article, the codes from the Combined Nomenclature, where such codes are not provided for by the rules adopted pursuant to Article 45(2)(b) of Regulation (EU) No xxxx/xxxx (*) [official controls Regulation].

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 2

Entry into the Union of certain goods other than animals, germinal products and products of animal origin from third countries and territories

Article 242

Disease agents and delegated acts

1. Any natural or legal person bringing disease agents into the Union shall:

(a) ensure that their entry into the Union does not pose a risk to animal health or public health within the Union with regard to listed diseases referred to in Article 8(1)(d) and emerging diseases;

(b) take appropriate disease control and preventive measures to ensure that entry into the Union of those disease agents does not present a risk of bioterrorism.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 laying down requirements for the entry into the Union of disease agents concerning:

(a) the packaging of disease agents;

(b) other risk mitigating measures required to prevent the release and spread of disease agents.

Article 243

Plant material and delegated and implementing acts

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) specific animal health requirements for the entry into the Union of plant material, which acts as a path of transmission of listed or emerging diseases;

(b) requirements on:

(i) animal health certification, taking into account the rules provided for in Article 239(1)(a) and Article 239 (2) and (3); or

(*) Reference number of 2013/0140(COD).

Tuesday 15 April 2014

(ii) declarations or other documents, taking into account the rules provided for in Article 239(1)(b).

2. The Commission shall lay down the animal health requirements provided for in paragraph 1 of this Article in the event of a unfavourable disease situation in third countries or territories concerning listed diseases referred to in Article 8(1)(d) or emerging diseases, and by taking into account the following criteria:

- (a) whether a listed or emerging disease that can be transmitted by means of plant material representing a serious risk to animal or to human health in the Union;
- (b) the likelihood that animals of listed species for a particular listed disease or emerging disease will be in direct or indirect contact with the plant material referred to in paragraph 1;
- (c) the availability and effectiveness of alternative risk mitigating measures in relation to that plant material, which may eliminate or minimise the risk of transmission referred to in 2(a).

3. The Commission may, by means of implementing acts lay down rules indicating, for the plant material referred to in paragraph 1 of this Article, the codes from the Combined Nomenclature, where such indication is not provided for by the rules adopted pursuant to Article 45(2)(b) of Regulation (EU) No xxxx/xxxx (*) [official controls Regulation].

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Article 244

Means of transport, equipment, packaging materials, transport water and feed and fodder and delegated and implementing acts

1. Operators bringing animals and products into the Union shall take the appropriate and necessary disease preventive measures during transport, as provided for in Articles 122(1) and 191(1).

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning:

(a) specific animal health requirements for the entry into the Union of:

- (i) means of transport for animals, germinal products, products of animal origin, animal by-products and derived products;
- (ii) equipment, packaging material or transport water for animals, germinal products, products of animal origin, animal by-products and derived products, or feed and fodder which may transmit animal diseases;

(b) requirements on:

- (i) animal health certification, taking into account the rules provided for in Article 239(1)(a) and Article 239 (2) and (3); or
- (ii) declarations or other documents, taking into account the rules provided for in Article 239(1)(b).

3. The Commission shall lay down the animal health requirements provided for in paragraph 2 in the event of a unfavourable disease situation concerning one or more listed diseases referred to in Article 8(1)(d) or emerging diseases, which present a serious risk to animal and to human health in the Union, in:

(a) a neighbouring third country;

(*) Reference number 2013/0140(COD).

Tuesday 15 April 2014

(b) the third country of origin;

(c) a third country of transit.

4. The Commission may, by means of implementing acts, lay down rules indicating, for the goods referred to in paragraph 2(a) of this Article, the codes from the Combined Nomenclature, where such indication is not provided for by the rules adopted pursuant to Article 45(2)(b) of Regulation (EU) No xxxx/xxxx (*) [official controls Regulation].

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

Chapter 3

Export

Article 245

Export from the Union

1. Member States shall take the appropriate measures to ensure that the export and re-export from the Union to a third country or territory of animals and products takes place in accordance with the rules for the movement of animals and products between Member States provided for in Part IV, while taking into account the animal health status within the third country or territory of destination, or zone or compartment thereof, with regard to the listed diseases referred to in Article 8(1)(d) and emerging diseases.

However, if requested by the competent authority of the importing third country or territory, or if established by the laws, regulations, standards, codes of practice and other legal and administrative procedures in force in that country or territory, export and re-export from the Union may take place in accordance with those provisions.

2. Where the provisions of a bilateral agreement concluded between the Union and a third country or territory is applicable, animals and products exported from the Union to that third country or territory shall comply with those provisions.

PART VI

EMERGENCY MEASURES

Section 1

Emergency measures concerning movements of animals and products within the Union and means of transport and other material that may have come into contact with such animals and products

Article 246

Emergency measures to be taken by the competent authority of the affected Member State in the event of an outbreak of a listed disease or an emerging disease or the occurrence of a hazard in their territory

1. In the event of an outbreak of a listed disease or an emerging disease, or the occurrence of a hazard which is likely to constitute a serious risk, the competent authority of the Member State where it occurred shall, depending on the gravity of the situation and the disease or hazard in question, immediately take one or more of the following emergency measures to prevent the spread of the disease or hazard:

(a) for listed diseases:

(i) referred to in Article 8(1)(a) the disease control measures laid down in in of Chapter 1 of Title II of Part III;

(*) Reference number of 2013/0140(COD).

Tuesday 15 April 2014

- (ii) referred to in Article 8(1)(b) and (c), the disease control measures laid down in Chapter 2 of Title II of Part III;
 - (b) for emerging diseases and hazards:
 - (i) movement restrictions on animals and products originating from the establishments, or where relevant the restricted zones or compartments, where the outbreak or the hazard occurred, and on means of transport and other material that may have come into contact with those animals or products;
 - (ii) quarantine of animals and isolation of products;
 - (iii) surveillance and traceability measures;
 - (iv) any emergency disease control measures provided for in Chapter 1 of Title II of Part III that are appropriate;
 - (c) any other emergency measure which it deems appropriate to effectively and efficiently control and prevent the spread of the disease or hazard.
2. The competent authority referred to in paragraph 1 shall inform the Commission and the other Member States:
- (a) immediately of an outbreak or the occurrence of a hazard referred to in paragraph 1;
 - (b) without delay of the emergency measures taken pursuant to paragraph 1.

Article 247

Emergency measures to be taken by Member States other than the Member State where the outbreak or hazard occurred

1. The competent authority of Member States other than the Member State where the outbreak or hazard referred to in Article 246(1) occurred, shall take one or more of the emergency measures referred to in Article 246(1), where it detects on its territory animals or products from the Member State referred to in Article 246(1) or means of transport or any other material that may have come into contact with such animals and products.
2. The competent authority referred to in paragraph 1 of this Article may, where a serious risk exists pending the adoption of emergency measures by the Commission in accordance with Article 248, take the emergency measures referred to in Article 246(1) on an interim basis, depending on the gravity of the situation with regard to animals or products originating from the establishments or any other locations, or where relevant from the restricted zones of the Member State where the disease or hazard referred to in Article 246(1) occurred, or means of transport or other material that may have come into contact with such animals.
3. The competent authority referred to in paragraph 1 shall inform the Commission and other Member States:
- (a) immediately of the outbreak or occurrence of a hazard referred to in paragraph 1;
 - (b) without delay of the emergency measures taken pursuant to paragraphs 1 and 2.

Article 248

Commission emergency measures

1. In the event of an outbreak or the occurrence of a hazard, as referred to in Article 246(1) and of emergency measures taken by the competent authorities of the Member States in accordance with Articles 246(1) and 247(1) and (2), the Commission shall review the situation and the emergency measures taken, and adopt, by means of an implementing act one or more of the emergency measures provided for in Article 246(1) concerning the animals and products and means of transport and other material that may have come into contact with those animals or products, in any of the following cases:
- (a) the Commission has not been informed of any measures taken pursuant to Article 246(1) and Article 247(1) and (2);

Tuesday 15 April 2014

- (b) the Commission considers the measures taken pursuant to Article 246(1) and Article 247(1) and (2) to be inadequate;
- (c) the Commission considers it necessary to approve or replace the measures taken by the competent authorities of the Member States pursuant to Articles 246(1) and 247(1) and (2) in order to avoid unjustified disruptions in the movement of animals and products.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

2. On duly justified imperative grounds of urgency relating to serious risks of the spread of a disease or a hazard the Commission may adopt immediately applicable implementing acts in accordance with Article 255(3).

Section 2

Emergency measures concerning consignments of animals and products originating from Third countries and territories and means of transport and other material that may have come into contact with such consignments

Article 249

Emergency measures to be taken by the competent authority of the Member State

Where the competent authority of a Member State becomes aware of a consignment of animals or products originating from a third country or territory, or means of transport or materials which may have come into contact with such a consignment, that is likely to constitute a serious risk in the Union due to possible infection or contamination by listed diseases or emerging diseases or hazards, it shall immediately:

- (a) take one or more of the following emergency measures necessary to mitigate that risk depending on the gravity of the situation:
 - (i) destruction of the consignment;
 - (ii) quarantine of animals and isolation of products;
 - (iii) surveillance and traceability measures;
 - (iv) any disease control measures referred to in Chapter 1 of Title II of Part III, where appropriate;
 - (v) any other emergency measure which it deems appropriate to prevent the spread of the disease or a hazard into the Union;
- (b) immediately inform the Commission and the other Member States of the risks associated with the consignment in question and of the origin of the consignment by means of IMSOC.

Article 250

Commission emergency measures

1. Where a listed disease, an emerging disease or a hazard that is likely to constitute a serious risk occurs or spreads in a third country or territory, or if any other serious animal or public health reason so warrants, the Commission may, by means of an implementing act and acting on its own initiative or at the request of a Member State, adopt one or more of the following emergency measures and, depending on the gravity of the situation:

- (a) suspend the entry into the Union of consignments of animals and products, and means of transport or other material that may have come into contact with such consignments, which may spread that disease or hazard into the Union;

Tuesday 15 April 2014

- (b) establish special requirements for the entry into the Union of consignments of animals and products and means of transport and other material that may have come into contact with such consignments, which may spread that disease or hazard into the Union;
- (c) take any other appropriate emergency disease control measures to prevent the spread of that disease or hazard into the Union.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

2. On duly justified imperative grounds of urgency relating to serious risks, the Commission shall after consulting the Member State concerned, adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).

Article 251

Emergency measures taken by the Member States when the Commission does not act

1. Where a Member State requests the Commission to take emergency measures in accordance with Article 250 and the Commission has not done so, that Member State:

- (a) may, pending the adoption of emergency measures by the Commission in accordance with paragraph 2 of this Article, take one or more emergency measures referred to in point (a) of Article 249 on an interim basis in respect of the consignments of animals and products and means of transport and other material that may have come into contact with such consignments, originating from the third country or territory referred to in Article 250(1) depending on the gravity of the situation within its territory;
- (b) shall inform the Commission and the competent authorities of the other Member States of such emergency measures without delay, giving the reason for their adoption.

2. The Commission shall review the situation and the emergency measures taken by the Member State in accordance with paragraph 1 of this Article and shall, where necessary adopt by means of an implementing act one or more emergency measures provided for in Article 250.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 255(2).

3. On duly justified imperative grounds of urgency relating to serious risks, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 255(3).

PART VII

COMMON PROVISIONS

TITLE I

Procedural provisions

Article 252

Amendment to Annexes I and II

The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning amendments to ~~the Annexes I and II~~ in order to take account of technical progress, scientific developments and changed circumstances in public and animal health. [Am. 318]

Article 253

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article **and the requirement for coherent legislation that is easy to understand and apply. In order to ensure the full accessibility and the correct interpretation and application of the provisions of the delegated acts referred to in paragraph 2 of this article, the Commission is required to specify an organizational criterion to simplify the structure and the number of delegated acts it will adopt.** [Am. 319]

Tuesday 15 April 2014

2. The power to adopt delegated acts referred to in Articles 4(2), **5(2)**, 6(2), **7(2)**, **8(1)**, 9(2), 11(3), 13(2), 15(2), 16(3), **17(3)**, 18(3), 24, 28, 30(4), 31(2), 34(2), **35(2a)**, 37(5), 39, 41(3), 42(5), 44(1), 47, 48(3), 53(2), 54(3), 55(2), 58(2), 63, 64 (4), 67, 68(2), 70(3), 72(2), 73(3), 74(3), 76(2), 79, 80(4), 85(3), 89(3), 92(2), 96(3), 100(1), 103(2), 114, 115, 119(1), 122 (2), 128(1), 129(2), 132, 133(2), 134(2), 135(3), 136(4), 137, 141(1), 143(1), 144, 146(4), 148(3), 151(1), 152(2), 154(1), 158, 159(5), 160(3), 162(2), 163(3), 164(3), 165(5), 166(3), 174(3), 179(2), 184(1), 188(1), 191(2), 196(2), 199(3), 200 (3), 201(2), 202(2), 203(2), 204(3), 205, 211, 213(1), 214, 216(4), 218(3), 221(1), 222(3), 223(3), 224(5), 225(3), 229(1), 231(3), 233(3), 235, 236(1), 239(4), 240(3), 241(1), 242(2), 243(1), 244(2), 252, 259(2), 260(2) and 261(2) shall be conferred on the Commission for ~~an indeterminate~~ a period of ~~time~~ **5 years** from (*). ***The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.*** [Am. 320]

~~3. The power to adopt delegated acts referred to in Article 229(1) shall be conferred on the Commission for a period of five years from:~~

(*) Date of entry into force of the basic legislative act or any other date set by the legislator. [Am. 321]

3a. Delegated acts shall be based on the scientific evidence available and be adopted after consultation with stakeholders and experts and having taken due account of the scientific opinions of the European Food Safety Authority. [Am. 322]

4. The delegation of power listed in paragraph 1 of this Article and referred to in Article 229(1) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to provisions listed in paragraph 2 of this Article and pursuant to Article 229(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

(*) Date of entry into force of the basic legislative act (or any other date set by the legislator).

Tuesday 15 April 2014

Article 254

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 253(6). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 255

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

TITLE II

Penalties

Article 256

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that those rules are implemented. The penalties provided for must be effective, proportionate and dissuasive.

The Member States shall notify those provisions to the Commission by ... (*) at the latest and shall notify it without delay of any subsequent amendments affecting them.

TITLE III

Member States measures

Article 257

Member States measures

1. Member States may apply additional or more stringent measures within their territories than those laid down in this Regulation concerning only:
 - (a) responsibilities for animal health provided for in Chapter 3 of Part I;
 - (b) notification within Member States provided for in Article 16;
 - (c) surveillance provided for in Chapter 2 of Part II;
 - (d) registration, approval, record keeping and registers provided for in Chapter 1 of Titles I and Chapter 1 of Title II of Part IV;

(*) One year from the date of application of this Regulation.

Tuesday 15 April 2014

- (e) traceability requirements for kept terrestrial animals and germinal products provided for in Chapter 2 of Title I of Part IV.
2. The national measures referred to in paragraph 1 shall be in accordance with the rules laid down in this Regulation and shall ~~not~~:
- (a) **only** hinder the movement of animals and products between Member States **when this is scientifically justified on the grounds of controlling infectious disease**;
- (b) **not** be in contradiction with the rules referred to in paragraph 1. [Am. 323]

PART VIII

TRANSITIONAL AND FINAL PROVISIONS

Article 258

Repeals

1. Decision 78/642/EEC, Directive 79/110/EEC, Directive 81/6/EEC, Decision 89/455/EEC, Directive 90/423/EEC, Decision 90/678/EEC are repealed.
2. The following acts are repealed as from ... (*):
- Directive 64/432/EEC,
 - Directive 77/391/EEC,
 - Directive 78/52/EEC,
 - Directive 80/1095/EEC,
 - Directive 82/894/EEC,
 - Directive 88/407/EEC,
 - Directive 89/556/EEC,
 - Directive 90/429/EEC,
 - Directive 91/68/EEC,
 - Decision 91/666/EEC,
 - Directive 92/35/EEC,
 - Directive 92/65/EEC,
 - Directive 92/66/EEC,
 - Directive 92/118/EEC,
 - Directive 92/119/EEC,
 - Decision 95/410/EC,
 - Directive 2000/75/EC,
 - Decision 2000/258/EC,
 - ~~Regulation (EC) No 1760/2000~~; [Am. 324]
 - Directive 2001/89/EC,
 - Directive 2002/60/EC,

(*) Date of application of this Regulation.

Tuesday 15 April 2014

- Directive 2002/99/EC,
- Directive 2003/85/EC,
- ~~Regulation (EU) No [XXX/XXX [Number to be inserted... non-commercial movements of pet animals and repealing Regulation (EC) No 998/2003], [Am. 325]~~
- ~~Regulation (EC) No 21/2004, [Am. 326]~~
- Directive 2004/68/EC,
- Directive 2005/94/EC,
- Directive 2006/88/EC,
- ~~Directive 2008/71/EC, [Am. 327]~~
- Directive 2009/156/EC,
- Directive 2009/158/EC.

References to those repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex III hereto.

3. The acts adopted by the Commission pursuant to the acts of the Council and the European Parliament referred to in paragraph 2 shall remain in force in so far as they are not in contradiction with the rules laid down in this Regulation.

Article 259

~~Transitional measures related to the repeal of Regulation (EC) No 1760/2000, Regulation (EC) No 21/2004 and Directive 2008/71/EC~~

~~1. Notwithstanding Article 258(2) of this Regulation, Regulations (EC) No 1760/2000, and (EC) No 21/2004 and Directive 2008/71/EC shall continue to apply until the date to be determined in a delegated act adopted in accordance with paragraph 2 of this Article.~~

~~2. The Commission shall be empowered to adopt delegated acts in accordance with Article 252 concerning the date on which the acts referred to in paragraph 1 of this Article shall no longer apply.~~

~~That date shall be the date of application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Article 103(2) and Articles 114 and 115 of this Regulation. [Am. 328]~~

Article 260

~~Transitional measures related to the repeals of Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC and 2005/94/EC~~

~~1. Notwithstanding Article 258(2) of this Regulation, Directives 92/66/EEC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2003/85/EC and 2005/94/EC shall continue to apply until the date to be determined in a delegated act adopted in accordance with paragraph 2 of this Article.~~

~~2. The Commission shall be empowered to adopt delegated acts in accordance with Article 253 concerning the date on which the Directives referred to in paragraph 1 of this Article shall no longer apply.~~

~~That date shall be the date of the application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Articles 44(1), 47(1) 48(3), 53(1) 54(3) and 58(2), Article 63, Article 64(4), Article 67, and Articles 68(2) and 70(3) of this Regulation.~~

Tuesday 15 April 2014

~~Article 261~~~~Transitional measures related to the repeal of Regulation (EU) No [XXX/XXX on the non-commercial movement of pet animals]~~

- ~~1. Notwithstanding Article 258(2) of this Regulation, Regulation (EU) No [XXX/XXX] shall continue to apply until the date to be determined in a delegated act adopted in accordance with paragraph 2 of this Article.~~
- ~~2. The Commission shall be empowered to adopt delegated acts in accordance to Article 253 concerning the date on which Regulation XXX/XXX shall no longer apply.~~

~~That date shall be the date of the application of the corresponding rules to be adopted pursuant to the delegated acts provided for in Article 114(f), and Articles 152(2) and 222(3) of this Regulation. [Am. 329]~~**Article 261a****Report to the European Parliament and the Council**

No later than 31 December 2019, the Commission shall submit a report to the European Parliament and the Council. The Commission report shall contain a review of the impact of this Regulation, including the experience gained from its delegated powers according to Article 253 and, if appropriate, shall be accompanied by relevant proposals. [Am. 330]

Article 262

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [36 months from the date of entry into force of the Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament
The President

For the Council
The President

Annex -I

Part I

Diseases of terrestrial animals

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification, reporting & surveillance	Listed species
Classical Swine Fever	X	X	0	X	X	<i>Suidae and Tayassuidae</i>
Bluetongue	X	X	0	X	X	All ruminants VECTORS: Culicoides, etc.
Epizootic haemorrhagic disease of deer	X	X	0	X	X	All ruminants VECTORS: Culicoides, etc.
Swine Vesicular Disease	X	X	0	X	X	<i>Suidae and Tayassuidae</i>
Highly Pathogenic Avian Influenza	X	X	0	X	X	Poultry, captive birds and wild birds
Low Pathogenic Avian Influenza (H5, H7)	X	X	0	X	X	Poultry and captive birds
African Swine Fever	X	X	0	X	X	<i>Suidae and Tayassuidae</i> VECTORS /RESERVOIRS SOFT TICKS — Genus <i>Ornithodoros</i>)
Foot and Mouth Disease	X	X	0	X	X	Any domestic or wild animal of order Artiodactyla, suborders Ruminantia, Suina and Tylopoda; (Also, some measures: Rodentia and Proboscidae)

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification, reporting & surveillance	Listed species
Rinderpest	X	X	0	X	X	Ungulates
Peste des Petits Ruminants (PPR)	X	X	0	X	X	Bovidae and Suidae
Rift Valley Fever	X	X	0	X	X	All species of ungulates other than those of family Suidae VECTORS: mosquitos (Aedes, Culex) midges (Culicoides)
Lumpy Skin Disease	X	X	0	X	X	Bovidae and Giraffidae
Sheep and Goat Pox (Capripox)	X	X	0	X	X	Bovidae
Contagious bovine pleuropneumonia	X	0	0	X	X	Species of the genus Bos
African Horse Sickness	X	X	0	X	X	Equidae VECTORS: Midges: Culicoides
Equine encephalomyelitis (Incl. EEE, WEE and equine encephalomyelitis Japanese encephalomyelitis)	X	0	0	X	X	Equidae VECTORS: Mosquitoes, birds, other reservoirs
Venezuelan equine encephalomyelitis)	X	0	0	X	X	Equidae VECTORS: Mosquitoes, birds, other reservoirs
West Nile Virus	0	0	0	X	X	Equidae VECTORS: Mosquitoes

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification, reporting & surveillance	Listed species
Newcastle Disease	X	X	0	X	X	Poultry, other captive birds, including pigeons
Vesicular stomatitis	X	X	0	X	X	Ungulates
Teschen Disease	X	0	0	X	X	Suidae
Glanders	0	0	0	X	X	Equidae
Dourine	0	0	0	X	X	Equidae
Equine Infectious Anaemia	0	0	0	X	X	Equidae
Rabies	0	0	0	X	X	Bovidae, Suidae, Ovidae, Capridae, Equidae, Carnivora and Chiroptera
Anthrax	0	0	0	X	X	Bovidae, Camelidae, Cervidae, Elephantidae, Equidae and Hippopotamidae
Bovine tuberculosis (COMMENT: Mycobacterium tuberculosis complex: bovis, caprae)	0	X	X (for apes and felids)	X	X	Mammalia, in particular Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, and Tragulidae
Brucella melitensis*	0	X	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae
Brucella abortus*	0	X	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae
Brucella ovis* (contagious epididymitis)	0	0	0	X	X	Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae and Tragulidae

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification, reporting & surveillance	Listed species
<i>Brucella suis</i> *	0	0	X	X	X	Cervidae, Leporidae, Oribos moschatus, Suidae and Tayassuidae
Avian chlamydiosis	0	0	0	X	X	Psittaciformes
Enzootic bovine leukosis	0	X	0	X	X	Bovine animals (including Bison bison and Bubalus bubalis)
Small Hive Beetle (<i>Aethina tumida</i>)	0	0	0	X	X	Apis and Bombus
Tropilaelaps mite (<i>Tropilaelaps</i> spp.)	0	0	0	X	X	Apis
American Foulbrood	0	0	0	X	X	Apis
Monkey Pox	0	0	0	0	X	Rodentia and non-human primates
Ebola	0	0	0	0	X	Non-human primates (Apes)
Aujeszky's Disease	0	0	X	X	X	Pigs
Caseous Lymphadenitis (<i>Corynebacterium pseudotuberculosis</i>)	0	0	X	X	0	Ovine and caprine
Pulmonary Adenomatosis	0	0	X	X	0	Ovine and caprine
Paratuberculosis	0	0	X	X	0	Ovine and caprine
Maedi-visna	0	0	X	X	0	Ovine and caprine
Caprine Viral Arthritis/Encephalitis	0	0	X	X	0	Ovine and caprine

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification, reporting & surveillance	Listed species
Contagious Agalactia	0	0	X	X	0	Ovine and caprine
Border Disease	0	0	0	X	0	Ovine and caprine
Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis	0	0	X	X	0	Bovine animals
Bovine [genital] campylobacteriosis — <i>C. foetus</i> ssp. <i>Venerialis</i>	0	0	0	X	0	Bovine animals
Bovine Viral Diarrhoea/Mucosal Disease	0	0	0	X	0	Bovine animals
Trichomonas foetus	0	0	0	X	0	Bovine animals
Transmissible gastroenteritis	0	0	X	X	0	Pigs
European Foulbrood	0	0	X	X	0	Bees
Echinococcus multilocularis	0	0	X	X	X	Dogs
Salmonella of animal health relevance <i>Salmonella Pullorum</i> , <i>Salmonella Gallinarum</i> and <i>Salmonella arizonae</i>	0	0	X	X	0	Poultry
Zoonotic Salmonellosis (other than above)	X	0	X	X	X	Poultry (Also, some measures: pigs)

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification, reporting & surveillance	Listed species
<i>Mycoplasma gallisepticum</i> and <i>Mycoplasma meleagridis</i>	0	0	X	X	X	Poultry: <i>M. gallisepticum</i> — fowls and turkeys <i>M. meleagridis</i> — turkeys
Tuberculosis (other than Bovine tuberculosis)**	0	0	X	X	X	Apes, felids, ruminants
Tularaemia	0	0	X	X	0	Lagomorphs
Myxomatosis	0	0	X	X	0	Lagomorphs
Rabbit haemorrhagic disease	0	0	X	X	0	Lagomorphs
Viral Enteritis (Mink)	0	0	X	X	0	Mink
Aleutian Disease (Mink)	0	0	X	X	0	Mink
Varioosis	0	0	X	X	0	Bees
Acariasis	0	0	X	X	0	Bees
Crimean Congo haemorrhagic fever	0	0	0	X	0	Ratites
TSEs (Regulation (EC) No 999/2001 and Directive 92/65/EEC)						
Bovine Spongiform Encephalopathy	X	X	0	X	X	Bovine animals, ovine and caprine animals
Scrapie	X	X	0	X	X	Ovine or caprine animals

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification, reporting & surveillance	Listed species
Chronic Wasting Disease	X	X	0	X	X	Cervidae
TSEs not BV/OV/CP	X	X	0	0	X	All animals
Zoonoses (Directive 2003/99/EC and Regulation (EC) No 2075/2005 for Trichinellosis)						
Trichinellosis	0	0	X	X	X	Pigs, horses, wild boar and other wild animals (susceptible to Tricinellosis infestation)
Listeriosis	0	0	0	0	X	Not specified
Campylobacteriosis	0	0	0	0	X	Not specified
Verotoxigenic E.coli	0	0	0	0	X	Not specified
Leptospirosis	0	0	0	0	X***	Not specified
Yersiniosis	0	0	0	0	X***	Not specified
Vibriosis	0	0	0	0	X***	Not specified
Toxoplasmosis	0	0	0	0	X***	Not specified
Cryptosporidiosis	0	0	0	0	X***	Not specified
Cysticercosis	0	0	0	0	X***	Not specified
Anisakiasis	0	0	0	0	X***	Not specified

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification, reporting & surveillance	Listed species
Borreliosis	0	0	0	0	X***	Not specified
Botulism	0	0	0	0	X***	Not specified
Influenza Virus	0	0	0	0	X***	Not specified
Echinococcosis [<i>hydatidosis</i>] - ' <i>echinococcosis and agents thereof</i> '	0	0	0	0	X	Not specified
Antimicrobial Resistance (AMR) hazards (<i>resistant microorganism and resistance determinants</i>)	0	0	0	0	X	Poultry, pigs and bovine animals
Calicivirus	0	0	0	0	X***	Not specified
Hepatitis A virus	0	0	0	0	X***	Not specified
Viruses transmitted by arthropods	0	0	0	0	X***	Not specified
Other zoonoses and zoonotic agents	0	0	0	0	X***	Not specified

Part 2

Aquatic animal diseases

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification & surveillance	Listed species
Epizootic haematopoietic necrosis	X	X	0	X	X	Rainbow trout (<i>Oncorhynchus mykiss</i>) and redfin perch (<i>Perca fluviatilis</i>)
Infection with <i>Bonamia exitiosa</i>	X	X	0	X	X	Australian mud oyster (<i>Ostrea angasi</i>) and Chilean flat oyster (<i>O. chilensis</i>)
Infection with <i>Perkinsus marinus</i>	X	X	0	X	X	Pacific oyster (<i>Crassostrea gigas</i>) and Eastern oyster (<i>C. virginica</i>)
Infection with <i>Microcytos mackini</i>	X	X	0	X	X	Pacific oyster (<i>Crassostrea gigas</i>), Eastern oyster (<i>C. virginica</i>), Olympia flat oyster (<i>Ostrea conchaphila</i>) and European flat oyster (<i>O. edulis</i>) 2002/99 (95/70)
Taura syndrome	X	X	0	X	X	Gulf white shrimp (<i>Penaeus setiferus</i>), Pacific blue shrimp (<i>P. stylirostris</i>), and Pacific white shrimp (<i>P. vannamei</i>)

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification & surveillance	Listed species
Yellowhead disease	X	X	0	X	X	Gulf brown shrimp (<i>Penaeus aztecus</i>), Gulf pink shrimp (<i>P. duorarum</i>), Kuruma prawn (<i>P. japonicus</i>), black tiger shrimp (<i>P. monodon</i>), Gulf white shrimp (<i>P. setiferus</i>), Pacific blue shrimp (<i>P. stylirostris</i>), and Pacific white shrimp (<i>P. vannamei</i>)
Viral haemorrhagic septicaemia (VHS)	0	0	X	X	X	Herring (<i>Clupea</i> spp.), whitefish (<i>Coregonus</i> sp.), pike (<i>Esox lucius</i>), haddock (<i>Gadus aeglefinus</i>), Pacific cod (<i>G. macrocephalus</i>), Atlantic cod (<i>G. morhua</i>), Pacific salmon (<i>Oncorhynchus</i> spp.) rainbow trout (<i>O. mykiss</i>), rockling (<i>Onos mustelus</i>), brown trout (<i>Salmo trutta</i>), turbot (<i>Scophthalmus maximus</i>), sprat (<i>Sprattus sprattus</i>), grayling (<i>Thymallus thymallus</i>) and olive flounder (<i>Paralichthys olivaceus</i>)
Infectious haematopoietic necrosis (IHN)	0	0	X	X	X	Chum salmon (<i>Oncorhynchus keta</i>), coho salmon (<i>O. kisutch</i>), Masou salmon (<i>O. masou</i>), rainbow or steelhead trout (<i>O. mykiss</i>), sockeye salmon (<i>O. nerka</i>), pink salmon (<i>O. rhodurus</i>) chinook salmon (<i>O. tshawytscha</i>), and Atlantic salmon (<i>Salmo salar</i>)
Koi herpes virus (KHV) disease	0	0	X	X	X	Common carp and koi carp (<i>Cyprinus carpio</i>)
Infectious salmon anaemia (ISA)	0	0	X	X	X	Rainbow trout (<i>Oncorhynchus mykiss</i>), Atlantic salmon (<i>Salmo salar</i>), and brown and sea trout (<i>S. trutta</i>)

Subject to rules as set out in	Article 8(1)(a) Immediate disease control & eradication	Article 8(1)(b) Compulsory eradication	Article 8(1)(c) Optional 'voluntary' eradication	Article 8(1)(d) Trade	Article 8(1)(e) Notification & surveillance	Listed species
Infection with <i>Marteilia refringens</i>	0	0	X	X	X	Australian mud oyster (<i>Ostrea angasi</i>), Chilean flat oyster (<i>O. chilensis</i>), European flat oyster (<i>O. edulis</i>), Argentinian oyster (<i>O. puelchana</i>), blue mussel (<i>Mytilus edulis</i>) and Mediterranean mussel (<i>M. galloprovincialis</i>)
Infection with <i>Bonamia ostreae</i>	0	0	X	X	X	Australian mud oyster (<i>Ostrea angasi</i>), Chilean flat oyster (<i>O. chilensis</i>), Olympia flat oyster (<i>O. chaphila</i>), Asiatic oyster (<i>O. denselamellosa</i>), European flat oyster (<i>O. edulis</i>), and Argentinian oyster (<i>O. puelchana</i>)
White spot disease	0	0	X	X	X	All decapod crustaceans (order Decapoda)

Notes:

- * OIE Code = in future *B. abortus*, *B. melitensis* or *B. suis* in one chapter, with recommendations for (according to current draft): bovids [cattle (*Bos taurus*, *B. indicus*, *B. frontalis*, *B. javanicus* and *B. grunniens*), bison (*Bison bison* and *B. bonasus*) and water buffalo (*Bubalus bubalis*)], sheep (*Ovis aries*) and goats (*Capra aegagrus*), pigs (*Sus scrofa*), camelids [dromedary camel (*Camelus dromedarius*), Bactrian camel (*Camelus bactrianus*), llama (*Lama glama*), alpaca (*Lama pacos*), guanaco (*Lama guanicoe*) and vicuna (*Vicugna vicugna*)], cervids [roe deer (*Capreolus capreolus*), red deer (*Cervus elaphus elaphus*), wapiti/elk (*C. elaphus canadensis*), sika (*C. nippon*), samba (*C. unicolor unicolor*), rusa (*C. timorensis*), fallow deer (*Dama dama*), white-tailed, black-tailed, mule deer (*Odocoileus spp.*) and reindeer (*Rangifer tarandus*), European hare (*Lepus europaeus*).
- ** *M. tuberculosis* not OIE listed; however included in Chapter 6.11. on Zoonoses transmissible form non-human primates as *M. tuberculosis* complex, for specific testing / treatment recommendations during quarantine
- *** Optional in Directive 2003/99/EC, depending on the epidemiological situation in MS

Commission Regulation (EU) No 142/2011⁽¹⁾ defines 'serious transmissible diseases' as follows: 'The diseases listed by the OIE in Article 1.2.3 of the Terrestrial Animal Health Code, 2010 edition, and in Chapter 1.3 of the Aquatic Animal Health Code, 2010 edition, shall be regarded as serious transmissible diseases for the purposes of general animal health restrictions, as provided for in Article 6(1)(b)(ii) of Regulation (EC) No 1069/2009'.

[Am. 331]

⁽¹⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

Tuesday 15 April 2014

ANNEX I

Species of pet animals

PART A

Dogs (*Canis lupus familiaris*)

Cats (*Felis silvestris catus*)

Ferrets (*Mustela putorius furo*)

PART B

Invertebrates (except bees, and bumble bees and molluscs and crustaceans)

Ornamental aquatic animals

Amphibia

Reptiles

Birds: all species of birds except poultry

Mammals: rodents and rabbits other than those intended for food production.

Tuesday 15 April 2014

ANNEX II

Species of Ungulates

Taxon		
Order	Family	Genera/Species
Perissodactyla	Equidae	Equus spp.
	Tapiridae	Tapirus spp.
	Rhinocerotidae	Ceratotherium spp., Dicerorhinus spp., Diceros spp., Rhinoceros spp.
Artiodactyla	Antilocapridae	Antilocapra spp.
	Bovidae	Addax spp., Aepyceros spp., Alcelaphus spp., Ammodorcas spp., Ammotragus spp., Antidorcas spp., Antilope spp., Bison spp., Bos spp.(including Bibos, Novibos, Poephagus), Boscaphus spp., Bubalus spp. (including Anoa), Budorcas spp., Capra spp., Cephalophus spp., Connochaetes spp., Damaliscus spp.(including Beatragus), Dorcatragus spp., Gazella spp., Hemitragus spp., Hippotragus spp., Kobus spp., Litocranius spp., Madogua spp., Naemorhedus spp. (including Nemorhaedus and Capricornis), Neotragus spp., Oreamuos spp., Oreotragus spp., Oryx spp., Ourebia spp., Ovibos spp., Ovis spp., Patholops spp., Pelea spp., Procapha spp., Pseudois spp., Pseudoryx spp., Raphicerus spp., Redunca spp., Rupicapra spp., Saiga spp., Sigmoceros-Alecelaphus spp., Sylvicapra spp., Syncerus spp., Taurotragus spp., Tetracerus spp., Tragelaphus spp. (including Boocerus).
	Camelidae	Camelus spp., Lama spp., Vicugna spp.
	Cervidae	Alces spp., Axis-Hyelaphus spp., Blastocerus spp., Capreolus spp., Cervus-Rucervus spp., Dama spp., Elaphurus spp., Hippocamelus spp., Hydropotes spp., Mazama spp., Mergamuntiacus spp., Muntiacus spp., Odocoileus spp., Ozotoceros spp., Pudu spp., Rangifer spp.
	Giraffidae	Giraffa spp., Okapia spp.
	Hippopotamidae	Hexaprotodon-Choeropsis spp., Hippopotamus spp.
	Moschidae	Moschus spp.
	Suidae	Babyrousa spp., Hylochoerus spp., Phacochoerus spp., Potamochoerus spp., Sus spp.,
	Tayassuidae	Catagonus spp., Pecari-Tayassu spp.
	Tragulidae	Hyemoschus spp., Tragulus-Moschiola spp.
Proboscidae	Elephantidae	Elephas spp., Loxodonta spp.

Tuesday 15 April 2014

ANNEX III

Correlation table referred to in Article 257(2)

1. Directive 64/432/EEC

Directive 64/432/EEC	This Regulation
Article 1	—
Article 2	Articles 4 (partially), 150(3) and 220(3)
Article 3(1) Article 3(2)	Articles 121 and 123 Articles 121 (2), 123(1) and 146(3) and (4)
Article 4(1) Article 4(2) and (3)	Article 121(1) Article 122(1) and (2)
Article 5(1) Article 5(2) Article 5(2)(a) Article 5(2)(b) Article 5(3) Article 5(4) Article 5(5)	Article 140(1), 142 and 143, Article 146(3) and (4), Article 144(a) Article 141(1)(b), Article 146(3) and (4), Article 150, Articles 130, 132 and 150
Article 6	Articles 127, 128, 129
Article 6a	—
Article 7	Articles 129, 130, 131(a) and 132
Article 8	Articles 16, 17, 18 and Articles 16(3), 17(3), 18(3) and 19
Article 9	Articles 30(1), 31, 32 and Article 30 (3) and (4), 31(2)
Article 10	Articles 30(2), 31, 32, 36, 41, 42 and Articles 39, 40, 41(3) and 42(5) and (6)

Tuesday 15 April 2014

Directive 64/432/EEC	This Regulation
Article 11(1) Article 11(2) Article 11(3) Article 11(4) Article 11(5)-(6)	Article 89(1)(a), 92, 93 and Article 92(2), Articles 97, 100 and 101 Article 93, 94 Article 95 Article 92(1)(d) and (2)(d)
Article 12(1) Article 12(2) Article 12(3) Article 12(4) Article 12(5) and (6)	Article 122, Article 99 and Article 100 Article 122(1)(a) and (b) Article 140(3) —
Article 13(1) and (2) Article 13(3) Article 13(4) Article 13(5) and (6)	Articles 89, 92, 93, 94, 97, 100 and 101 Article 95 — Article 96
Article 14(1) and (2) Article 14(3)A and B Article 14(3) C Article 14(4) to (6)	— — Article 103 —
Article 15(1) Article 15(2) to (4)	Article 256 —
Article 16	—
Article 17	—
Article 17a	—
Article 18	Article 103
Article 19	—
Article 20	—

Tuesday 15 April 2014

2. Directive 77/391/EEC

Directive 77/391/EEC	This Regulation
Article 1	—
Article 2(1)	Article 30(1)
Article 2(2)	Articles 31, 32
Article 2(3)	Article 33
Article 2(4)	Articles 36 and 41
Article 3(1)	Article 30(1)
Article 3(2)	Articles 31, 32
Article 3(3)	Article 33
Article 3(4)	Articles 36 and 41
Article 4	Articles 30(1), 31, 32, 33, 36 and 41
Article 5	—
Article 6	—
Article 7	—
Article 8	—
Article 9	—
Article 10	—
Article 11	—
Article 12	—
Article 13	—
Article 14	—
Article 15	—

3. Directive 78/52/EEC

Directive 78/52/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)

Tuesday 15 April 2014

Directive 78/52/EEC	This Regulation
Article 3(1)	Articles 30(1), 31, 34 and 35
Article 3(2)	—
Article 3(3)	—
Article 3(4)	Articles 30(1) and 31
Article 4	Articles 30(1), 31 and 35
Article 5	Articles 16, 17, 18, 46 and 47
Article 6(1)	Articles 73 to 75
Article 6(2)	Articles 76 and 77
Article 6(3)	Articles 78 and 79
Article 7	Articles 78 and 79
Article 8	Articles 78 and 79
Article 9	Articles 78 and 79
Article 10	Articles 78 and 79
Article 11	Articles 78 and 79
Article 12	Articles 78 and 79
Article 13	Articles 16, 17, 18, 46 and 47
Article 14(1)	Articles 73 to 75
Article 14(2)	Articles 76 and 77
Article 14(3)	Articles 78 and 79
Article 15	Articles 78 and 79
Article 16	Articles 78 and 79
Article 17	Articles 78 and 79
Article 18	Articles 78 and 79
Article 19	Articles 78 and 79
Article 20	Articles 78 and 79
Article 21	—
Article 22	Articles 16, 17, 18, 46 and 47
Article 23	Articles 73 to 79

Tuesday 15 April 2014

Directive 78/52/EEC	This Regulation
Article 24	Articles 78 and 79
Article 25	Articles 78 and 79
Article 26	Articles 78 and 79
Article 27	Article 121(1), 123(1)(b)
Article 28	—
Article 29	—
Article 30	—

4. Directive 80/1095/EEC

Directive 80/1095/EEC	This Regulation
Article 1	Articles 30(1) and 36
Article 2	Article 4 (partially)
Article 3	Articles 30(1), 34 and 35
Article 3a	Articles 30(1), 34 and 35
Article 4	Articles 31, 32 and 35
Article 4a	Articles 31, 32 and 35
Article 5	—
Article 6	Article 30(1)(b), 30(3) and Article 31
Article 7	Articles 36, 39 and 40
Article 8	Articles 41 and 42
Article 9	—
Article 11	—
Article 12	—
Article 12a	—
Article 13	—

Tuesday 15 April 2014

5. Directive 82/894/EEC

Directive 82/894/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 17, 19, 20 and 21
Article 4	Articles 17,18, 19, 20 and 21
Article 5	Article 21(b) and (c)
Article 6	—
Article 7	—
Article 8	—

6. Directive 88/407/EEC

Directive 88/407/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 157 and 158
Article 4	Article 158(b) and (c)
Article 5	Article 89, 92, 95 and 96
Article 6(1)	Articles 159 and 160
Article 6(2)	—
Article 6(3) and (4)	—
Article 8	Articles 230(1)(a) and 231
Article 9	Articles 230(1)(b), 234 and 235
Article 10	Articles 230(1)(c), 231, 236 and 238
Article 11	Article 230(1)(d) and Articles 239, 240
Article 12	Article 230(2)
Article 15	Articles 246 to 251
Article 16	—

Tuesday 15 April 2014

Directive 88/407/EEC	This Regulation
Article 17	—
Article 18	—
Article 20	—
Article 21	—
Article 22	—

7. Directive 89/556/EEC

Directive 89/556/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 157, 158, 159
Article 5(1)	Articles 89 and 92
Article 5(2)	Article 96
Article 5(2a) and (3)	Article 92
Article 6	Article 159 and 160
Article 7	Articles 230(1)(a) and 231
Article 8	Articles 230(1)(b), 234 and 235
Article 9	Articles 230(1)(c), 236 and 238
Article 10	Articles 230(1)(d), 239, 240
Article 11	Articles 230(2) and 249 to 251
Article 14	Articles 246 to 248
Article 15	—
Article 16	—
Article 17	—
Article 18	—
Article 19	—

Tuesday 15 April 2014

Directive 89/556/EEC	This Regulation
Article 20	—
Article 21	—

8. Directive 90/429/EEC

Directive 90/429/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 157 and 158
Article 4	—
Article 5(1)	Articles 89 and 92
Article 5(2)	Article 96
Article 6(1)	Articles 159 and 160
Article 6(2)	—
Article 7	Articles 230(1)(a) and 231
Article 8	Articles 230(1)(b), 234 and 235
Article 9	Articles 230(1)(c), 236 and 238
Article 10	Article 230(1)(d), 239, 240
Article 11(1)	Article 230(2)
Article 11(2) and (3)	—
Article 12	Article 239
Article 13	—
Article 14	—
Article 15	Articles 246 to 251
Article 16	—
Article 17	—
Article 18	—
Article 19	—
Article 20	—

Tuesday 15 April 2014

Directive 90/429/EEC	This Regulation
Article 21	—
Article 22	—

9. Directive 91/68/EEC

Directive 91/68/EEC	This Regulation
Article 1	—
Article 2	Articles 4 (partially), 150(3) and 220(3)
Article 3(1)(2)(3) and (5)	Articles 127 and 128
Article 3(4)	Article 136
Article 4(1)	Articles 121(2)(b), 127 and 128
Article 4(2)	Article 125
Article 4(3)	Article 128
Article 4a	Article 128
Article 4b(1) to (3)	Article 128
Article 4b(4)	Article 130
Article 4b(5)	Article 129
Article 4b(6)	Articles 121(1) and 122
Article 4c(1) and (2)	Article 128
Article 4c(3)	Articles 130 and 132
Article 5	Article 128
Article 6	Article 128
Article 7(1) to (3)	Articles 30, 31 and 32
Article 7(4)	—
Article 8(1) to (3)	Articles 36, 39 and 40
Article 8(4)	—
Article 8a(1)	Articles 89(1)(a), 92, 93 and 131
Article 8a(2)	Article 97, 100
Article 8a(3)	Articles 93, 94 and 96
Article 8a(4)	Article 95
Article 8a(5)	Article 92(1)(d) and (2)(d)

Tuesday 15 April 2014

Directive 91/68/EEC	This Regulation
Article 8b(1)	Articles 82, 89(1)(a), 92, 93, 97, 100 and 131
Article 8b(2)	Articles 89, 92, 93
Article 8b(3)	Article 95
Article 8b(4)	—
Article 8c(1)	Articles 85 and 122
Article 8c(2)	Article 99
Article 8c(3)	Article 122(1)(a)
Article 8c(4) and (5)	—
Article 9	Articles, 140, 141, 142, 143, 144, 145, 146 and 150
Article 10	—
Article 11	—
Article 12	Article 141(b)
Article 14	—
Article 15	—
Article 17	—
Article 18	—

10. Decision 91/666/EEC

Decision 91/666/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 48
Article 4	Articles 48, 49 and 50
Article 5	Articles 48 and 50
Article 6	Articles 15 and 48(3)(b)
Article 7	Article 50
Article 8	—
Article 9	—

Tuesday 15 April 2014

Decision 91/666/EEC	This Regulation
Article 10	—
Article 11	—
Article 12	—

11. Directive 92/35/EEC

Directive 92/35/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 16
Article 4	Articles 53 to 57 and 59
Article 5	Articles 46 and 47
Article 6	Articles 60 to 69
Article 7	Article 57
Article 8	Article 64
Article 9	Articles 65, 66 and 67
Article 10	Articles 65, 66 and 67
Article 11	Article 68
Article 12	Article 71(1)
Article 13	Article 65(2)
Article 14	—
Article 15	—
Article 16	—
Article 17	Articles 43, 44 and 45
Article 18	—
Article 19	—
Article 20	—

Tuesday 15 April 2014

Directive 92/35/EEC	This Regulation
Article 21	—
Article 22	—

12. Directive 92/65/EEC

Directive 92/65/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	—
Article 4	Articles 121, 123, 16, 17, 18, 30(2), 140 to 143, 146 and 148
Article 5	Articles 133, 134, 140, 141
Article 6(A)	Articles 121, 123, 127, 128, 134, 137, 140 to 143
Article 6(B)	—
Article 7(A)	Articles 121, 123, 127, 128, 134, 137 and 140 to 143
Article 7(B)	—
Article 8	Articles 121, 123, 133 and 140 to 143
Article 9	Articles 121, 123, 133 and 140 to 143
Article 10(1) to (4)	Articles 121, 123, 133, 140 to 143
Article 10(5) to (7)	—
Article 10a	—
Article 11(1)	Article 155
Article 11(2) and (3)	Articles 155, 157 and 158, 140 to 143
Article 11(4)	Articles 92 and 96
Article 11(5)	Article 162
Article 12(1)	—
Article 12(2)	Article 246 to 248
Article 12(3)	Articles 82, 97, 100
Article 12(4)	Articles 140 to 146 and 149 to 151
Article 12(5)	—
Article 12(6)	Article 256

Tuesday 15 April 2014

Directive 92/65/EEC	This Regulation
Article 13(1)	Articles 133, 140 to 146 and 148
Article 13(2)	Articles 90, 92, 93 to 96
Article 14	Articles 30, 31 and 32
Article 15	Articles 36, 39, 40 and 41
Article 16	Articles 230(1) and 236
Article 17(1)	Article 230(1)(a)(b) and (c)
Article 17(2)	Article 231,
Article 17(3)	Article 231, 234, 235
Article 17(4) and (5)	—
Article 18	Article 230(1)(d), 239
Article 19	Article 236
Article 20	Articles 230(2), 246 to 248
Article 21	Article 141, 142, 143, 160, 209 and 211
Article 22	—
Article 23	—
Article 24	Articles 230(1)(d), 239 and 241(1)(a)(v) and (1)(c)(iv)
Article 25	—
Article 26	—
Article 27	—
Article 28	—
Article 29	—
Article 30	—

13. Directive 92/66/EEC

Directive 92/66/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 16

Tuesday 15 April 2014

Directive 92/66/EEC	This Regulation
Article 4	Articles 53 to 56, 57(1) and 59
Article 5	Articles 60 to 63
Article 6	Article 63
Article 7	Articles 57, 43(2)(d)
Article 8	Articles 55 and 56
Article 9(1)	Article 64
Article 9(2) to (7)	Articles 65 to 68
Article 10	Articles 65 and 67
Article 11	Articles 67(b), 68(1)(b) and (2)(a)
Article 12	Article 54
Article 13	Article 65(2)
Article 14	—
Article 15	—
Article 16	Articles 46 and 47
Article 17	Article 47
Article 18	Articles 65(e), 67 and 69
Article 19(1) to (3)	Articles 53 to 56
Article 19(4)	Articles 57(1), 60 to 63
Article 19(5)	Article 71(2)
Article 20	—
Article 21	Articles 43 and 44
Article 22	—
Article 23	—
Article 24	—
Article 25	—

Tuesday 15 April 2014

Directive 92/66/EEC	This Regulation
Article 26	—
Article 27	—

14. Directive 92/118/EEC

Directive 92/118/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 164, 223 and 228(c)(v)
Article 4(1)	Articles 164, 223 and 228(c)(v)
Article 4(2)	—
Article 5	Articles 164 and 223
Article 6	Article 15(1)(b) and (2)(b)
Article 7(1)	—
Article 7(2)	Articles 246 to 248
Article 7(3)	—
Article 7(4)	Article 256
Article 8	—
Article 9	Articles 230 and 236
Article 10	Articles 230, 236, 239 and 241
Article 11	Article 241(1)(c)(ii)
Article 12	—
Article 13	Article 241(1)(c)(i)
Article 14	—
Article 15	—
Article 16	Article 241(1)(c)(v)
Article 17	—
Article 18	—

Tuesday 15 April 2014

Directive 92/118/EEC	This Regulation
Article 19	—
Article 20	—

15. Directive 92/119/EEC

Directive 92/119/EEC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 16
Article 4	Articles 53 to 57 and 59
Article 5	Articles 60 to 63
Article 6	Article 70 and 71(2)
Article 7	Article 63
Article 8	Article 57
Article 9	Articles 62 and 63
Article 10	Article 64
Article 11	Articles 65 to 68 and 71(2)
Article 12	Articles 65 to 68
Article 13	Article 67(a)
Article 14	Article 65(2)
Article 15	—
Article 16	Articles 63(b), 67(b), 68(1)(b) and (2)(a)
Article 17	—
Article 18	—
Article 19	Articles 46, 47 and 69
Article 20	Articles 43, 44 and 45
Article 21	—
Article 22	—

Tuesday 15 April 2014

Directive 92/119/EEC	This Regulation
Article 23	—
Article 24	—
Article 25	—
Article 26	—
Article 27	—
Article 28	—

16. Decision 95/410/EEC

Decision 95/410/EEC	This Regulation
Article 1	Articles 127 to 129
Article 2	Article 128(1)(c)
Article 3	Articles 140, 142 and 143
Article 4	—
Article 5	—
Article 6	—

17. Directive 2000/75/EC

Directive 2000/75/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 16
Article 4(1) and (2)	Articles 54 and 55
Article 4(3)	Article 53
Article 4(4)	Article 56
Article 4(5)	Article 70
Article 4(6)	Article 59
Article 5	Articles 46 and 47
Article 6	Articles 60 to 64
Article 7	Article 57

Tuesday 15 April 2014

Directive 2000/75/EC	This Regulation
Article 8	Articles 64,68 and 71(3)
Article 9	Articles 65 and 67
Article 10(1)	Articles 64 and 67
Article 10(2)	Articles 46 and 47
Article 11	—
Article 12	Articles 65 and 67
Article 13	Article 71(1)
Article 14	Article 65(2)
Article 15	—
Article 16	—
Article 17	—
Article 18	Articles 43, 44 and 45
Article 19	—
Article 20	—
Article 21	—
Article 22	—
Article 23	—

18. Regulation (EC) No 1760/2000

Regulation (EC) No 1760/2000	This Regulation
Article 1	Article 102
Article 2	Article 4 (partially)
Article 3	Article 102(2) and 105
Article 4	Articles 106(a), 108, 114, 115 and 117
Article 5	Article 103(1)(a)
Article 6	Article 104, 106(b), 108, 114, 115 and 117
Article 7	Article 97, 100, 101 and 106(b)(i) and (c)

Tuesday 15 April 2014

Regulation (EC) No 1760/2000	This Regulation
Article 8	Article 105
Article 9	—
Article 10(a) to (c)	Articles 114, 115, 117
Article 10(d) and (e)	—
Article 10(f)	Article 258
Article 11	—
Article 12	—
Article 13	—
Article 14	—
Article 15	—
Article 16	—
Article 17	—
Article 18	—
Article 19	—
Article 20	—
Article 21	—
Article 22	—
Article 23	—
Article 24	—
Article 25	—

[Am. 332]

19. Directive 2001/89/EC

Directive 2001/89/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 16, 17, 18 and 21
Article 4	Articles 53 to 57(1) and 59

Tuesday 15 April 2014

Directive 2001/89/EC	This Regulation
Article 5	Articles 60 to 63 and 71(2)
Article 6	Articles 63 and 71
Article 7	Articles 62, 63 and 65(1)(b)
Article 8	Article 57
Article 9	Article 64
Article 10	Articles 65 to 68
Article 11	Articles 65 to 68
Article 12	Articles 65(1)(f), 67(b) and 68(1)(b)
Article 13	Articles 61(3), 63(d) and 68
Article 14	Articles 62 and 63
Article 15	Article 70
Article 16	Article 70 and Articles 30 to 35
Article 17	Articles 15, 54(2) and (3), 65(1)(b) and 67(c)
Article 18	Articles 15, 46 and 47
Article 19	Articles 65(1)(e), 67 and 69
Article 20	Article 70
Article 21	—
Article 22	Articles 43, 44 and 45
Article 23	Articles 43(2)(d) and 44
Article 24	—
Article 25	—
Article 26	—
Article 27	—
Article 28	—
Article 29	—

Tuesday 15 April 2014

Directive 2001/89/EC	This Regulation
Article 30	—
Article 31	—

20. Directive 2002/60/EC

Directive 2002/60/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 16, 17, 18 and 21
Article 4	Articles 53 to 56, 57(1) and 59
Article 5	Articles 60 to 63 and 71(2)
Article 6	Articles 63 and 71
Article 7	Articles 62 and 63
Article 8	Article 57
Article 9	Article 64
Article 10	Articles 65, 67 and 68
Article 11	Articles 65, 67 and 68
Article 12	Article 65(1)(f), 67(b) and 68(1)(b)
Article 13	Articles 61(3), 63(d) and 68
Article 14	Articles 62 and 63
Article 15	Article 70
Article 16	Article 70 and Articles 30 to 35
Article 17	Articles 61(f) and 63
Article 18	Articles 15, 54(2) and (3), 65(1)(b) and 67(c)
Article 19	Articles 15, 46 and 47
Article 20	—
Article 21	Articles 43, 44 and 45

Tuesday 15 April 2014

Directive 2002/60/EC	This Regulation
Article 22	Articles 43(2)(d) and 44
Article 23	—
Article 24	—
Article 25	—
Article 26	—
Article 27	—
Article 28	—
Article 29	—
Article 30	—

21. Directive 2002/99/EC

Directive 2002/99/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 164, 223 and 228(c)(v)
Article 4	Articles 65(1)(c),(d)(i),(g),(h),(i), 67, 164, 223 and 229(1)(d)
Article 5	Articles 165, 166, 224 and 225
Article 6	—
Article 7	Articles 236 and 238
Article 8	Article 231, 232 and 233
Article 9	Articles 239 and 240
Article 10	—
Article 11	—
Article 12	—
Article 13	—
Article 14	—

Tuesday 15 April 2014

Directive 2002/99/EC	This Regulation
Article 15	—
Article 16	—

22. Directive 2003/85/EC

Directive 2003/85/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 16, 17, 18 and 21
Article 4	Articles 53 to 56 and 57(1)
Article 5	Article 55(1)(d),(e) and (2)
Article 6	Articles 55(1)(f)(i) and (2), and 56(b)
Article 7	Article 55(1)(f)(ii)
Article 8	Article 55(1)(f) and (2)
Article 9	Article 59
Article 10	Articles 60, 61, 63
Article 11	Articles 61(1)(f) 63(b), 65(1)(f) and 67(b)
Article 12	Article 65(1)(h),(i) and Article 67
Article 13	Article 57
Article 14	Articles 61 and 63
Article 15	Articles 61 and 63
Article 16	Articles 61, 62 and 63
Article 17	Article 71(2) and (3)
Article 18	Articles 61 and 63
Article 19	Articles 62 and 63
Article 20	Article 71(2) and (3)
Article 21	Articles 64

Tuesday 15 April 2014

Directive 2003/85/EC	This Regulation
Article 22	Articles 65 to 67
Article 23	Articles 65 to 67
Article 24	Articles 67 and 71(1)
Article 25	Article 65(1)(c),(d)(i),(g), (h), (i) and Article 67
Article 26	Articles 65(1)(c),(d)(i),(g),(h),(i), 67 and 164
Article 27	Articles 65(1)(c),(d)(i),(g), (h), (i), 67, 164
Article 28	Article 65(1)(c),(d)(iii) and Article 67
Article 29	Article 65(1)(c),(d)(ii) and 67
Article 30	Article 65(1)(c),(d)(ii) and 67
Article 31	Article 65(1)(c),(d)(ii) and 67
Article 32	Articles 65 and 67
Article 33	Article 65(1)(c)(d)(ii) and 67
Article 34	Articles 67, 140(2), 159(1)(b), 165(1)(b)
Article 35	Article 71
Article 36	Article 68
Article 37	Articles 65 and 67
Article 38	Articles 65 and 67
Article 39	Articles 65(1)(c),(d)(i),(g), (h), (i), 67, 164
Article 40	Articles 65(1)(c),(d)(i),(g), (h), (i), 67, 164
Article 41	Article 65(1)(c),(d)(ii) and 67
Article 42	Articles 65 and 67
Article 43	Article 71
Article 44	Article 68

Tuesday 15 April 2014

Directive 2003/85/EC	This Regulation
Article 45	Articles 64, 69 and 71
Article 46	Articles 65 and 67
Article 47	Article 65(1)(h) and 67
Article 48	Article 140
Article 49	Articles 15, 46 and 47
Article 50	Articles 46,47 and 69
Article 51	Articles 46, 47 and 69
Article 52	Articles 46 and 47
Article 53	Articles 46 and 47
Article 54	Articles 46, 47, 65, 67 and 69(3)
Article 55	Articles 46, 47, 65, 67, and 69(3)
Article 56	Articles 47, 68(1)(c) and 69(3)
Article 57	Articles 47, 68(1)(c) and 69(3)
Article 58	Article 65(1)(c) and 67
Article 59	Articles 36, 38, 39, 40 and 68
Article 60	Articles 36, 38, 39, 40 and 68
Article 61	Articles 36, 38, 39, 40 and 68
Article 62	Article 68
Article 63	Articles 140(2), 159 and 165
Article 64	Articles 69(3) and 128
Article 65	Article 15
Article 66	—
Article 67	—
Article 68	—
Article 69	—

Tuesday 15 April 2014

Directive 2003/85/EC	This Regulation
Article 70	Article 15
Article 71	Articles 54(2) and (3), 58, 61(1)(g), 63(c) and 65(1)(b), 67(c), 68(1)(c) and 2(b)
Article 72	Article 43
Article 73	Article 45
Article 74	Article 43(2)(d)
Article 75	Article 44
Article 76	Article 43(2)(d) and 44
Article 77	Article 44
Article 78	Article 43(2)(d)
Article 79	Article 52
Article 80	Article 48
Article 81	Articles 48(3) and 50
Article 82	Articles 48(3) and 50
Article 83	Article 49
Article 84	Articles 48(3) and 50
Article 85	Articles 70 and 71
Article 86	Article 256
Article 87	—
Article 88	Article 71(3)
Article 89	—
Article 90	—
Article 91	—
Article 92	—
Article 93	—

Tuesday 15 April 2014

Directive 2003/85/EC	This Regulation
Article 94	—
Article 95	—

23. Regulation (EC) No 998/2003

Regulation (EC) No 998/2003	This Regulation
Article 1	—
Article 2	—
Article 3	Article 4 (partially)
Article 4	Articles 112, 114(e) and 117
Article 5	Articles 152, 222 and 228
Article 6	—
Article 7	Articles 152(2) and (3) and 222(2) and (3)
Article 8	Article 241(1)(a)(ii)
Article 9	Article 241(1)(a)(ii)
Article 10	Article 231
Article 11	—
Article 12	—
Article 13	—
Article 14 (1st and 2nd paragraph)	Article 239
Article 14 (3rd paragraph)	—
Article 14 (4th paragraph)	Articles 236(1)(b) and 241(1)(a)(ii)
Article 15	—
Article 16	—
Article 17	Articles 152(2) and (3), 222(2) and (3), 228, and 241(1)(a)(ii)
Article 18	Articles 246 to 251

Tuesday 15 April 2014

Regulation (EC) No 998/2003	This Regulation
Article 19	Articles 4(2)(b), 152(2) and (3), 222(2) and (3), 228, and 241 (1)(a)(ii)
Article 19a(1)	Article 114(e) and 117
Article 19a(2)	Article 152(2) and (3)
Article 20	—
Article 21	—
Article 22	—
Article 23	—
Article 24	—
Article 25	—

~~24. Regulation (EC) No 21/2004~~

Regulation (EC) No 21/2004	This Regulation
Article 1	Article 102
Article 2	Article 4 (partially)
Article 3(1)	Article 102(2)
Article 3(2)	Article 105
Article 4(1) and (2)	Articles 107(a), 114, 115 and 117
Article 4(3)	Articles 114(b) and 115(a)
Article 4(4) to (7)	Article 114
Article 4(8)	Article 105
Article 4(9)	Article 114(b)
Article 5	Articles 97, 100, 101, 105 and 106(b) and (c)
Article 6	Articles 105(b), 107(b), 108, 114(c)(ii), 115 and 117
Article 7	Article 96
Article 8(1)	Article 103,
Article 8(2)	Article 107(c),
Article 8(3) to (5)	Article 103

Tuesday 15 April 2014

Regulation (EC) No 21/2004	This Regulation
Article 9	Articles 114(b) and 117
Article 10(1)(a)	—
Article 10(1)(b)	Article 256
Article 10(1)(c)	Article 258
Article 10(2)	Article 117
Article 11	Article 105
Article 12(1)	—
Article 12(2)	Article 256
Article 12(4) to (7)	—
Article 13	—
Article 14	—
Article 15	—
Article 16	—
Article 17	—

[Am. 333]

25. Directive 2004/68/EC

Directive 2004/68/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3(1)	Article 230(1)(a)
Article 3(2)	Article 233(1)
Article 4	Article 231(1)
Article 5	Articles 231(1),(3) and 232
Article 6	Articles 236 and 237
Article 7	Article 236(1)(a) and 2 and Article 237
Article 8	Articles 236, 239(4) and 241(1)(a)
Article 9	Articles 236(1) and 239 (4)

Tuesday 15 April 2014

Directive 2004/68/EC	This Regulation
Article 10	Article 236(1) and 239(4)
Article 11	Articles 230(1)(d), 239 and 240
Article 12	—
Article 13	—
Article 14	—
Article 16	—
Article 17	—
Article 18	—
Article 19	—
Article 20	—
Article 21	—

26. Directive 2005/94/EC

Directive 2005/94/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Article 9
Article 4	Articles 27 and 28
Article 5	Article 16, 17, 18 and 21
Article 6	Article 57
Article 7	Articles 53 to 56 and 57(1)
Article 8	Article 55(2)
Article 9	Article 59
Article 10	Articles 55(1)(e),(f) and 56
Article 11	Articles 61 and 63
Article 12	Article 63
Article 13	Articles 61 and 63

Tuesday 15 April 2014

Directive 2005/94/EC	This Regulation
Article 14	Article 63(a)
Article 15	Articles 62 and 63(e)
Article 16	Article 64
Article 17	Articles 65 and 67
Article 18	Articles 65(1)(a) and (b) and 67
Article 19	Articles 65 and 67
Article 20	Article 65(1)(d)(ii) and 67
Article 21	Articles 65(1)(c) and (i) and 67
Article 22	Article 65(1)(c) and (i) and Article 67
Article 23	Articles 65(1)(c) and 67
Article 24	Articles 65(1)(c) and 67
Article 25	Articles 65(1)(c) and 67
Article 26	Articles 65(1)(c) and 67
Article 27	Articles 65(1)(d)(ii) and 67
Article 28	Articles 65(1)(f) and 67(b)
Article 29	Article 68
Article 30	Articles 65 and 67
Article 31	Article 68
Article 32	Articles 64, 65, 67 and 71(3)
Article 33	Articles 67 and 71(3)
Article 34	Articles 37, 65(1)(i), 67 and 71(3)
Article 35	Articles 54 and 61
Article 36	Articles 61 and 63
Article 37	Articles 61 and 63
Article 38	Articles 61, 63, 65 and 67
Article 39	Articles 61, 63 and 71(3)

Tuesday 15 April 2014

Directive 2005/94/EC	This Regulation
Article 40	Articles 61,63 and 71(3)
Article 41	Articles 61,63 and 71(3)
Article 42	Articles 62 and 63
Article 43	Article 64
Article 44	Articles 65 and 67
Article 45	Article 68
Article 46	Article 64(4), 67 and 71(3)
Article 47	Article 61, 63 and 71
Article 48	Article 68(1)(b) and 2(a)
Article 49	Articles 61(3) and 68
Article 50	Articles 15, 54(2)(b), (c) and (3), 58(2), 63(5)
Article 51	—
Article 52	Articles 46 and 47
Article 53	Article 69
Article 54	Articles 46, 47, 65, 67 and 69
Article 55	Articles 46, 47, 65, 67 and 69
Article 56	Articles 46 and 47
Article 57	Article 47
Article 58	Articles 48 to 51
Article 59	Article 52
Article 60	—
Article 61	Article 256
Article 62	Articles 43 to 45
Article 63	—
Article 64	—

Tuesday 15 April 2014

Directive 2005/94/EC	This Regulation
Article 65	—
Article 66	—
Article 67	—
Article 68	—
Article 69	—

27. Directive 2006/88/EC

Directive 2006/88/EC	This Regulation
Article 1	—
Article 2	Articles 2 and 3(2)
Article 3	Article 4 (partially)
Article 4(1)	Articles 170, 171, 174 and 175
Article 4(2)	Article 177
Article 4(3)	Article 183(2)
Article 4(4)	Articles 170, 171, 172 and 173
Article 4(5)	—
Article 5	Article 179
Article 6	Articles 183, 184
Article 7	—
Article 8	Articles 185, 186, 187 and 188
Article 9	Article 179(1)(a)(i), (2) and (3)
Article 10	Articles 179 (1)(a)(ii), (2) and (3)
Article 11	Articles 190 and 204
Article 12	Article 190
Article 13	Articles 191
Article 14(1) and (2)	Article 208
Article 14(3) and (4)	Articles 219 and 220

Tuesday 15 April 2014

Directive 2006/88/EC	This Regulation
Article 15(1) and (2)	Articles 195, 196
Article 15(3)	Article 192
Article 15(4)	Articles 195, 196 and 198
Article 16	Article 196
Article 17	Article 196
Article 18	Articles 200 and 201
Article 19	Articles 200 and 201
Article 20	Article 199
Article 21	Articles 202, 203 and 205
Article 22	Article 230(1)(a)
Article 23	Articles 231 and 232
Article 24	Articles 230(1)(d) and 239
Article 25	Articles 236, 239 and 240
Article 26	Article 16
Article 27	Articles 17 and 18
Article 28	Articles 53 to 55 and 72 to 74
Article 29	Article 57
Article 30	Articles 59 and 77
Article 31	—
Article 32	Articles 60, 61, 62 and 64
Article 33	Articles 65 and 67
Article 34	Article 61(1)(b) and (c) and Article 63
Article 35	Article 61(3) and 63
Article 36	—
Article 37	Article 68
Article 38	Articles 76 and 78
Article 39	Articles 78 and 79

Tuesday 15 April 2014

Directive 2006/88/EC	This Regulation
Article 40	Article 80
Article 41	Article 246(1)(b) and (c)
Article 42	Article 71(3)
Article 43	Article 227
Article 44	Articles 26, 27, 30 and 31
Article 45	Article 32
Article 46	Article 34
Article 47	Articles 43 and 44
Article 48	Article 46 and 47
Article 49	Article 36
Article 50	Article 36 and 37
Article 51	Article 38
Article 52	Article 41
Article 53	Article 42
Article 54	—
Article 55	—
Article 56	—
Article 57(a)	—
Article 57(b)	Articles 54(2)(c) and (3), 58, 61(1)(h), 63(c), 67(1)(b) and 67(c)
Article 57(c)	—
Article 58	—
Article 59	Article 38, 183 (partially)
Article 60	Article 256
Article 61	—
Article 62	—
Article 63	—

Tuesday 15 April 2014

Directive 2006/88/EC	This Regulation
Article 64	—
Article 65	—
Article 66	—
Article 67	—

28. Directive 2008/71/EC

Directive 2008/71/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3(1)	Article 96 Article 115
Article 3(2)	—
Article 4(1)	Articles 97 and 115
Article 4(2)	Article 110
Article 5(1)	Article 110(a), 114(b) and 117
Article 5(2)	Article 110(a) and 111
Article 6(1)	Article 110(a), 115 and 117
Article 6(2)	—
Article 7	Article 103(1)(b) and (2)
Article 8	Articles 110, 114(d)
Article 9	Article 256
Article 10	—
Article 11	—
Article 12	—
Article 13	—

[Am. 334]

Tuesday 15 April 2014

29. Directive 2009/156/EC

Directive 2009/156/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	Articles 123 and 136
Article 4(1)	Articles 127 and 146(3)
Article 4(2)	Articles 127 and 128
Article 4(3)	Article 125
Article 4(4)	Articles 109, 114 and 117
Article 4(5)	Articles 123(1)(a), 127 and 128
Article 4(6)	Articles 30 to 35
Article 5	Articles 127 and 128
Article 6	Articles 127, 128 and 141(b)
Article 7(1)	Articles 123(2) and 130
Article 7(2)	Articles 127, 128 and 129
Article 7(3)	Article 127, 128 and 129
Article 8	Articles 109(1)(c), 114, 117 and Articles 140 to 143
Article 9	Articles 246 to 248 (partially)
Article 10	—
Article 11	—
Article 12(1),(2) and (3)	Articles 230(1)(a) and 231
Article 12(4) and (5)	Article 236
Article 13	Articles 231 and 236
Article 14	Article 236
Article 15	Article 236
Article 16	Articles 236, 238 and 239
Article 17	Article 236
Article 18	—
Article 19	Article 236

Tuesday 15 April 2014

Directive 2009/156/EC	This Regulation
Article 20	—
Article 21	—
Article 22	—
Article 23	—
Article 24	—

30. Directive 2009/158/EC

Directive 2009/158/EC	This Regulation
Article 1	—
Article 2	Article 4 (partially)
Article 3	—
Article 4	—
Article 5	Articles 123, 127, 128, 157 and 158
Article 6	Articles 121, 123 and 157
Article 7	Article 96
Article 8	Articles 157 and 158
Article 9	Articles 127 and 128
Article 10	Articles 127 and 128
Article 11	Articles 127 and 128
Article 12	Articles 127 and 128
Article 13	Article 128
Article 14	Article 128
Article 15(1)(a)	Articles 157 and 158
Article 15(1)(b) to (d)	Articles 127 and 128
Article 15(2)	Articles 30 to 35
Article 16	Articles 30 to 35
Article 17	Articles 36, 39 and 40

Tuesday 15 April 2014

Directive 2009/158/EC	This Regulation
Article 18	Articles 121, 122, 123(1)(a) and (2), 129 and 155(3)
Article 19	Article 128
Article 20	Articles 140 to 147 and Articles 159 and 160
Article 21	—
Article 22	—
Article 23	Articles 230(1)(a), 231 and 232
Article 24	Article 236
Article 25	Article 236
Article 26	Article 239
Article 27	—
Article 28	Articles 236, 237 and 238
Article 29	Article 236 and 241
Article 30	Article 236
Article 31	Articles 246 to 248
Article 32	—
Article 33	—
Article 34	—
Article 35	—
Article 36	—
Article 37	—
Article 38	—

Tuesday 15 April 2014

P7_TA(2014)0382

Protective measures against pests of plants *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on protective measures against pests of plants (COM(2013)0267 — C7-0122/2013 — 2013/0141(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/61)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0267),
 - having regard to Article 294(2) and Article 43 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0122/2013),
 - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Austrian Federal Council, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 10 December 2013 ⁽¹⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Agriculture and Rural Development and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0147/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0141**Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on protective measures against pests of plants**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43 thereof,

Having regard to the proposal from the European Commission,

⁽¹⁾ OJ C 170, 5.6.2014, p. 104.

Tuesday 15 April 2014

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Council Directive 2000/29/EC ⁽³⁾ sets out a plant health regime.
- (2) On 21 November 2008, the Council invited the Commission to proceed to an evaluation of that plant health regime ⁽⁴⁾.
- (3) In the light of the outcome of that evaluation and the experience gained from the application of Directive 2000/29/EC, that Directive should be replaced. To ensure uniform application of the new rules, the act replacing that Directive should take the form of a Regulation.
- (4) Plant health is very important for plant production, public and private green, natural ecosystems, ecosystem services and biodiversity in the Union. Plant health is threatened by species injurious to plants and plant products, hereinafter 'pests', **which now present a greater risk of being introduced into the Union territory owing to globalisation of trade and climate change**. To fight that threat, it is necessary to adopt measures concerning the determination of the phytosanitary risks posed by those pests and the reduction of those risks to an acceptable level. [Am. 1]
- (5) The need for such measures has long been recognised. They have formed the subject of international agreements and international conventions, including the International Plant Protection Convention (IPPC) of 6 December 1951 concluded at the United Nations Food and Agricultural Organisation (FAO) and its new revised text approved by the Food and Agriculture Organisation Conference in November 1997 at its 29th session **as well as the International Convention on Biological Diversity (CBD) of 29 December 1993**. The Union is party to **both the IPPC and the CBD**. [Am. 2]
- (6) It has appeared that for the determination of the scope of this Regulation it is important to take into account biogeographical factors to avoid that pests not present in the European territory of the Union spread to that territory. Consequently, non-European territories (outermost regions) of Member States referred to in Article 355(1) of the Treaty on the Functioning of the European Union (TFEU) should be excluded from the territorial scope of this Regulation. Those territories should be listed. Where the status of such a territory or a territory referred to in Article 355(2) TFEU is amended pursuant to Article 355(6) TFEU, that list should be amended to ensure that the territorial scope of this Regulation remains confined to the European part of the Union territory. References to third countries should be read as references also to the territories included in that list.
- (7) Directive 2000/29/EC sets out rules concerning official controls to be carried out by the competent authorities as regards protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. Such rules are presently set out by Regulation (EU) No .../.... of the European Parliament and of the Council ⁽⁵⁾ [*number of Regulation on Official Controls and, in the footnote, the reference to the Official Journal*] and therefore should not be part of this Regulation.

⁽¹⁾ OJ C 170, 5.6.2014, p. 104.

⁽²⁾ Position of the European Parliament of 15 April 2014.

⁽³⁾ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

⁽⁴⁾ Council of the European Union, 2906th Economic and Financial Affairs / Budget, 21 November 2008. Council Conclusions on the Review of the EU Plant Health Regime. Document no. 104228.

⁽⁵⁾ Regulation (EU) No .../.... of the European Parliament and of the Council of ... on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 1/2005, (EC) No 396/2005, (EC) No 834/2007, (EC) No 1099/2009, (EC) No 1069/2009, (EC) No 1107/2009, Regulations (EU) No 1151/2012, (EU) No 652/2014, and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation).

Tuesday 15 April 2014

- (8) Criteria should be set out in order to allow pests to be identified for which it is necessary to adopt measures of control for the entire Union territory. Such pests are referred to as 'Union quarantine pests'. Criteria should also be set out for the identification of pests for which it is necessary to adopt measures of control only as regards one or more parts of that territory. Such pests are referred to as 'protected zone quarantine pests'.
- (9) In order to allow efforts for the control of Union quarantine pests to concentrate on pests whose economic, environmental or social impact is most severe for the Union territory as a whole, a restricted list of such pests, hereinafter 'priority pests', should be established.
- (10) It is appropriate to provide for exemptions from the prohibition of introduction into and movement within the Union territory of Union quarantine pests for scientific purposes, trials, varietal selections, breeding and exhibitions.
- (11) In order to ensure effective and timely action in case of the presence of a Union quarantine pest, notification obligations should apply to the public, professional operators and to the Member States. **It is essential to raise awareness of plant pests among green space workers, local authority officials, garden centres, nurseries, importers, landscape gardeners, arboriculturalists, teachers, researchers, business operators, staff of official agencies, elected representatives and ordinary citizens, and to train them in combating such pests.** [Am. 3]
- (12) Where those notification obligations imply that personal data of natural or legal persons should be disclosed to the competent authorities, this may constitute a limitation of Article 8 (Protection of Personal Data) of the Charter on Fundamental Rights. However that limitation would be necessary and proportionate to achieve the public interest objective of this Regulation.
- (13) A professional operator becoming aware of the presence of a Union quarantine pest in a plant, plant product or other object which is or was under its control should be under an obligation to take all measures that may be appropriate as regards the elimination of the pest, the withdrawal or recall of the plants, plant products or other objects concerned and the information of the competent authority, other persons in the trade chain and the public.
- (14) Member States should take all necessary measures to eradicate Union quarantine pests, when found present in their territories. It is appropriate to set out measures which may be taken by Member States in such a case and the principles based on which they are to decide what measures to take. Those measures should include the establishment of restricted areas, consisting of an infested zone and a buffer zone.
- (15) In certain cases, Member States should impose measures for the eradication of quarantine pests on plants in private premises, because eradication of pests can only be successful if all sources of infestation are removed. For this purpose, the competent authorities of Member States should have legal access to those premises. This may constitute a limitation of Article 7 (Respect for Private and Family Life) and Article 17 (Right to Property) of the Charter on Fundamental Rights. That limitation is necessary and proportionate to achieve the public interest objective of the regime, in so far as Member States ensure fair compensation in good time for the loss of private property.
- (16) **Prevention, protective measures and** early detection of the presence of pests is extremely important for timely and effective eradication. Member States should therefore conduct surveys for the presence of Union quarantine pests in the areas where those pests were not known to be present. In view of the number of Union quarantine pests and the time and resources required to carry out those surveys, Member States should establish multi-annual survey programmes. [Am. 4]
- (16a) **Preventative agronomic measures and integrated pest management in line with Directive 2009/128/EC of the European Parliament and of the Council⁽¹⁾ should not include systematic prophylaxis with pesticides, that is, applying biocides before the pest is even detected.** [Am. 5]

(¹) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

Tuesday 15 April 2014

- (17) The Commission should be empowered to adopt measures in case of the suspected or confirmed presence of specific Union quarantine pests, concerning in particular their eradication and containment, and the establishment of restricted areas, surveys, contingency plans, simulation exercises and eradication plans as regards those pests. ***The Commission shall consult the Member States on the measures to be adopted.*** [Am. 6]
- (18) In order to ensure swift and effective action against pests which are no Union quarantine pests but which Member States consider may fulfil the conditions for inclusion in the list of Union quarantine pests, provision should be made for measures to be taken by Member States in case they become aware of the presence of such a pest. Similar provisions should be set out for the Commission.
- (19) Under certain conditions Member States should be allowed to adopt more stringent eradication measures than required by Union legislation, ***as long as they are applied in a sustainable way.*** [Am. 7]
- (20) Special provisions should apply to priority pests as regards the information of the public, surveys, contingency plans, eradication plans and co-financing of measures by the Union, in particular.
- (21) Quarantine pests which are present in the Union territory but absent from specific parts of that territory designated as 'protected zones', and whose presence would have unacceptable economic, social or environmental impacts only for those protected zones, should be specifically identified and listed as 'protected zone quarantine pests'. The introduction into, movement within, and release into the respective protected zones of protected zone quarantine pests should be prohibited.
- (22) Rules should be set out concerning the recognition, modification or revocation of recognition of protected zones, survey obligations for protected zones, and actions to be taken in case protected zone quarantine pests are found present in the respective protected zones. In case of findings of the presence of the protected zone quarantine pest inside the respective protected zone, strict rules should apply for the amendment and revocation of those protected zones.
- (23) A pest, which is no Union quarantine pest, should be referred to as a 'Union quality pest' in case that pest is mainly transmitted through specific plants for planting, its presence on those plants for planting has an unacceptable economic impact as regards the intended use of those plants and it is listed as a Union quality pest. To limit the presence of such pests their introduction into or movement within the Union territory on the plants for planting concerned should be prohibited unless provided otherwise in that list.
- (24) Certain plants, plant products and other objects pose an unacceptable phytosanitary risk by their likelihood to host a Union quarantine pest. For some of those, acceptable risk mitigation measures are available, while not for others. Depending on the availability of acceptable risk mitigation measures, their introduction into, and movement within, the Union territory should be either prohibited or subject to special requirements. Those plants, plant products and other objects should be listed.
- (25) Derogations from the prohibitions or special requirements as regards the introduction of plants, plant products and other objects into the Union territory should be provided for. The Commission should be empowered to recognise certain measures of third countries as equivalent to the requirements for the movement within the Union territory of plants, plant products and other objects concerned.
- (26) Those prohibitions or requirements should neither apply to small quantities of plants, plant products and other objects, other than plants for planting, for non-commercial and non-professional purposes nor to the introduction into and movement within frontier zones of plants, plant products and other objects. Nor should they apply to the introduction into and movement within the Union territory of plants, plant products and other objects for scientific purposes, trials, varietal selection, breeding and exhibitions. Proper safeguards should be set and information should be provided to those concerned.

Tuesday 15 April 2014

- (27) A derogation from the Union rules for introduction into and movement within the Union territory should be provided for plants, plant products and other objects in transit.
- (28) The international trade of plants for planting with which there is limited phytosanitary experience can involve serious risks of the establishment of quarantine pests for which no measures have been adopted pursuant to this Regulation. In order to ensure swift and effective action against newly identified risks associated with plants for planting which are not subject to permanent requirements or prohibitions, but may qualify for such permanent measures, the Commission should have the possibility to adopt temporary measures in accordance with the precautionary principle.
- (29) It is necessary to set out prohibitions and special requirements, similar to those set out for the Union territory, in respect of the introduction into and movement within protected zones of plants, plant products and other objects that would pose a phytosanitary risk of an unacceptable level by their likelihood to host the respective protected zone quarantine pest.
- (30) General requirements should be adopted concerning vehicles and packaging material of plants, plant products and other objects to ensure that they are free from quarantine pests.
- (31) Member States should designate quarantine stations. Requirements concerning the designation, operation and supervision of those quarantine stations as well as the release of plants, plant products or other objects from those stations should be set out. Where those requirements include the maintenance of lists of staff and visitors entering the stations, this may constitute a limitation of Article 8 (Protection of Personal Data) of the Charter on Fundamental Rights. However that limitation would be necessary and proportionate to achieve the public interest objective of this Regulation.
- (32) Where so required by a bilateral agreement concluded by the Union with a third country, or by the legislation of a third country, plants, plant products and other objects moved out of the Union territory to the third country concerned should comply with those rules.
- (33) Where, as regards certain plants, plant products or other objects moved out of the Union territory to third countries, no bilateral phytosanitary agreement concluded by the Union with a third country and no phytosanitary legislation of a third country applies, protection should be offered to third countries against Union quarantine pests because of their acknowledged harmful nature, except where a Union quarantine pest is officially known to be present in the third country concerned and not under official control, or where it can be reasonably assumed that that Union quarantine pest does not meet the criteria to qualify as a quarantine pest for the third country concerned.
- (33a) ***Distance sales of plants may pose a high phytosanitary risk when commodities are infested with non-native pests including quarantine pests. In particular, consignments of plants imported from third countries and purchased through distance sales are in many cases non-compliant with the phytosanitary import requirements of the Union. In order to tackle these shortcomings, raising awareness of consumers and plant traders and ensuring the traceability of distance sales established both within the Union and in third countries are essential. [Am. 9]***
- (33b) ***Member States should take measures to raise awareness of the potential economic, environmental and social impacts of plant pests, the key principles of prevention and spread as well as the responsibility of society as a whole to ensure phytosanitary health in the Union. Furthermore, the Commission should keep a publicly available, updated list of emerging plant pests in third countries which may pose a risk to plant health in the Union territory. [Am. 10]***
- (34) In order to ensure effective implementation of this Regulation, professional operators subject to obligations under this Regulation should be registered in registers set up by the Member States. In order to reduce administrative burden, those registers should also include professional operators falling within the ambit of Regulation (EU) No .../... of the European Parliament and of the Council⁽¹⁾ [Number, title and, in a footnote, the OJ reference for the Regulation on plant reproductive material law].

⁽¹⁾ Regulation (EU) No .../... of the European Parliament and of the Council of... on the production and making available on the market of plant reproductive material (OJ L ...,, p.).

Tuesday 15 April 2014

- (35) Professional operators operating at more than one premise should be given the possibility to register separately for each of those premises.
- (36) To facilitate the detection of the source of an infestation by a quarantine pest, it is appropriate to require professional operators to keep records in respect of the plants, plant products and other objects supplied to them by professional operators and supplied by them to other professional operators. In view of the latency periods of some quarantine pests, and the time required for the detection of the source of infestation, records should be kept for three years.
- (37) Professional operators should also have in place systems and procedures to allow identification of the movements of their plants, plant products and other objects within their own premises.
- (38) A phytosanitary certificate should be required for the introduction from third countries into the Union territory, and into protected zones, of certain plants, plant products and other objects. Those plants, plant products and other objects should be listed in the interest of clarity.
- (39) Those phytosanitary certificates should comply with the requirements of the IPPC and attest compliance with the requirements and measures established pursuant to this Regulation. In order to ensure the credibility of the phytosanitary certificates, rules should be established concerning the conditions of their validity and cancellation.
- (40) The movement within the Union territory, and into and within protected zones, of certain plants, plant products and other objects should only be permitted if accompanied by a plant passport, attesting compliance with the requirements and measures established pursuant to the provisions of this Regulation. Those plants, plant products and other objects should be listed in the interest of clarity.
- (41) Plant passports should not be required for plants, plant products and other objects intended for final users, **including home gardeners**. [Am. 11]
- (42) In order to ensure the credibility of the plant passports, rules should be established concerning their contents.
- (43) Plant passports should generally be issued by the professional operator. Where professional operators do not have the resources to issue plant passports, the possibility should exist that, upon their request, plant passports are issued by the competent authorities **of the Member States**. [Am. 12]
- (44) Rules should be set out for the issuance of plant passports, the examinations required for issuance, the authorisation and supervision of professional operators issuing plant passports, the obligations of authorised operators and the withdrawal of that authorisation.
- (45) In order to reduce the burden of authorised operators, examinations for issuing plant passports should be combined with the examinations required under Regulation (EU) No .../... [number of Regulation on plant reproductive material law], where appropriate.
- (46) Authorised operators should possess the necessary knowledge concerning pests.
- (47) Certain **authorised** operators may desire to establish a phytosanitary risk management plan, ensuring and demonstrating a high level of competence and awareness as regards phytosanitary risks as regards critical points in their professional activities and justifying special control arrangements with the competent authorities. ~~Union rules should be established concerning the contents of those plans.~~ [Am. 13]
- (48) It is appropriate to provide for the replacement of plant passports and of phytosanitary certificates.
- (49) In cases of non-compliance with the Union rules, plant passports should be removed, invalidated and, for reasons of traceability, kept.
- (50) FAO International Standard for Phytosanitary Measures No 15 requires that wood packaging material is marked with a specific mark, applied by duly authorised and supervised professional operators. This Regulation should set out the model and contents of that mark and the authorisation and supervision of professional operators in the Union territory applying that mark.

Tuesday 15 April 2014

- (51) Where so required by a third country, the respective plants, plant products or other objects should move from the Union territory to that third country with a phytosanitary certificate for export or re-export. In respect of the relevant provisions of IPPC, those certificates should be issued by the competent authorities, respecting the contents of the model certificates for export and re-export set out by the IPPC.
- (52) Where a plant, plant product or other object is moved through more than one Member States before it is exported to a third country, it is important that the Member State in which the plants, plant product or other objects were produced or processed exchanges information with the Member State which issues the phytosanitary certificate for export. This exchange of information is important to enable attestation of compliance with the requirements of the third country. Therefore, a harmonised 'pre-export certificate' should be established to ensure that the exchange of that information takes place in a uniform manner.
- (53) The Commission should establish an electronic system for the notifications required in accordance with this Regulation.
- (53a) *In order to take into account the technical progress, scientific developments and changed circumstances in plant health, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules amending or supplementing the lists of Union quarantine pests, priority pests as well as of Union quality pests and the plants for planting concerned. In case of a serious phytosanitary risk, the power to adopt acts in accordance with the urgency procedure should be delegated to the Commission in order to list Union quarantine pests as priority pests. [Am. 14]***
- (54) In order to ensure that the exceptions for Union quarantine pests used for scientific purposes, trials, varietal selections, breeding or exhibitions are implemented in a manner that does not pose any phytosanitary risk to the Union territory or parts of it, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning the exchange of information between Member States and the Commission as regards the introduction into and movement within the Union territory of the pests concerned, the respective assessments and authorisation, and the monitoring of compliance, the action in case of non-compliance and the notification thereof.
- (55) In order to ensure an effective system of notifications, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning notification obligations concerning the suspected presence of particular Union quarantine pests which has not yet been officially confirmed.
- (56) In order to take into account the technical and scientific developments concerning surveys on the presence of pests, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules amending or supplementing the elements to be covered by the multi-annual survey programmes.
- (57) In order to ensure the effective functioning of simulation exercises, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the frequencies, contents, format and other provisions on simulation exercises.
- (58) In order to ensure that protected zones are established and function in a reliable manner, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules on surveys to be carried out for purposes of the recognition of protected zones and on whether protected zones comply with the respective requirements.
- (59) In order to ensure a proportionate and restricted application of the exemptions concerning the movement of plants, plant products or other objects into or within frontier zones, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning the maximum width of third country frontier zones and Member State frontier zones, the maximum distance of the movement of the plants, plant products and other objects concerned within the third country frontier zones and Member State frontier zones and the procedures concerning the authorisation of the introduction into and movement within the Member State frontier zones of plants, plant products and other objects.
- (60) In order to avoid phytosanitary risks during transit of plants, plant products or other objects, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the contents of a declaration concerning the passing of plants, plant products or other objects through the Union territory for the purpose of moving to a third country.

Tuesday 15 April 2014

- (61) In order to ensure that the registration of professional operators is proportionate to the objective of controlling phytosanitary risk, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out categories of, and conditions for, professional operators to be exempted from the obligation to register in a register.
- (62) In order to ensure the credibility of phytosanitary certificates of third countries which are not parties to the IPPC, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules supplementing the conditions for acceptance of phytosanitary certificates from those third countries.
- (63) In order to minimise the phytosanitary risks of plants, plant products or other objects moved within the Union territory, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the maximum figure for small quantities of particular plants, plant products or other objects to be exempted from plant passports.
- (64) In order to ensure the reliability of examinations of plants, plant products and other objects carried out for the issuance of plant passports, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules on visual examination, sampling and testing and the use of certification schemes.
- (65) In order to enhance the credibility of plant passports, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out qualification requirements to be fulfilled by the professional operators in order for them to be authorised to issue plant passports.
- (66) In order to enhance the scope and utility of the phytosanitary risk management plan, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules supplementing or amending the elements covered by such plan.
- (67) In order to take into account the development of international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning attestations for commodities of a specific nature, other than wood packaging material, which would require the application of a specific attestation of compliance with the rules of this Regulation.
- (68) In order to ensure the utility and reliability of official attestations and pre-export certificates, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the contents of official attestations, the authorisation and supervision of professional operators issuing those attestations, and the contents of the pre-export certificate.
- (69) In order to adapt to the technical and scientific developments, and to adapt to a decision of the European Council pursuant to Article 355(6) TFEU, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules amending the Annexes of this Regulation.
- (70) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (71) In order to ensure uniform conditions for the implementation of this Regulation with respect to establishing a list of Union quarantine pests, establishing a list of the priority pests, setting out measures against specific Union quarantine pests, adopting measures for a limited time as regards the phytosanitary risks posed by pests provisionally qualifying as Union quarantine pests, recognising the protected zones recognised in accordance with the first subparagraph of Article 2(1)(h) of Directive 2000/29/EC and establishing a list of the respective protected zone quarantine pests, amending or revoking protected zones, amending the list of those protected zones, listing of Union quality pests and the plants for planting concerned, listing the plants, plant products and other objects whose introduction into and movement within the Union territory is to be prohibited, and the third countries concerned, listing the plants, plant products and other objects, and the requirements for their introduction into and movement within the Union territory, setting out equivalent requirements of third countries to the requirements for movement within the Union territory of plants, plant products or other objects, setting out specific conditions or measures concerning the introduction of particular plants, plant products and other objects into frontier zones of Member States, adoption of temporary measures as regards the introduction into and movement within the Union territory of

Tuesday 15 April 2014

plants for planting from third countries, listing of plants, plant products and other objects, whose introduction into, and movement within, particular protected zones is to be prohibited, listing requirements for the introduction into, and movement within, particular protected zones of plants, plant products and other objects, listing of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is to be required for their introduction into the Union territory, listing of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is to be required for their introduction into certain protected zones from those third countries, listing of the plants, plant products and other objects, for which a plant passport is to be required for their movement within the Union territory, listing of the plants, plant products and other objects, for which a plant passport is to be required for their introduction into certain protected zones, and setting out the format of the plant passport, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽¹⁾.

- (72) The advisory procedure should be used for the adoption of the initial list of Union quarantine pests given that that initial list should merely contain, without any modifications, the pests listed in Part A of Annex I to Directive 2000/29/EC and Section I of Part A of Annex II to that Directive, for the amendment of the scientific name of a pest, where such an amendment is justified on the basis of the development of scientific knowledge, for the adoption of the initial list of protected zones and the respective protected zone quarantine pests given that that initial list should merely contain, without any modifications, the protected zones recognised in accordance with the first subparagraph of Article 2(1)(h) of Directive 2000/29/EC and the protected zone quarantine pests listed in Part B of Annex I and Part B of Annex II to Directive 2000/29/EC, for the amendment and revocation of protected zones, for the adoption of the initial list of Union quality pests given that that initial list should merely contain, without any modifications, the pests listed in certain Directives on the production and marketing of seeds and propagating material, for the adoption of the initial list of plants, plant products and other objects whose introduction into and movement within the Union territory is to be prohibited given that that initial list should merely contain, without any modifications, the plants, plant products and other objects, and the prohibitions and the third countries concerned, as set out in Part A of Annex III to Directive 2000/29/EC, together with their Combined Nomenclature (CN) codes, for the adoption of the initial list of plants, plant products and other objects whose introduction into and movement within the Union territory is to be subject to special requirements given that that initial list should merely contain, without any modifications, the plants, plant products and other objects, and the requirements and the third countries concerned, as set out in Part A of Annex IV to Directive 2000/29/EC, together with their Combined Nomenclature (CN) codes, for the adoption of the initial list of plants, plant products and other objects whose introduction into certain protected zones is to be prohibited given that that initial list should merely contain, without any modifications, the plants, plant products and other objects, and the prohibitions and the third countries concerned, as set out in Part B of Annex III to Directive 2000/29/EC, together with their Combined Nomenclature (CN) codes, for the adoption of the initial list of plants, plant products and other objects whose introduction into, and movement within, certain protected zones is to be subject to special requirements given that that initial list should merely contain, without any modifications, the plants, plant products and other objects, and the requirements, as set out in Part B of Annex IV to Directive 2000/29/EC, together with their Combined Nomenclature (CN) codes, for the adoption of the initial list of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is required for their introduction into the Union territory, given that that initial list should merely contain, without any modifications, the plants, plant products and other objects listed in Point I of Part B of Annex V to Directive 2000/29/EC, for the adoption of the initial list of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is required for their introduction into certain protected zones, given that that initial list should merely contain, without any modifications, the plants, plant products and other objects listed in Point II of Part B of Annex V to Directive 2000/29/EC, for the adoption of the initial list of the plants, plant products and other objects, for which a plant passport is required for their movement within the Union territory, given that that initial list should merely contain, without any modifications, the plants, plant products and other objects listed in Point I of

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Tuesday 15 April 2014

Part A of Annex V to Directive 2000/29/EC, and for the adoption of the initial list of the plants, plant products and other objects, for which a plant passport is required for their introduction into certain protected zones, given that that initial list should merely contain, without any modifications, the plants, plant products and other objects listed in Point II of Part A of Annex V to Directive 2000/29/EC.

- (73) Council Directive 74/647/EEC⁽¹⁾ and Council Directive 69/466/EEC⁽²⁾ set out measures on the control of the respective pests. Following the entry into force of those Directives, the concerned pests have become widely spread throughout the Union territory, thus their containment is not feasible any more. Those Directives should therefore be repealed.
- (74) Council Directive 69/464/EEC⁽³⁾, Council Directive 93/85/EEC⁽⁴⁾, Council Directive 98/57/EC⁽⁵⁾ and Council Directive 2007/33/EC⁽⁶⁾ should be repealed, as new measures on the pests concerned should be adopted in accordance with the provisions of this Regulation. In view of the time and resources required to adopt those new measures, those acts should be repealed by **1 January 2021**. [Am. 15]
- (75) Regulation (EU) No 652/2014 of the European Parliament and of the Council⁽⁷⁾ sets out that grants for measures against pests are to concern certain pests listed in the Annexes to Directive 2000/29/EC, and certain pests not listed in those Annexes but subject to temporary Union measures adopted with regard to them. This Regulation establishes the category of priority pests. It is ~~appropriate~~ **essential** that certain measures taken by the Member States as regards, **in particular**, priority pests are to be eligible for Union grants, including compensation paid to professional operators for the value of plants, plant products and other objects, subject to destruction pursuant to the eradication measures set out in this Regulation, **as well as for the implementation of enhanced biosecurity measures essential for prevention, detection and control of priority pests at farm level**.

In addition, measures taken by the Member States in accordance with Article 15 of Regulation (EU) No .../2014 of the European Parliament and of the Council⁽⁸⁾ [Number and, in the footnote, the OJ reference of the Regulation on the prevention and management of the introduction and spread of invasive alien species] with a view to early eradication of potentially harmful alien species at an early stage of invasion should equally be eligible for Union grants. This should also include compensation paid to professional operators for the value of plants, plant products and other objects, subject to destruction pursuant to Article 15 of Regulation (EU) No .../2014 [Number of the Regulation on the prevention and management of the introduction and spread of invasive alien species]. Regulation (EU) No 652/2014 should therefore be amended. [Am. 16]

- (75a) ***The Common Agricultural Policy includes provisions linking Union funding/support for farmers to their compliance with specific standards concerning the environment, public health, animal and plant health and animal welfare. [Am. 17]***

⁽¹⁾ Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers (OJ L 352, 28.12.1974, p. 41).

⁽²⁾ Council Directive 69/466/EEC of 8 December 1969 on control of San José Scale (OJ L 323, 24.12.1969, p. 5).

⁽³⁾ Council Directive 69/464/EEC of 8 December 1969 on control of Potato Wart Disease (OJ L 323, 24.12.1969, p. 1).

⁽⁴⁾ Council Directive 93/85/EEC of 4 October 1993 on control of Potato Ring Rot (OJ L 259, 18.10.1993, p. 1).

⁽⁵⁾ Council Directive 98/57/EC of 20 July 1998 on control of *Ralstonia solanacearum* (Smith) Yabuuchi et al. (OJ L 235, 21.8.1998, p. 1).

⁽⁶⁾ Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC (OJ L 156, 16.6.2007, p. 12).

⁽⁷⁾ Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1)

⁽⁸⁾ ***Regulation (EU) No .../2014 of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species (OJ L ...).***

Tuesday 15 April 2014

- (76) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to protective measures against pests of plants, cannot be sufficiently achieved by the Member States and can therefore, by reason of its effect, complexity, trans-border and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not exceed what is necessary in order to achieve that objective.
- (77) For small and medium enterprises, this Regulation does not create disproportionate administrative burden or economic impact. Under this Regulation, based on consultation with stakeholders, the special situation of small and medium enterprises has been taken into account where possible. A potential universal exemption for micro-enterprises, which make up the majority of companies, has not been considered, in view of the public policy objective(s) to protect plant health.
- (78) This Regulation respects the IPPC, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the guidelines set out under these.
- (78a) ***In accordance with the principle of smart regulation, this Regulation shall be coordinated with Regulation (EU) No .../2014 [Number of the Regulation on the prevention and management of the introduction and spread of invasive alien species] in order to guarantee that plant health legislation applies fully and its entirety. [Am. 18]***
- (79) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably respect for private and family life, the right to property, the protection of personal data, freedom to conduct business and the freedom of art and science. This Regulation should be applied by the Member States in accordance with those rights and principles,

HAVE ADOPTED THIS REGULATION:

Chapter I

Subject matter, scope and definitions

Article 1

Subject matter and scope

1. This Regulation lays down rules ~~to determine~~ **regarding phytosanitary inspections and other official measures by the Member State authorities for the purpose of identifying** the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or ~~parasitic~~ plants injurious to plants or plant products (hereinafter 'pests'), **including invasive alien plant species which are injurious to plants and measures to reduce those risks to an acceptable level phytosanitary measures necessary to prevent the entry of pests from other Member States or third countries.** [Am. 19]
2. For the purposes of this Regulation references to third countries shall be read as references to third countries and to the territories listed in Annex I.

For the purposes of this Regulation, references to the Union territory shall be read as references to the Union territory without the territories listed in Annex I.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Annex I to ensure that the scope of this Regulation is confined to the European part of the Union territory. That amendment shall be either of the following:

- (a) an addition to Annex I of one or more territories that are referred to in Article 355(1) of the Treaty;
- (b) a removal from Annex I of one or more territories that are referred to in Article 355(2) of the Treaty.

Tuesday 15 April 2014

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (1) 'plants' means living plants and the following living parts of plants:
- (a) seeds, in the botanical sense, other than those not intended for planting;
 - (b) fruits, in the botanical sense;
 - (c) vegetables;
 - (d) tubers, corms, bulbs, rhizomes, roots, rootstocks, stolons;
 - (e) shoots, stems, runners;
 - (f) cut flowers;
 - (g) branches with foliage;
 - (h) cut trees retaining foliage;
 - (i) leaves, foliage;
 - (j) plant tissue cultures, including cell cultures, germplasm, meristems, chimaeric clones, micro-propagated material;
 - (k) live pollen;
 - (l) buds, budwood, cuttings, scions, grafts;

- (2) 'plant products' means products of plant origin, unprocessed or having undergone simple preparation, in so far as these are not plants.

Except where otherwise provided, wood shall only be considered as a 'plant product' if it has not undergone processing eliminating the phytosanitary risks, and complies with one or more of the following points:

- (a) it retains all or part of its natural round surface, with or without bark;
 - (b) it has not retained its natural round surface due to sawing, cutting or cleaving;
 - (c) it is in the form of chips, particles, sawdust, wood waste, shavings or scrap, and has not undergone processing involving the use of glue, heat or pressure or a combination thereof to produce pellet, briquettes, plywood or particle board;
 - (d) it is, or is intended to be, used as packaging material or dunnage, whether or not it is actually in use for transport of goods;
- (3) 'plants for planting' ~~means:~~
- plants which are ~~capable of~~ **already planted** and ~~are~~ intended for ~~producing entire plants, and which are~~ **destined to remain planted or to be planted, or replanted after their introduction, or remain planted**
 - **plants which are not planted at the time of introduction, but are destined to be planted thereafter; [Am. 20]**
- (4) 'other object' means any material or object, other than plants or plant products, capable of harbouring or spreading pests, including soil or growing medium;

Tuesday 15 April 2014

- (5) 'competent authority' means a competent authority as defined in Article 2(5) of Regulation (EU) No .../.... [*number of Regulation on Official Controls*];
- (6) 'lot' means a number of units of a single commodity, identifiable for phytosanitary purposes by its homogeneity of composition and origin, forming part of a consignment;
- (7) 'professional operator' means any person, governed by public or private law, involved professionally in one or more of the following activities concerning plants, plant products and other objects:
- (a) planting;
 - (b) growing;
 - (c) production;
 - (d) introduction into, and movement within, and out of the Union territory;
 - (e) making available on the market;
 - (ea) breeding; [Am. 21]**
 - (eb) multiplication; [Am. 22]**
 - (ec) maintaining; [Am. 23]**
 - (ed) providing services; [Am. 24]**
 - (ee) preserving, including storing; [Am. 25]**
- (8) 'final user' means any person, acting for purposes which are outside its trade, business or profession, who acquires for its own use plants or plant products;
- (9) 'test' means an official examination, other than visual, to determine if pests are present or to identify pests;
- (10) 'treatment' means a procedure for the killing, inactivation or removal of pests, or for rendering those pests infertile or for their devitalisation;
- (10a) 'operator' means operator as defined in Article 2(26) of Regulation (EU) No .../2014 [Number of the Official controls Regulation]; [Am. 26]**
- (10b) 'phytosanitary inspection' means official inspection of:**
- (a) plants or goods;**
 - (b) measures falling within the scope of the rules referred to in Article 1(1), as well as equipment and means of transport used for these purposes;**
 - (c) locations or areas in which such measures are carried out; [Am. 27]**
- (10c) 'phytosanitary measure' means all measures intended to eliminate risks or prevent the entry of pests to the Union territory from other Member States or third countries; [Am. 28]**
- (10d) 'quarantine units' mean areas designated by the competent authorities, in which plants from third countries shall be stored for a sufficient period of time until it is considered that the risk of introducing pests from third countries has been eliminated. [Am. 29]**

Tuesday 15 April 2014

Chapter II

Quarantine pests

Section 1

Quarantine pests

Article 3

Definition of quarantine pests

A pest shall be referred to as a 'quarantine pest', with respect to a defined territory, if it fulfils all of the following conditions:

- (a) its identity is established, within the meaning of point (1) of Section 1 of Annex II;
- (b) it is not present in that territory, within the meaning of point (2)(a) of Section 1 of Annex II, or, if present, only distributed to a limited extent within that territory, within the meaning of points (2)(b) and (c) of Section 1 of Annex II;
- (c) it is capable of entering into that territory, of perpetuating its presence in that territory for the foreseeable future after its entry into it (hereinafter: 'to establish') and of spreading within that territory, or, if present, those parts of it where it is distributed to a limited extent, in accordance with point (3) of Section 1 of Annex II;
- (d) its entry, establishment and spread would, within the meaning of point (4) of Section 1 of Annex II, have an unacceptable economic, environmental or social impact for that territory, or, if present, those parts of it where it is distributed to a limited extent; and
- (e) feasible and effective measures are available to prevent the entry into, establishment or spread of that pest within that territory, and mitigate its phytosanitary risks and impacts.

Section 2

Union Quarantine Pests

Article 4

Definition of Union quarantine pests

A quarantine pest shall be referred to as a Union quarantine pest if the defined territory as referred to in the introductory words of Article 3 is the Union territory and it is included in the list referred to in Article 5(2).

Article 5

Prohibition of introduction and movement of Union quarantine pests

1. A Union quarantine pest shall not be introduced into or moved within the Union territory.

No action shall be taken intentionally which may contribute to the introduction into, and establishment and spread within, the Union territory of a Union quarantine pest.

2. ~~The Commission shall, by means of an implementing act, establish~~ A list of pests fulfilling the conditions referred to in Article 3(b), (c) and (d), in respect of the Union territory, **is set out in Annex Ia and shall be** referred to as 'list of Union quarantine pests'. [Am. 30]

~~That list shall include the pests listed in Part A of Annex I to Directive 2000/29/EC and Section I of Part A of Annex II to that Directive.~~ [Am. 31]

Tuesday 15 April 2014

Pests which are indigenous to any part of the Union territory, whether naturally or due to their introduction from outside the Union territory, shall be marked in that list as pests known to occur in the Union territory.

Pests which are not indigenous to any part of the Union territory shall be marked in that list as pests not known to occur in the Union territory.

~~That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).~~ [Am. 32]

3. The Commission shall ~~amend the implementing act~~ **be empowered to adopt delegated acts in accordance with Article 98 concerning the amendment of the list** referred to in paragraph 2, where an assessment shows that a pest not listed in that ~~act~~ **list** fulfils the conditions referred to in Article 3(b), (c) and (d) in respect of the Union territory, or a pest listed in that ~~act~~ **list** no longer fulfils one or more of those conditions. In the first case it shall add the pest concerned to the list referred to in paragraph 2, in the second case it shall delete the pest concerned from that list. [Am. 33]

The Commission shall make that assessment available to the Member States.

~~The implementing acts amending the implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 99(3). The same procedure~~ **The Commission shall apply to a be empowered to adopt delegated acts in accordance with Article 98 concerning the** repeal or a replacement of the ~~implementing act~~ **list** referred to in paragraph 2. [Am. 34]

4. The Commission shall ~~amend the implementing act referred to in paragraph 2 by amending the scientific name of a pest~~ **be empowered to adopt delegated acts in accordance with Article 98 concerning the amendment of the scientific name of a pest included in the list referred to in paragraph 2**, where such an amendment is justified by the development of scientific knowledge. [Am. 35]

~~Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 99(2).~~ [Am. 36]

Article 6

Priority pests

1. A Union quarantine pest is a 'priority pest' if it fulfils all of the following conditions:

- (a) it fulfils, as regards the Union territory, the condition set out in point (a) or in point (b) of point (2) of Section 1 of Annex II;
- (b) its potential economic, environmental or social impact is most severe for the Union territory as set out in Section 2 of Annex II;
- (c) it is listed in accordance with paragraph 2.

2. The Commission shall, ~~by means of an implementing act, establish and amend a~~ **be empowered to adopt delegated acts in accordance with Article 98 modifying the** list of the priority pests **established in Annex Ib**, hereinafter: 'list of priority pests'. [Am. 37]

Where the results of an assessment show that a Union quarantine pest fulfils the conditions referred to in paragraph 1, or a pest no longer fulfils one or more of those conditions, the Commission shall ~~amend~~ **be empowered to adopt delegated acts in accordance with Article 98 modifying the** ~~implementing act~~ **list** referred to in the first subparagraph by adding the pest concerned to, or removing it from, that list. [Am. 38]

The Commission shall make that assessment available to the Member States **without delay**. [Am. 39]

~~The number of priority pests shall not exceed 10 % of the number of the Union quarantine pests listed pursuant to Article 5(2) and (3). Where the number of priority pests has exceeded 10 % of the number of the Union quarantine pests listed pursuant to Article 5(2) and (3), the Commission shall amend the implementing act referred to in the first subparagraph by accordingly adjusting the number of pests in that list, on the basis of their potential economic, environmental or social impact as set out in Section 2 of Annex II.~~ [Am. 40]

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).~~ [Am. 41]

Tuesday 15 April 2014

~~On duly justified imperative grounds of urgency relating to~~ **Where in the case of** a serious phytosanitary risk, ~~the Commission shall adopt immediately applicable implementing acts, in accordance with~~ **imperative grounds of urgency so require**, the procedure referred to in Article 99(4), listing Union quarantine pests as priority pests **provided for in Article 98a shall apply to delegated acts adopted pursuant to this Article.** [Am. 42]

Article 7

Amendment of Section 1 and Section 2 of Annex II

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 98 amending Section 1 of Annex II on criteria to identify pests which qualify as a quarantine pest, as regards the identity of the pest, its presence, its capability of entry, establishment and spread, and its potential economic, social and environmental impact, taking into account the developments of technical and scientific knowledge **and international standards.** [Am. 43]
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 98 amending Section 2 of Annex II on criteria to identify Union quarantine pests which qualify as a priority pest, as regards their potential economic, social and environmental impact, taking into account the developments of technical and scientific knowledge.

Article 8

Union quarantine pests used for scientific purposes, trials, varietal selections, breeding or exhibitions

1. By way of derogation from Article 5(1), Member States may, on application, authorise the introduction into, and the movement within, their territory of Union quarantine pests for use for scientific purposes, trials, varietal selections, breeding or exhibitions if all of the following requirements are fulfilled:
 - (a) the introduction, movement and use of the pest concerned do not result in the establishment or spread of that pest within the Union territory if adequate restrictions are imposed;
 - (b) the storage facilities in which that pest is to be kept and the quarantine stations, as referred to in Article 56, in which that pest is to be used are appropriate;
 - (c) the scientific and technical qualifications of the personnel by whom the activity involving that pest is to be carried out are appropriate.
2. The competent authority shall assess the risk of establishment and spread of the pest concerned, as referred to in paragraph 1(a), taking into account the identity, biology and means of dispersal of the pest, the activity envisaged, the interaction with the environment and other relevant factors relating to the risk posed by that pest.

It shall assess the storage facilities in which that pest is to be kept, as referred to in paragraph 1(b), and the scientific and technical qualifications of the personnel by whom the activity involving the pest is to be carried out, as referred to in paragraph 1(c).

On the basis of those assessments the competent authority shall authorise introduction of the pest into, or movement within, the Union territory if the requirements set out in paragraph 1 are fulfilled.

3. Where an authorisation is granted, it shall include all of the following conditions:
 - (a) the pest is to be kept in storage facilities found to be appropriate by the competent authorities and referred to in the authorisation;
 - (b) the activity involving the pest is to be carried out in a quarantine station designated in accordance with Article 56 by the competent authority and referred to in the authorisation;
 - (c) the activity involving the pest is to be carried out by personnel whose scientific and technical qualifications are found to be appropriate by the competent authority and referred to in the authorisation;

Tuesday 15 April 2014

(d) the pest is to be accompanied by the authorisation when introduced into or moved within the Union territory.

4. The authorisation shall be limited to the amount that is adequate for the activity concerned and shall not exceed the capacity of the designated quarantine station.

It shall include the restrictions necessary to adequately mitigate the risk of establishment and spread of the Union quarantine pest concerned.

5. The competent authority shall monitor compliance with the conditions referred to in paragraph 3 and the limitation and the restrictions referred to in paragraph 4 and take the necessary action in case those conditions, that limitation or those restrictions are not complied with. Where appropriate, that action shall be the revocation of the authorisation referred to in paragraph 1.

6. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down detailed rules concerning:

- (a) the exchange of information between Member States and the Commission concerning the introduction into, and movement within, the Union territory of the pests concerned;
- (b) the assessments and authorisation referred to in paragraph 2; and
- (c) the monitoring of compliance, the action in case of non-compliance and the notification thereof, as referred to in paragraph 5.

Article 9

Notification of Union quarantine pests to the competent authorities

1. Where anyone becomes aware of the presence of a Union quarantine pest or has reason to suspect such a presence, that person shall notify **the competent authority immediately and shall confirm notification**, in writing, **to** the competent authority within ten calendar days. [Am. 44]

2. If so requested by the competent authority, the person referred to in paragraph 1 shall provide that authority with the information concerning that presence which is in its possession.

Article 10

Measures in case of suspicion of the presence of a Union quarantine pest

Where a competent authority suspect the presence of a Union quarantine pest, in a part of the territory of the respective Member State where that pest was previously not known to be present, it shall immediately take any measures necessary to officially confirm whether that pest is present or not.

Article 11

Notification of Union quarantine pests to the Commission and the other Member States

1. A Member State shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States, in case one of the following points is fulfilled:

- (a) its competent authority has received a diagnosis of an official laboratory, as referred to in Article 36 of Regulation (EU) No .../... [number of the Regulation on Official Controls], confirming (hereinafter: 'officially confirming') the presence in its territory of a Union quarantine pest not known to be present in that Member State;
- (b) its competent authority has officially confirmed the presence in its territory of a Union quarantine pest, if that pest is found to be present in a part of its territory where it was previously not present;
- (c) its competent authority has officially confirmed the presence in its territory of a Union quarantine pest in a consignment of plants, plant products or other objects introduced into, intended to be introduced into or moved within the Union territory.

Tuesday 15 April 2014

2. The notifications referred to in paragraph 1 shall be submitted within three working days following the date of the official confirmation by the competent authority of the presence of the respective Union quarantine pest.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down that the notification obligations referred to in paragraph 1 shall also apply to the suspected presence of particular Union quarantine pests, which has not yet been officially confirmed. Those delegated acts may also determine the time limit within which those notifications shall be submitted.

Article 12

Information on Union quarantine pests provided to professional operators by the competent authorities

Where the conditions of one of the points of Article 11(1) are fulfilled, the competent authority concerned shall ensure that professional operators, whose plants, plant products or other objects may be affected, are immediately informed of the presence of the Union quarantine pest concerned.

Article 13

Information on priority pests provided to the public by the competent authorities

Where the conditions of one of the points of Article 11(1)(a) or (b) are fulfilled as regards a priority pest, the competent authority shall inform the public about the measures taken and to be taken by that competent authority and, where applicable, to be taken by particular professional operators or other persons.

Member States shall ensure that information is made available to the public on the potential economic, environmental and social impacts of plant pests, on the key principles of prevention and spread, as well as on the responsibility of society as a whole to ensure phytosanitary health in the Union territory.

The Commission shall establish and keep up to date a publicly available list of emerging plant pests in third countries which may pose a risk to plant health in the Union territory. [Am. 45]

Article 14

Notification of imminent dangers

1. Where a Member State has evidence that there is an imminent danger of the entry of a Union quarantine pest into the Union territory or into a part of that territory where it is not yet present, that Member State shall immediately and in writing notify the Commission and the other Member States of that evidence.

2. Professional operators shall immediately notify the competent authorities of any evidence they may have concerning an imminent danger as referred to in paragraph 1 concerning Union quarantine pests.

2a. In case of an imminent danger as set out in paragraph 1 and 2, Member States and professional operators shall take all necessary measures, as appropriate to the risk involved, to prevent the entry of such pests in the Union territory. [Am. 46]

Article 15

Measures to be taken immediately by professional operators

1. Where a professional operator becomes aware that a Union quarantine pest is present in plants, plant products or other objects which are under its control, it shall, immediately, and after informing and consulting with the competent authority concerned, take the phytosanitary measures necessary to eliminate that pest from the plants, plant products or other objects concerned and from its premises, where applicable, and prevent the spread of that pest.

That professional operator shall, immediately and after informing and consulting with the competent authority concerned, inform the persons in the trade chain from whom those plants, plant products or other objects had been obtained.

Tuesday 15 April 2014

That competent authority shall, where appropriate, ensure that the professional operator concerned withdraws from the market the plants, plant products and other objects in which that pest may be present.

2. Where the plants, plant products or other objects referred to in paragraph 1 have left the control of the professional operator concerned, that professional operator shall, immediately and after informing and consulting with the competent authority concerned, inform the persons in the trade chain from whom those plants, plant products or other objects had been obtained and to whom those plants, plant products and other objects had been supplied, of the presence of the pest.
3. The competent authority shall, where appropriate, ensure that the professional operator concerned recalls from the market the plants, plant products and other objects in which the pest may be present and, where the plants, plant products and other objects may have reached the final user, to recall them from those final users.
4. Where paragraph 1 or 2 applies, the professional operator concerned shall provide all information which is relevant for the public to the competent authority concerned. That authority shall inform the public in case action needs to be taken with regard to the plants, plant products or other objects in which the respective pest may be present.

Article 16

Eradication of Union quarantine pests

1. Where the presence of a Union quarantine pest is officially confirmed, the competent authority shall immediately take all necessary measures to eliminate that pest ~~in~~, **if possible, from** the area concerned ~~and~~ **(hereinafter: ‘to eradicate’) or, where eradication is not possible,** to prevent its spread out of that area (hereinafter: ‘to ~~eradicate~~ contain’). Those measures shall be adopted in accordance with Annex IV on measures and principles for the management of the risks of pests. [Am. 47]

1a. Where Member States compensate professional operators, pursuant to point (ca) of Article 19(1) of Regulation (EU) No 652/2014, for the value of plants, plant products or other objects destroyed as part of the measures referred to in paragraph 1 and implemented in a cross-border area, they shall ensure that adequate compensation is coordinated between the Member States concerned so as to avoid, wherever possible, undue market distortion. [Am. 48]

2. Where the presence of the Union quarantine pest concerned may be related to movements of plants, plant products or other objects, the competent authority shall investigate the source of that presence and the possibility that the pest concerned has been spread to further plants, plant products or other objects by those movements.
3. Where the measures referred to in paragraph 1 concern the introduction into, or movement within, the Union territory of plants, plant products and other objects, the Member State concerned shall immediately notify those measures to the Commission and the other Member States.
4. Private premises of citizens shall not be exempted from the measures, referred to in paragraph 1, and the investigations, referred to in paragraph 2.

Article 17

Establishment of restricted areas

1. Following the official confirmation referred to in Article 11(1)(a), the competent authority shall immediately establish an area where the measures referred to in that Article are to be taken (hereinafter: ‘restricted area’).

The restricted area shall consist of an infested zone, as provided for in paragraph 2, and a buffer zone, as provided for in paragraph 3.

2. The infested zone shall contain:

- (a) all plants known to be infested by the pest concerned;

Tuesday 15 April 2014

- (b) all plants showing signs or symptoms indicating possible infestation by that pest;
- (c) all other plants liable to be infested by that pest due to their susceptibility to that pest and their close proximity to infested plants, or common source of production, if known, with infested plants, or plants grown from them.

3. The buffer zone shall be adjacent to the infested zone and shall surround it.

Its size shall be appropriate in view of the risk of the pest concerned spreading out of the infested zone naturally, or by human activities in the infested zone and its surroundings, and shall be decided in accordance with the principles set out in Section 2 of Annex IV on measures and principles for the management of the risks of pests.

However, where any risk of the pest spreading out of the infested zone is sufficiently mitigated through natural or artificial barriers, no buffer zone need be established.

4. By way of derogation from paragraph 1, where upon first sight the competent authority concludes, in view of the nature of the pest concerned and the site where it was found, that the pest concerned can be eliminated immediately, the competent authority may decide not to establish a restricted area.

In that case, it shall carry out a survey to determine whether any further plants or plant products have been infested. On the basis of that survey, the competent authority shall determine whether there is a need to establish a restricted area. The competent authority concerned shall notify to the Commission and the other Member States the conclusions of that survey.

5. Where in accordance with paragraphs 2 and 3 a restricted area is to extend into the territory of another Member State, the Member State where the pest concerned was found to be present shall immediately contact the Member State into whose territory the restricted area is to extend in order to allow that Member State to take all appropriate actions, as referred to in paragraphs 1 to 4.

6. By 31 March of each year, Member States shall notify to the Commission and the other Member States the number and locations of the restricted areas established, the pests concerned, and the respective measures taken during the preceding year.

Article 18

Surveys and modifications of restricted areas, and lifting of restrictions

1. Competent authorities shall ~~annually~~, **on a risk basis and with appropriate frequency**, carry out a survey of each restricted area as regards the development of the presence of the pest concerned. **[Am. 49]**

Those surveys shall be carried out in accordance with the provisions on surveys as set out in Article 21(1) and (2).

2. Where as a result of ~~an annual~~ **the** survey a competent authority finds a presence of the pest concerned in the buffer zone, the Member State concerned shall immediately notify that presence to the Commission and the other Member States specifying that the pest was found present in a buffer zone. **[Am. 50]**

3. Competent authorities shall modify the boundaries of infested zones, buffer zones and restricted areas, where appropriate, in view of the results of the surveys referred to in paragraph 1.

4. Competent authorities may decide to abolish a restricted area and terminate the respective eradication measures, provided that during the surveys referred to in paragraph 1 no presence of the pest concerned has been found in that restricted area for a sufficiently long period **to verify the pest free status**. **[Am. 51]**

5. When deciding on the modifications referred to in paragraph 3 or the abolition of the restricted area referred to in paragraph 4, the competent authority concerned shall at least take into account the biology of the pest and the vector concerned, the presence of host plants, the eco-climatic conditions and the likelihood of the eradication measures having been successful.

Tuesday 15 April 2014

Article 19

Reports on measures taken in accordance with Articles 16, 17 and 18

Member States shall prepare a report on the measures taken in accordance with Articles 16, 17 and 18.

Where those measures are taken by a Member State in an area adjacent to the border with another Member State, that report shall be submitted to the latter Member State.

That report shall be submitted, on request, to the Commission and the other Member States.

Article 20

Amendment of Annex IV

The Commission shall be empowered to adopt delegated acts in accordance with Article 98, amending Section 1 of Annex IV on measures to manage the risks of quarantine pests, as regards the measures targeting prevention and elimination of infestation of cultivated and wild plants, measures targeting consignments of plants, plant products and other objects, measures targeting other pathways for quarantine pests, and amending Section 2 of that Annex on principles for the management of the risks of pests, as regards principles for the management of the risks of pests, taking into account the developments of technical and scientific knowledge **as well as International Standards for Phytosanitary Measures (ISPMs), agreed under the International Plant Protection Convention (IPPC)**. [Am. 52]

Article 21

Surveys on Union quarantine pests and pests provisionally qualifying as Union quarantine pest

1. Member States shall conduct surveys **based on apparent risks**, over specific periods of time, checking for the presence of any Union quarantine pest, and signs or symptoms of any pest provisionally qualifying as Union quarantine pest, pursuant to Section 3 of Annex II, in all areas where that pest was not known to be present. [Am. 53]

2. Those surveys shall consist, at least, of visual examinations by the competent authority, and, where appropriate, collection of samples and performance of tests. They shall be based on sound scientific and technical principles, and shall be carried out at appropriate times with regard to the possibility to detect the pest concerned.

Those surveys shall take account of scientific and technical evidence, and any other appropriate information, concerning the presence of the pests concerned.

3. Member States shall report to the Commission and the other Member States by 30 April of each year the results of the surveys referred to in paragraph 1, which have been carried out in the preceding year.

Article 22

Multi-annual survey programmes and collection of information

1. Member States shall establish multi-annual programmes setting out the content of the surveys to be carried out pursuant to Article 21. Those programmes shall provide for the collection and recording of the scientific and technical evidence and other information as referred to in the second subparagraph of Article 21(2).

Those programmes shall set out the following elements: the specific objective of each survey, its spatial and temporary scope, the pests, plants and commodities targeted, the survey methodology and quality management including a description of the procedures for visual examination, sampling and testing and their technical justification, the timing, frequency and numbers of scheduled visual examinations, samples and tests, the methods of recording of the information collected and their reporting.

The multi-annual programmes shall be for a period of five to seven years.

2. Member States shall notify their multi-annual survey programmes upon their establishment to the Commission and the other Member States.

Tuesday 15 April 2014

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, ~~amending~~ **requiring Member States to amend** or ~~supplementing~~ **supplement** the elements to be covered by the multi-annual survey programmes, as set out in paragraph 1. [Am. 54]

Article 23

Surveys of priority pests

1. For each priority pest, Member States shall annually carry out a separate survey, as set out in Article 21(1). Those surveys shall include a sufficiently high number of visual examinations, sampling and testing, as appropriate for the relevant pests, to ensure, at a high level of probability, their timely detection.
2. Member States shall report to the Commission and the other Member States by 30 April of each year the results of the surveys referred to in paragraph 1, which were carried out in the preceding year.

Article 24

Contingency plans for priority pests

1. Each Member State shall draw up and keep up to date, for each priority pest which is capable of entering into and establishing in its territory, or a part thereof, a separate plan containing information concerning the decision making processes, procedures and protocols to be followed, and resources to be made available, in case of a confirmed or suspected presence of the pest concerned, hereinafter 'the contingency plan'. **Member States shall at an early stage involve all relevant stakeholders in the process drawing up and keeping up to date the contingency plan.** [Am. 55]
2. The contingency plan shall include the following:
 - (a) the roles and responsibilities of the bodies involved in the execution of the plan, in case of a confirmed or suspected presence of the priority pest concerned, the chain of command and procedures for the co-ordination of actions taken by competent authorities, other public authorities, as referred to in Article 3(2) of Regulation (EU) No .../... [number of Regulation of Official Controls], delegated bodies or natural persons involved, as referred to in Article 25(1) of Regulation (EU) No .../... [number of Regulation of Official Controls], laboratories and professional operators, including co-ordination with neighbouring Member States and neighbouring third countries, where appropriate;
 - (b) access of competent authorities to premises of professional operators and of natural persons, where necessary, laboratories, equipment, personnel, external expertise and resources necessary for the rapid and effective eradication or, where appropriate, containment of the priority pest concerned;
 - (c) measures to be taken concerning the information of the Commission, the other Member States, the professional operators concerned and the public, as regards the presence of the priority pest concerned and the measures taken against it, in case a presence of the pest concerned is officially confirmed or suspected;
 - (d) arrangements for recording findings of the presence of the priority pest concerned;
 - (e) the available assessments as set out in Article 6(2), and any assessment of the Member State as regards the risk of the priority pest concerned for its territory;
 - (f) the risk management measures to be implemented as regards the priority pest concerned, in accordance with Section 1 of Annex IV, and the procedures to be followed;
 - (g) principles for the geographical demarcation of restricted areas;
 - (h) protocols describing the methods of visual examinations, sampling and laboratory testing; and
 - (i) principles concerning the training of personnel of the competent authorities.

Tuesday 15 April 2014

Where appropriate, points (a) to (i) shall take the form of instruction manuals.

3. Within one year from the date of the inclusion of the pest concerned in the list of priority pests, Member States shall establish a contingency plan for the priority pest concerned.

Member States shall regularly review and, where appropriate, update their contingency plans.

4. Member States shall communicate their contingency plans to the Commission and to the other Member States on request, **and shall inform all relevant operators.** [Am. 56]

Article 25

Simulation exercises

1. Member States shall carry out simulation exercises concerning the implementation of the contingency plans at intervals set according to the biology of the priority pest concerned and the phytosanitary risk posed by that pest.

Those exercises shall take place with ~~regards~~ **regard** to all priority pests concerned within a reasonable period of time **and with the involvement of the stakeholders concerned.** [Am. 57]

2. As regards priority pests whose presence in one Member state could have impacts for neighbouring Member States, the simulation exercises ~~shall~~ **may** be carried out together by the Member States concerned on the basis of their respective contingency plans. [Am. 58]

Where appropriate, Member States shall carry out those simulation exercises with neighbouring third countries.

3. Member States shall, on request, make available a report on the results of each simulation exercise to the Commission and to the other Member States.

~~4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out:~~

~~(a) the frequencies, contents and format of simulation exercises;~~

~~(b) simulation exercises covering more than one priority pest;~~

~~(c) co-operation between Member States, and of Member States with third countries;~~

~~(d) contents of the reports on simulation exercises provided for in paragraph 3.~~ [Am. 59]

Article 26

Eradication plans for priority pests

1. Where the presence of a **one or more** priority pest ~~pests~~ is officially confirmed in the territory of a Member State pursuant to Article 11(1)(a), the competent authority, **after consulting the operators concerned**, shall immediately adopt a plan setting out the measures for the eradication of the pest(s) concerned, as provided for in Articles 16, 17 and 18, and a time schedule for the application of those measures. That plan is referred to as the 'eradication plan'. [Am. 60]

The eradication plan shall include a description of the design and organisation of the surveys to be carried out and set out the number of visual examinations, samples to be taken and laboratory tests to be carried out.

2. Member States shall notify, on request, to the Commission and the other Member States the eradication plans and an annual report on the measures taken in accordance with Articles 16, 17 and 18 under the eradication plans concerned.

Tuesday 15 April 2014

Article 27

Union measures for specific Union quarantine pests

1. The Commission ~~may, by means of implementing acts, set~~ **shall be empowered to adopt delegated acts in accordance with Article 98 setting** out measures against specific Union quarantine pests. Those measures shall implement, specifically for each of the pest(s) concerned, one or more of the following provisions: **[Am. 61]**

- (a) Article 10 concerning measures in case of suspicion of the presence of a Union quarantine pest;
- (b) Article 15 concerning measures to be taken immediately by professional operators;
- (c) Article 16 concerning eradication of Union quarantine pests;
- (d) Article 17 concerning establishment of restricted areas;
- (e) Article 18 concerning surveys, modifications of restricted areas and lifting of restrictions;
- (f) Article 21 concerning surveys on Union quarantine pests and pests provisionally qualifying as Union quarantine pest;
- (g) Article 23 concerning surveys for priority pests, as regards the number of visual examinations, samples and tests for particular priority pests;
- (h) Article 24 concerning contingency plans for priority pests;
- (i) Article 25 concerning simulation exercises;
- (j) Article 26 concerning eradication plans for priority pests.

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).~~ **[Am. 62]**

2. Where, as regards a restricted area, the Commission concludes, on the basis of the surveys referred to in Article 18 or other evidence, that the eradication of the Union quarantine pest concerned is not possible, the Commission ~~may~~ **shall be empowered to** adopt ~~implementing delegated~~ acts, as referred to in paragraph 1, which ~~set~~ **in accordance with Article 98, setting** out measures with the single purpose of prevention of the spread of those pests out of the areas concerned. Such prevention is referred to as 'containment'. **[Am. 63]**

3. In case the Commission concludes that prevention measures in locations outside restricted areas are necessary to protect the part of the Union territory where the Union quarantine pest concerned is not present, the Commission ~~may~~ **shall be empowered to** adopt ~~implementing delegated~~ acts, as referred to in paragraph 1 **in accordance with Article 98,** setting out such measures. **[Am. 64]**

4. The measures referred to in paragraphs 1, 2 and 3 shall be taken in accordance with Annex IV on measures and principles for the management of the risks of pests, taking into account the specific risks of the Union quarantine pests concerned and the need to implement the necessary risk mitigation measures in a harmonised manner at Union level.

5. The ~~implementing delegated~~ acts referred to in paragraph 1 may provide that the measures, referred to in points (a) to (j) of paragraph 1, taken by the Member States are to be repealed or amended. Until a measure has been adopted by the Commission, the Member State may maintain the measures that it has employed. **[Am. 65]**

6. ~~On duly justified imperative grounds of urgency to address~~ **Where in the case of** a serious phytosanitary risk, ~~the Commission imperative grounds of urgency so require, the procedure provided for in Article 98(a) shall adopt immediately applicable implementing~~ **apply to delegated** acts ~~in accordance with the procedure referred to in Article 99(4)~~ **adopted pursuant to this Article.** **[Am. 66]**

7. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States of any cases of non-compliance by professional operators with the measures adopted pursuant to this Article.

Tuesday 15 April 2014

Article 28

Measures by Member States concerning pests not listed as Union quarantine pests

1. Where the presence of a pest that is not included in the list of Union quarantine pests in the territory of a Member State is officially confirmed, and the competent authority concerned considers that that pest may fulfil the conditions for inclusion in the list of Union quarantine pests, it shall immediately assess whether that pest fulfils the criteria of Subsection 1 of Section 3 of Annex II. If it concludes that those criteria are fulfilled, it shall immediately take eradication measures in accordance with Annex IV on measures and principles for the management of the risks of pests. Articles 16 to 19 shall apply.

Where a competent authority suspects the presence in its territory of a pest fulfilling the criteria referred to in the first subparagraph, Article 10 shall apply accordingly.

2. Following the actions referred to in paragraph 1, the Member State shall assess whether the pest concerned fulfils, as regards the Union territory, the criteria for quarantine pests set out in Section 1 of Annex II.

3. The Member State concerned shall immediately notify to the Commission and the other Member States the presence of that pest, the assessment referred to in paragraph 1, the measures taken and the evidence justifying those measures.

It shall notify to the Commission the results of the assessment referred to in paragraph 2 within 24 months of the official confirmation of the presence of that pest.

Notifications of the presence of that pest shall be submitted through the electronic notification system referred to in Article 97.

Article 29

Measures by the Union concerning pests not listed as Union quarantine pests

1. Where the Commission receives the notification referred to in the first subparagraph of Article 28(3), or has other evidence concerning the presence in, or imminent danger of entry into, the Union territory of a pest which is not included in the list of Union quarantine pests and it considers that that pest may fulfil the conditions for inclusion in that list, it shall immediately assess whether, as regards the Union territory, that pest fulfils the criteria of Subsection 2 of Section 3 of Annex II.

Where it concludes that those criteria are fulfilled, it shall immediately, by means of implementing acts, adopt measures for a limited time as regards the phytosanitary risks posed by that pest. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

Those measures shall implement, specifically for each of the pests concerned, one or more of the provisions referred to in Article 27(1)(a) to (f).

2. Where the Commission concludes, on the basis of surveys referred to in Article 18 and in Article 21, or other evidence, that the eradication of the pest concerned is not possible in certain restricted areas, the implementing acts referred to in the second subparagraph of paragraph 1 may set out measures with the single purpose to contain that pest.

3. In case the Commission concludes that prevention measures in locations outside restricted areas are necessary to protect the part of the Union territory where the pest concerned is not present, the implementing acts referred to in paragraph 1 may set out such measures.

4. The measures referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with Section 1 of Annex IV on measures to manage the risks of quarantine pests and Section 2 of that Annex on principles for the management of the risks of pests, taking into account the specific risks of the pests concerned and the need to implement the necessary risk mitigation measures in a harmonised manner at Union level.

Tuesday 15 April 2014

5. The implementing acts referred to in paragraph 1 may provide that the measures taken by the Member States pursuant to Article 28 are to be repealed or amended. Until a measure has been adopted by the Commission, the Member State may maintain the measures that it has employed.
6. On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 99(4).
7. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States of any cases of non-compliance by professional operators with the measures adopted pursuant to this Article.

Article 30

Amendment of Section 3 of Annex II

The Commission shall be empowered to adopt delegated acts in accordance with Article 98 amending Section 3 of Annex II on criteria to be fulfilled by pests, as provided for in Articles 28 and 29, as regards the criteria concerning the identity of the pest, its presence, the probability of its entry, establishment and spread, its potential economic, social and environmental impact, taking into account the developments of technical and scientific knowledge **and international standards**. [Am. 67]

~~Article 31~~

~~More stringent requirements adopted by Member States~~

~~1. Member States may apply within their territories more stringent measures than the measures adopted pursuant to Article 27(1), (2) and (3) and Article 29(1), (2) and (3), if justified by the objective of phytosanitary protection and in accordance with Section 2 of Annex IV on measures and principles for the management of the risks of pests.~~

~~Those measures shall not impose, or result in, any prohibitions or restrictions on the introduction into, or movement within, the Union territory of plants, plant products and other objects, other than those imposed by the provisions of Articles 40 to 54 and the provisions of Articles 67 to 96.~~

~~2. Member States shall immediately notify the Commission and the other Member States of measures adopted by them within the ambit of paragraph 1.~~

~~Member States shall, on request, submit to the Commission and the other Member States an annual report on the measures taken in accordance with paragraph 1. [Am. 68]~~

Section 3

Protected zone quarantine pests

Article 32

Recognition of protected zones

1. Where a quarantine pest is present in the Union territory but not present in the Member State concerned, and is not a Union quarantine pest, the Commission may, upon application of that Member State pursuant to paragraph 4, recognise the territory of that Member State as a protected zone in accordance with paragraph 3.

Where a protected zone quarantine pest is absent from a part of the territory of a Member State the same shall apply with respect to that part.

Such a quarantine pest is referred to as 'a protected zone quarantine pest'.

Tuesday 15 April 2014

2. A protected zone quarantine pest shall not be introduced into or moved within the respective protected zone.

Nobody shall intentionally take an action which contributes to the introduction into, and establishment and spread within, a protected zone of the respective protected zone quarantine pest.

3. The Commission shall, by means of an implementing act, establish a list of protected zones and the respective protected zone quarantine pests. That list shall include the protected zones recognised in accordance with the first subparagraph of Article 2(1)(h) of Directive 2000/29/EC and the respective pests, listed in Part B of Annex I and Part B of Annex II to Directive 2000/29/EC. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

The Commission may recognise additional protected zones, by amending the implementing act referred to in the first subparagraph, where the conditions provided for in paragraph 1 are fulfilled. Such an amendment shall be adopted in accordance with the examination procedure referred to in Article 99(3). The same procedure shall apply to a repeal or replacement of the implementing act referred to in the first subparagraph.

Where Article 35 applies, an implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

4. With the application referred to in paragraph 1, the Member State concerned shall submit:
 - (a) a description of the boundaries of the protected zone concerned, including maps; and
 - (b) the results of surveys showing that during the three years preceding the application, the quarantine pest concerned was not present in the territory concerned.

Those surveys shall have been carried out at appropriate times and have been of appropriate intensity with regard to the possibility to detect the presence of the quarantine pest concerned. They shall have been based on sound scientific and technical principles.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones.

Article 33

General obligations concerning protected zones

1. With regard to a protected zone, the obligations set out in the following Articles shall apply accordingly to the protected zone quarantine pests:
 - (a) Articles 9 to 12 concerning the confirmation, notification and information as regards the presence of Union quarantine pests;
 - (b) Article 15 concerning measures to be taken immediately by professional operators;
 - (c) Articles 16, 17 and 18 concerning the eradication of Union quarantine pests, the establishment and modification of restricted areas and surveys in those restricted areas.
2. A plant, plant product or other object originating in a restricted area established, in accordance with Article 17, in a protected zone for the protected zone quarantine pest concerned, may not be moved within or into any protected zone established for that protected zone quarantine pest. When moved out of the protected zone concerned, that plant, plant product or other object shall be packed and moved in such a way that there is no risk of spreading the respective protected zone quarantine pest within that protected zone.
3. The restricted areas established within a protected zone and the eradication measures taken in those areas pursuant to Articles 16, 17 and 18 shall be immediately notified to the Commission and the other Member States.

Tuesday 15 April 2014

Article 34

Surveys on protected zone quarantine pests

1. The competent authority shall carry out an annual survey of each protected zone as regards the presence of the protected zone quarantine pest concerned. Those surveys shall be carried out at appropriate times and be of an appropriate intensity with regard to the possibility to detect the presence of the protected zone quarantine pest concerned. They shall be based on sound scientific and technical principles.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down detailed rules for those surveys to be carried out to confirm that the protected zones continue to fulfil the conditions set out in Article 32(1).

2. Member States shall notify the Commission and the other Member States, by 30 April of each year, of the results of the surveys referred to in paragraph 1, which have been carried out in the preceding year.

Article 35

Amendment and revocation of the protected zones

1. The Commission may amend the size of the protected zone on application by the Member State whose territory is concerned.

Where the Commission amends the protected zone, the Member State concerned shall notify the Commission, the other Member States and, via the internet, the professional operators of the amendment to that protected zone, including maps.

Where that amendment concerns the extension of a protected zone, Articles 32, 33 and 34 shall apply.

2. On application by the Member State referred to in paragraph 1, the Commission shall revoke the recognition of a protected zone or shall reduce its size.

3. The Commission shall revoke the recognition of a protected zone in case the surveys referred to in Article 34 have not been carried out in accordance with that Article.

4. The Commission shall revoke the recognition of a protected zone, in case the respective protected zone quarantine pest has been found to be present in that zone and one of the following conditions is fulfilled:

- (a) no restricted area has been designated, in accordance with Article 33(1), within three months after the presence of that pest was confirmed;
- (b) the eradication measures taken in a restricted area pursuant to Article 33(1) have not been successful within 24 months after the presence of that pest was confirmed;
- (c) information at the disposal of the Commission demonstrates, with regard to the application of measures pursuant, by virtue of Article 33(1)(c), to Articles 16, 17 and 18, negligent reaction to the presence of that pest in the concerned protected zone.

Chapter III

Union quality pests

Article 36

Definition of Union quality pests

A pest shall be referred to as a 'Union quality pest' if it fulfils **all of** the following conditions and it is included in the list referred to in Article 37: [**Am. 69**]

- (a) its identity is established in accordance with point (1) of Section 4 of Annex II;

Tuesday 15 April 2014

- (b) it is present in the Union territory;
- (c) it is no Union quarantine pest;
- (d) it is transmitted mainly through specific plants for planting, in accordance with point (2) of Section 4 of Annex II;
- (e) its presence on those plants for planting has an unacceptable economic impact, as regards the intended use of those plants for planting, in accordance with point (3) of Section 4 of Annex II.
- (f) ~~feasible and effective measures are available to prevent its presence on the plants for planting concerned.~~ [Am. 70]

Article 37

Prohibition of the introduction and movement of Union quality pests on plants for planting

1. A Union quality pest shall not be introduced into or moved within the Union territory on the plants for planting through which it is transmitted, as specified in the list referred to in paragraph 2.
2. ~~The Commission shall, by means of an implementing act, establish~~ A list setting out the Union quality pests and the specific plants for planting, as referred to in Article 36(d), where appropriate with the categories referred to in paragraph 4 and thresholds referred to in paragraph 5 **is laid down in Annex Ic.** [Am. 71]

~~That list shall include the pests, and the respective plants for planting, as set out in the following acts:~~

- (a) ~~Section II of Part A of Annex II of Directive 2000/29/EC;~~
- (b) ~~points (3) and (6) of Annex I to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed⁽¹⁾ and point (3) of Annex II thereto;~~
- (c) ~~the Annex of Commission Directive 93/48/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by fruit plant propagating material and fruit plants intended for fruit production, pursuant to Council Directive 92/34/EEC⁽²⁾;~~
- (d) ~~the Annex of Commission Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC⁽³⁾;~~
- (e) ~~point (b) of Annex II to Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed⁽⁴⁾;~~
- (f) ~~point (6) of Annex I to Council Directive 2002/56/EC⁽⁵⁾ of 13 June 2002 on the marketing of seed potatoes and point B of Annex II thereto;~~
- (g) ~~point (4) of Annex I to Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants⁽⁶⁾ and point (5) of Annex II thereto.~~ [Am. 72]

~~That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).~~ [Am. 73]

3. The Commission shall ~~amend the implementing act referred to in paragraph 2~~ **be empowered to adopt delegated acts in accordance with Article 98 concerning the amendment of Annex Ic**, where an assessment shows that a pest not listed in that Annex fulfils the conditions referred to in Article 36, a pest listed in that ~~implementing act~~ **Annex** no longer fulfils one or more of those conditions or where amendments to that list are necessary, as regards categories referred to in paragraph 4 or thresholds referred to in paragraph 5. **Prior to adopting such delegated acts, the Commission shall consult stakeholders.** [Am. 74]

⁽¹⁾ OJ L 125, 11.7.1966, p. 2309.

⁽²⁾ OJ L 250, 7.10.1993, p. 1.

⁽³⁾ OJ L 250, 7.10.1993, p. 9.

⁽⁴⁾ OJ L 193, 20.7.2002, p. 33.

⁽⁵⁾ OJ L 193, 20.7.2002, p. 60.

⁽⁶⁾ OJ L 193, 20.7.2002, p. 74.

Tuesday 15 April 2014

The Commission shall make that assessment available to the Member States **without delay**. [Am. 75]

4. Where Article 36(e) is only fulfilled for one or more of the categories referred to in Article 12(1) of Regulation (EU) No .../.... [number of Regulation on plant reproductive material law], the list referred to in paragraph 1 shall set out those categories stating that the prohibition of introduction and movement provided for in paragraph 1 only applies to those categories.

5. Where Article 36(e) is only fulfilled if the pest concerned is present above a certain threshold, the list referred to in paragraph 1 shall set out that threshold stating that the prohibition of introduction and movement provided for in paragraph 1 only applies above that threshold.

A threshold shall only be set if the following points are fulfilled:

- (a) it is possible to ensure by measures taken by the professional operator that the presence of that Union quality pest on those plants for planting does not exceed that threshold; and
- (b) it is possible to verify whether that threshold is not exceeded in lots of those plants for planting.

The principles for the management of the risk of pests set out in Section 2 of Annex IV shall apply.

~~6. For amendments to the implementing act referred to in paragraph 2 which are necessary to adapt that implementing act in view of changes to the scientific name of a pest, the advisory procedure referred to in Article 99(2) shall apply.~~

~~All other amendments to the implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 99(3). The same procedure shall apply to a repeal or a replacement of the implementing act referred to in paragraph 2. [Am. 76]~~

Article 38

Amendment of Section 4 of Annex II

The Commission shall be empowered to adopt delegated acts in accordance with Article 98 amending Section 4 of Annex II on criteria to identify pests which qualify as a Union quality pest, as regards the criteria concerning the identity of the pest, its relevance, the probability of its spread, its potential economic, social and environmental impact, taking account of the developments of technical and scientific knowledge **and international standards**. [Am. 77]

Article 39

Union quality pests used for scientific purposes, trials, varietal selections, breeding or exhibitions

The prohibition provided for in Article 37 shall not apply to Union quality pests present on the plants for planting concerned, and used for scientific purposes, trials, varietal selections, breeding or exhibitions.

Chapter IV

Measures concerning plants, plant products and other objects

Section 1

Measures relating to the entire Union territory

Article 40

Prohibition of introduction of plants, plant products and other objects into the Union territory

1. The Commission shall adopt an implementing act, containing the plants, plant products and other objects, and the prohibitions and the third countries concerned, as set out in Part A of Annex III to Directive 2000/29/EC.

Tuesday 15 April 2014

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

In the list established by that implementing act, the plants, plant products and other objects shall be identified by their respective code in accordance with the classification in the Combined Nomenclature as laid down in Council Regulation (EEC) No 2658/87⁽¹⁾ (hereinafter: 'CN code').

2. In case a plant, plant product or other object, originating in or being dispatched from a third country, poses a phytosanitary risk of an unacceptable level by its likelihood to host a Union quarantine pest, and that risk cannot be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures and principles for the management of the risks of pests, the Commission shall amend, as appropriate, the implementing act referred to in paragraph 1, to include in it that plant, plant product or other object and the third countries, concerned.

In case a plant, plant product or other object included in that implementing act does not pose a phytosanitary risk of an unacceptable level, or it poses such a risk but that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures to manage the risks and pathways of quarantine pests, the Commission shall amend that implementing act, as appropriate.

The acceptability of the level of that phytosanitary risk shall be assessed in accordance with the principles set out in Section 2 of Annex IV on principles for the management of the risks of pests. Where appropriate, the acceptability of that level of phytosanitary risk shall be assessed with regards to one or more specific third countries.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt those amendments by immediately applicable implementing acts, in accordance with the procedure referred to in Article 99(4).

3. A plant, plant product or other object listed in the implementing act provided for in paragraph 1 shall not be introduced into the Union territory from the third country, concerned by that listing.

4. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where plants, plant products or other objects have been introduced into the Union territory in violation of paragraph 3.

The third country from which the plants, plant products or other objects were introduced into the Union territory shall be notified.

Article 41

Plants, plant products and other objects subject to special and equivalent requirements

1. The Commission shall adopt an implementing act, containing the plants, plant products and other objects, and the requirements and, where applicable, the third countries concerned, as set out in Part A of Annex IV to Directive 2000/29/EC.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

In the list established by that implementing act, those plants, plant products and other objects shall be identified by their respective CN code.

2. In case a plant, plant product or other object poses a phytosanitary risk of an unacceptable level by its likelihood to host a Union quarantine pest, and that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures and principles for the management of the risks of pests, the Commission shall amend the implementing act referred to in paragraph 1, to include in it that plant, plant product or other object and the measures to be applied to it. Those measures, and the requirements referred to in paragraph 1, are hereinafter referred to as 'special requirements'.

⁽¹⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

Tuesday 15 April 2014

Those measures may take the form of specific requirements, adopted in accordance with Article 42(1), for the introduction into the Union territory of particular plants, plant products or other objects, which are equivalent to special requirements for the movement of those plants, plant products or other objects within the Union territory (hereinafter: 'equivalent requirements').

In case a plant, plant product or other object included in that implementing act does not pose a phytosanitary risk of an unacceptable level, or it poses such a risk but that risk cannot be reduced to an acceptable level by the special requirements, the Commission shall amend that implementing act.

The acceptability of the level of that phytosanitary risk shall be assessed, and the measures to reduce that risk to an acceptable level shall be adopted, in accordance with the principles set out in Section 2 of Annex IV on principles for the management of the risks of pests. Where appropriate, the acceptability of that level of phytosanitary risk shall be assessed, and those measures shall be adopted, with regards to one or more specific third countries or parts thereof.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 99(4).

3. A plant, plant product or other object listed in the implementing act provided for in paragraph 1 may only be introduced into, or moved within, the Union territory if the special requirements, or equivalent requirements, are fulfilled.

4. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where plants, plant products or other objects have been introduced into, or moved within, the Union territory in violation of paragraph 3.

Where applicable, the third country from which the plants, plant products or other objects were introduced into the Union territory shall also be notified.

Article 42

Setting out of equivalent requirements

1. Equivalent requirements, as referred to in the second subparagraph of Article 41(2) shall be set out, by means of an implementing act, on request of a particular third country, if all of the following conditions are fulfilled:

- (a) the third country concerned ensures, through the application under its official control of one or more specified measures, a level of phytosanitary protection which is equivalent to the special requirements adopted pursuant to Article 41(1) and (2) in respect of the movement within the Union territory of plants, plant products and other objects concerned;
- (b) the third country concerned objectively demonstrates to the Commission that the specified measures referred to in point (a) achieve the level of phytosanitary protection referred to in that point.

2. Where appropriate, the Commission shall investigate, in the third country concerned, and in accordance with Article 119 of the Regulation (EU) No .../... [*number of Regulation on Official Controls*], whether points (a) and (b) are fulfilled.

3. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 99(3).

Article 43

Information to be provided to travellers, clients of postal services and internet clients

1. **The Commission**, Member States and international transport operators shall make information available to passengers concerning the prohibitions, set out pursuant to Article 40(3), the requirements, set out pursuant to Articles 41(1) and 42(2), and the exemptions, set out pursuant to Article 70(2), as regards the introduction of plants, plant products and other objects into the Union territory. [**Am. 86**]

Tuesday 15 April 2014

That information ~~shall~~ **may** be provided in the form of posters or brochures, which, where appropriate, shall be made available through the internet. [Am. 87]

Where that information is made available to passengers at seaports and airports, it shall be provided in the form of posters.

The Commission shall be empowered to adopt an implementing act, setting out those posters and brochures. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

2. The information referred to in paragraph 1 shall be made available by postal services, and by professional operators involved in sales through distance contracts, to their clients through the internet.

3. Member States shall ~~annually~~ **biennially** submit to the Commission a report summarising the information provided pursuant to this Article. [Am. 88]

Article 44

Exception from prohibitions and requirements for frontier zones

1. By way of derogation from Articles 40(3) and 41(3), Member States may authorise the introduction of plants, plant products and other objects into the Union territory, where the plants, plant products and other objects fulfil the following conditions:

- (a) they are grown or produced in areas of third countries in the vicinity of their **land** border with Member States (hereinafter: 'third country frontier zones'); [Am. 89]
- (b) they are introduced into areas of Member States immediately across that border (hereinafter: 'Member State frontier zones');
- (c) they are to be processed in the respective Member State frontier zones in such a manner that any phytosanitary risk is eliminated;
- (d) they do not pose any risk of spreading quarantine pests caused by movements within the frontier zone.

Those plants, plant products and other objects shall only move into and within the Member State frontier zones, and only under the official control of the competent authority.

2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out the following:

- (a) the maximum width of third country frontier zones and Member State frontier zones, as appropriate for the specific plants, plant products and other objects individually;
- (b) the maximum distance of the movement of the plants, plant products and other objects concerned within the third country frontier zones and Member State frontier zones; and
- (c) the procedures concerning the authorisation of the introduction into, and movement within, the Member State frontier zones of plants, plant products and other objects referred to in paragraph 1.

The width of those zones shall be such to ensure that the introduction and movement of those plants, plant products and other objects in the Union territory does not pose any phytosanitary risks to the Union territory or parts of it.

3. The Commission may lay down, by means of implementing acts, specific conditions or measures concerning the introduction into Member State frontier zones of particular plants, plant products and other objects, and specific third countries, which are subject to this Article.

Tuesday 15 April 2014

Those acts shall be adopted in accordance with Section 1 of Annex IV on measures to manage the risks of quarantine pests and Section 2 of that Annex on principles for the management of the risks of pests, taking into account the scientific and technical developments.

Those implementing acts shall be adopted, and as appropriate repealed or replaced, in accordance with the examination procedure referred to in Article 99(3).

4. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States where plants, plant products or other objects have been introduced into, or moved within, the frontier zones as referred to in paragraphs 1 and 2 in violation of those paragraphs.

The third country from which the plants, plant products or other objects were introduced into the frontier zone concerned shall also be notified.

Article 45

~~Exception from prohibitions and~~ Requirements for phytosanitary transit [Am. 90]

1. By way of derogation from Article 40(3) and Article 41(3), Member States may authorise the introduction of plants, plant products and other objects into, and their passing through, the Union territory to a third country (hereinafter 'phytosanitary transit'), where those plants, plant products and other objects fulfil the following conditions:

- (a) they are accompanied by a signed declaration of the professional operator in control of those plants, plant products and other objects stating that those plants, plant products or other objects are in phytosanitary transit;
- (b) they are packed and moved in such a way that there is no risk of spreading of Union quarantine pests during their introduction into, and passing through, the Union territory, **using an officially-approved phytosanitary seal that serves to guarantee the original packaging and means of transport (sealed lorry) and prevents the shipment being split up, hence providing official assurance of risk-free phytosanitary transit through the Union;** [Am. 91]
- (c) they are introduced into, passed through and, without delay, moved out of the Union territory under official control by the competent authorities concerned **and under the supervision of customs officers. The competent authority of the Member State where those plants, plant products or other objects are introduced into, or for the first time moved within, the Union territory shall inform the competent authorities of all other Member States through which those plants, plant products or other objects are to be moved prior to being moved out of the Union territory.** [Am. 92]

Plants, plant products and other objects that are in phytosanitary transit through Union territory from one third country to another are required to satisfy the plant health requirements under Article 40 without prejudice to other applicable plant health rules. [Am. 93]

In accordance with subparagraph 1a, where those plants, plant products or other objects are introduced into, or for the first time moved within, the Union territory, the competent authority of the Member State concerned must perform the documentary check on that introduction and shall be responsible for the sealing of goods pursuant to point b of the first subparagraph. [Am. 94]

Similarly, the competent authority of the Member State where the goods in transit are moved out of Union territory shall inform the competent authorities of the Member State into which they were introduced, and the Member State(s) through which they have been moved, of the fact that the goods have been moved out of Union territory. [Am. 95]

~~The competent authority of the Member State where those plants, plant products or other objects are introduced into, or for the first time moved within, the Union territory shall inform the competent authorities of all other Member States through which those plants, plant products or other objects are to be moved prior to being moved out of the Union territory.~~ [Am. 96]

2. Where so stipulated by the acts adopted pursuant to Article 27(1) and (2) and Article 29(1) and (2), this Article shall apply accordingly.

Tuesday 15 April 2014

3. The Commission shall be empowered, in accordance with Article 98, to adopt delegated acts setting out the contents of the declaration referred to in point (a) of paragraph 1.

4. The Commission may, by means of implementing acts, adopt format specifications for the declaration referred to in point (a) of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

5. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States where plants, plant products or other objects have been introduced into, or moved within, the Union territory as referred to in paragraph 1 in violation of the provisions of that paragraph.

The third country from which the plants, plant products or other objects were introduced into the Union territory shall also be notified.

Article 46

Plants, plant products and other objects used for scientific purposes, trials, varietal selection, breeding and exhibitions

1. By way of derogation from Articles 40(3) and 41(3), Member States may, on application, authorise the introduction into, and the movement within, their territory of plants, plant products and other objects used for scientific purposes, trials, varietal selection, breeding and exhibitions, if all of the following requirements are fulfilled:

- (a) the presence of the plants, plant products or other objects concerned does not cause an unacceptable risk of the spread of a Union quarantine pest if adequate restrictions are imposed;
- (b) the storage facilities in which those plants, plant products or other objects are to be kept and the quarantine stations, as referred to in Article 56, in which they are to be used are appropriate;
- (c) the scientific and technical qualifications of the personnel by whom the activity involving those plants, plant products or other objects is to be carried out are appropriate.

2. The competent authority shall assess the risk of the spread of Union quarantine pests by the plants, plant products or other objects concerned, as referred to in paragraph 1(a), taking into account the identity, biology and means of dispersal of the Union quarantine pests concerned, the activity envisaged, the interaction with the environment and other relevant factors relating to the risk posed by those plants, plant products or other objects.

It shall assess the storage facilities in which those plants, plant products or other objects are to be kept, as referred to in paragraph 1(b), and the scientific and technical qualifications of the personnel by whom the activity involving those plants, plant products or other objects is to be carried out, as referred to in paragraph 1(c).

On the basis of those assessments the competent authority shall authorise the introduction of those plants, plant products or other objects into, or their movement within, the Union territory if the requirements set out in paragraph 1 are fulfilled.

3. Where an authorisation is granted, it shall include all of the following conditions:

- (a) the plants, plant products or other objects concerned are to be kept in storage facilities found to be appropriate by the competent authorities and referred to in the authorisation;
- (b) the activity involving those plants, plant products or other objects is to be carried out in a quarantine station designated in accordance with Article 56 by the competent authority and referred to in the authorisation;
- (c) the activity involving those plants, plant products or other objects is to be carried out by personnel whose scientific and technical qualifications are found to be appropriate by the competent authority and referred to in the authorisation;
- (d) those plants, plant products or other objects are to be accompanied by the authorisation when introduced into or moved within the Union territory.

Tuesday 15 April 2014

4. The authorisation shall be limited to the amount that is adequate for the activity concerned and shall not exceed the capacity of the designated quarantine station.

It shall include the restrictions necessary to adequately mitigate the risk of the spread of the Union quarantine pests concerned.

5. The competent authority shall monitor compliance with the conditions referred to in paragraph 3 and the limitation and the restrictions referred to in paragraph 4 and take the necessary action in case those conditions, that limitation or those restrictions are not complied with.

6. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, laying down detailed rules concerning:

- (a) the exchange of information between Member States and the Commission concerning the introduction into, and movement within, the Union territory of the plants, plant products and other objects concerned;
- (b) the assessments and authorisation referred to in paragraph 2; and
- (c) the monitoring of compliance, the action in case of non-compliance and notification thereof, as referred to in paragraph 5.

7. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States where plants, plant products or other objects have been introduced into, or moved within, the Union territory in violation of the provisions of paragraphs 1 to 4.

Where applicable, those notifications shall also include the measures taken by the Member States on the plants, plant products and other objects concerned, and the whether the introduction into, or movement within, the Union territory of those plant, plant products or other objects has been allowed after the implementation of those measures.

Where applicable, the third country from which the plants, plant products or other objects were introduced into the Union territory shall also be notified.

Member States shall ~~annually~~ **biennially** submit to the Commission a report summarising the relevant information on the authorisations granted pursuant to paragraph 1 and the results of the monitoring referred to in paragraph 5. [Am. 97]

Article 47

Temporary measures concerning plants for planting

1. The Commission may adopt, by means of implementing acts, temporary measures as regards the introduction into, and movement within, the Union territory of plants ~~for planting~~, **plant products and other objects** from third countries, where the following conditions are fulfilled: [Am. 138]

- (a) there is no or little phytosanitary experience as regards trade in the plants ~~for planting~~, **plant products and other objects** concerned originating in or dispatched from the third country concerned; [Am. 139]
- (b) no assessment has been carried out as regards the phytosanitary risks for the Union territory in respect of those plants ~~for planting~~, **plant products and other objects** from the third country concerned; [Am. 140]
- (c) those plants ~~for planting~~, **plant products and other objects** are likely to pose phytosanitary risks which are not linked, or cannot yet be linked, to Union quarantine pests listed pursuant to Article 5(2) and (3) or pests for which measures have been adopted pursuant to Article 29. [Am. 141]

Tuesday 15 April 2014

Those implementing acts shall be adopted, and as appropriate repealed or replaced, in accordance with the examination procedure referred to in Article 99(3).

2. The temporary measures referred to in paragraph 1 shall be adopted in accordance with Annex III on elements to identify plants ~~for planting~~, **plant products and other objects** which pose phytosanitary risks for the Union territory and Section 2 of Annex IV on principles for the management of the risks of pests. [Am. 142]

Those measures shall provide for one of the following, as necessary in the case concerned:

- (a) intensive sampling, at the point of introduction, of each lot of plants ~~for planting~~, **plant products and other objects** introduced into the Union territory and testing of samples; [Am. 143]
- (b) where absence of the phytosanitary risk cannot be ensured by intensive sampling and testing at the introduction of the plants ~~for planting~~, **plant products and other objects** concerned into the Union territory, a quarantine period to verify the absence of that phytosanitary risk in those plants ~~for planting~~, **plant products and other objects**; [Am. 144]
- (c) where absence of the phytosanitary risk cannot be ensured by intensive sampling and testing at the introduction of the plants ~~for planting~~, **plant products and other objects** concerned into the Union territory and a quarantine period, prohibition of the introduction of those plants ~~for planting~~, **plant products and other objects** into the Union territory. [Am. 145]

3. The measures referred to in paragraph 1 shall apply for a maximum of ~~two~~ **five** years. This period may be prolonged once for a maximum of ~~two~~ **five** years. [Am. 146]

4. On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 99(4).

5. By way of derogation from the measures adopted pursuant to paragraph 1, Article 46 shall apply to the introduction into, and the movement within, the Union territory of plants for planting used for scientific purposes, trials, varietal selection, breeding and exhibitions.

6. Member States shall notify the Commission and the other Member States where a plant, plant product or other object has been subject to the measures referred to in points (a) or (b) of paragraph 2.

Member States shall notify the Commission and the other Member States where, following the application of the measures referred to in points (a) or (b) of paragraph 2, a pest has been found which is likely to pose new phytosanitary risks.

Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and the other Member States where the introduction of a plant, plant product or other object into the Union territory was refused, or its movement within the Union territory prohibited, because the Member State concerned considered that the prohibition referred to in point (c) of paragraph 2 was violated. Where applicable, those notifications shall include the measures taken by the Member States on the plants, plant products and other objects concerned pursuant to Article 64(3) of Regulation (EU) No .../... [number of Regulation on Official Controls].

Where applicable, the third country from which the plants, plant products or other objects were dispatched for introduction into the Union territory shall also be notified.

Tuesday 15 April 2014

Article 47a

By ... (*), the Commission shall present a report to the European Parliament and the Council, including a cost-benefit analysis, on the enforcement and effectiveness of measures relating to imports into the Union territory, and if appropriate present a legislative proposal. [Am. 98]

Article 48

Amendment of Annex III

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Annex III on elements to identify plants for planting which pose phytosanitary risks for the Union territory, as regards the characteristics and origin of those plants for planting, to adapt to the developments of technical and scientific knowledge **and international standards. [Am. 99]**

Section 2

Measures relating to protected zones

Article 49

Prohibition of introduction of plants, plant products and other objects into protected zones

1. The Commission shall adopt an implementing act, containing the plants, plant products and other objects, and the prohibitions and the protected zones concerned, as set out in Part B of Annex III to Directive 2000/29/EC.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

In the list established by that implementing act, the plants, plant products and other objects shall be identified by their respective CN code.

2. In case a plant, plant product or other object, coming from outside the protected zone concerned, poses a phytosanitary risk of an unacceptable level by its likelihood to host a protected zone quarantine pest, and that risk cannot be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures to manage the risks and pathways of quarantine pests, the Commission shall amend, as appropriate, the implementing act referred to in paragraph 1, to include in it that plant, plant product or other object and the protected zones concerned.

In case a plant, plant product or other object included in that implementing act does not pose a phytosanitary risk of an unacceptable level, or it poses such a risk but that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures to manage the risks and pathways of quarantine pests, the Commission shall amend that implementing act.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

The acceptability of the level of that phytosanitary risk shall be assessed in accordance with the principles set out in Section 2 of Annex II on principles for the management of the risks of pests.

3. A plant, plant product or other object listed in the implementing act provided for in paragraph 1 shall not be introduced into the respective protected zone from the third country, or area of the Union territory, concerned.

4. On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 99(4).

(*) **Five years after the date of entry into force of this Regulation.**

Tuesday 15 April 2014

5. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States of any cases where plants, plant products or other objects have been introduced into, or moved within the protected zone concerned, in violation of the prohibitions adopted pursuant to this Article.

Where applicable, the third country from which the plants, plant products or other objects were introduced into the protected zone concerned shall also be notified.

Article 50

Plants, plant products and other objects subject to special requirements for protected zones

1. The Commission shall adopt an implementing act, containing the plants, plant products and other objects, the respective protected zones and the requirements, as set out in Part B of Annex IV to Directive 2000/29/EC.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2) of this Regulation.

In the list established by that implementing act, the plants, plant products and other objects shall be identified by their respective CN code.

2. In case a plant, plant product or other object, coming from outside the protected zone concerned poses a phytosanitary risk of an unacceptable level for that protected zone by its likelihood to host a protected zone quarantine pest, and that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex IV on measures to manage the risks and pathways of quarantine pests, the Commission shall amend the implementing act referred to in paragraph 1, to include in it that plant, plant product or other object and the measures to be applied to it. Those measures, and the requirements referred to in paragraph 1, are hereinafter referred to as 'special requirements for protected zones'.

In case a plant, plant product or other object included in that implementing act does not pose a phytosanitary risk of an unacceptable level for the protected zone concerned, or it poses such a risk but that risk cannot be reduced to an acceptable level by the special requirements for protected zones, the Commission shall amend that implementing act.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

The acceptability of the level of that phytosanitary risk shall be assessed, and the measures to reduce that risk to an acceptable level shall be adopted, in accordance with the principles set out in Section 2 of Annex II on principles for the management of the risks of pests.

On duly justified imperative grounds of urgency to address a serious phytosanitary risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 99(4).

3. A plant, plant product or other object listed in the implementing act provided for in paragraph 1 may only be introduced into, or moved within, the respective protected zone if the special requirements for protected zones are fulfilled.

4. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where plants, plant products or other objects have been introduced into, or moved within, the protected zone concerned, in violation of the measures adopted pursuant to this Article.

Where applicable, the third country from which the plants, plant products or other objects were introduced into the Union territory shall also be notified.

Article 51

Information to be provided to travellers, clients of postal services and internet clients as regards protected zones

Article 43 concerning information to be provided to travellers, clients of postal services and internet clients shall apply accordingly as regards the introduction of plants, plant products and other objects from third countries into protected zones.

Tuesday 15 April 2014

Article 52

Exception from prohibitions and requirements for frontier zones as regards protected zones

Article 44 concerning the exceptions from prohibitions and requirements for frontier zones shall apply as regards the plants, plant products and other objects listed pursuant to Article 49(1) and (2) and Article 50(1) and (2) with regard to protected zones bordering third country frontier zones.

Article 53

Exception from prohibitions and requirements for phytosanitary transit as regards protected zones

Article 45 concerning the exceptions from prohibitions and requirements for phytosanitary transit shall apply accordingly as regards the plants, plant products and other objects listed pursuant to Article 49(1) and (2) and Article 50(1) and (2) with regard to phytosanitary transit through protected zones.

Article 54

Plants, plant products and other objects used for scientific purposes, trials, varietal selection, breeding and exhibitions as regards protected zones

By way of derogation from the prohibitions and requirements provided for in Articles 49(3) and 50(3), Article 46 shall apply as regards the plants, plant products and other objects listed pursuant to Article 49(1) and (2) and Article 50(1) and (2) with regard to the introduction into and the movement within protected zones of plants, plant products and other objects used for scientific purposes, trials, varietal selection, breeding and exhibitions.

Section 3

Other measures concerning plants, plant products and other objects

Article 55

General requirements for packaging and vehicles

1. Packaging material used for plants, plant products or other objects, referred to in the implementing acts adopted pursuant to Articles 27(1) and (2), 29(1) and (2), 40(1), 41(1) and (2), 47(1), 49(1) and 50(1) and moving into or within the Union territory, shall be free from Union quarantine pests.

The same shall apply to vehicles transporting such plants, plant products and other objects.

2. The packaging material referred to in paragraph 1, other than wood packaging material, shall cover the plants, plant products and other objects concerned in such a way that, during their movement into or within the Union territory, there is no risk of spreading of Union quarantine pests.

The vehicles referred to in paragraph 1 shall, as appropriate, be covered or closed in such a way that, during their movement into or within the Union territory, there is no risk of spreading of Union quarantine pests.

3. Paragraphs 1 and 2 shall apply to protected zones also as regards the respective protected zone quarantine pests.

Article 56

Designation of quarantine stations

1. Member States shall designate in their territory quarantine stations for plants, plant products, other objects and pests, or authorise the use of designated quarantine stations in other Member States, provided that those stations fulfil the requirements set out in paragraph 2.

Tuesday 15 April 2014

The competent authority may, in addition, on request, designate a facility as a quarantine station provided that it fulfils the requirements set out in paragraph 2.

2. Quarantine stations shall meet the following conditions:
 - (a) they provide physical isolation of the plants, plant products and other objects to be kept in quarantine and ensure they cannot be accessed or removed from those stations without consent of the competent authority;
 - (b) where the activities carried out in the quarantine stations concern plants, plant products or other objects, they provide suitable growing or incubation conditions conducive for the development on those plants, plant products and other objects of signs and symptoms of quarantine pests;
 - (c) they have surfaces of smooth and impervious material allowing effective cleaning and decontamination;
 - (d) they have surfaces resistant to deterioration and to attack by insects and other arthropods;
 - (e) they have irrigation, sewage and ventilation systems which exclude the transmission or escaping of quarantine pests;
 - (f) they have systems for sterilisation, decontamination or destruction of infested plants, plant products and other objects, waste and equipment before removal from the stations;
 - (g) they provide for protective clothing and shoe covering;
 - (h) they have, if appropriate, systems for de-contamination of personnel and visitors upon exit of the station;
 - (i) a definition of the tasks of those stations, and the conditions under which they shall carry out those tasks, is available;
 - (j) a sufficient number of suitably qualified, trained and experienced personnel is available.
3. Member States shall communicate a list of the designated quarantine stations in their territory to the Commission and the other Member States upon request.

Article 57

Operation of quarantine stations

1. The person responsible for the quarantine station shall monitor that station and the immediate vicinity of that station for the presence of quarantine pests.

Where such a pest is found to be present, the person responsible for the quarantine station concerned shall take the appropriate action. It shall notify the competent authority of that presence and of that action.

2. The person responsible for the quarantine station shall ensure that personnel and visitors wear protective clothing and shoe covering and, where appropriate, are subject to decontamination upon leaving that station.
3. The person responsible for the quarantine station shall keep records on the following points:
 - (a) the personnel employed;
 - (b) the visitors accessing the station;
 - (c) the plants, plant products and other objects entering and leaving the station;
 - (d) the place of origin of such plants, plant products and other objects;
 - (e) observations concerning the presence of pests on such plants, plant products and other objects.

Those records shall be kept for three years.

Tuesday 15 April 2014

Article 58

Supervision of quarantine stations and revocation of designation

1. The competent authority shall organise audits or inspections of the quarantine stations, at least ~~one per year~~ **once every two years**, to verify whether those stations meet the conditions referred to in Article 56(2) and Article 57. **[Am. 100]**
2. The competent authority shall revoke the designation referred to in Article 56(1) without delay where:
 - (a) following an audit or inspection, it appears that that quarantine station fails to fulfil the conditions referred to in Article 56(2) or Article 57;
 - (b) the person responsible for that quarantine station fails to take appropriate and timely remedial action.

Article 59

Release of plants, plant products and other objects from quarantine stations

1. Plants, plant products and other objects shall only leave the quarantine stations, upon authorisation by the competent authorities, if it is confirmed that they are free from Union quarantine pests, or, where applicable, protected zone quarantine pests.
2. Competent authorities may authorise the movement of plants, plant products and other objects from the quarantine stations to other quarantine stations or to any other locations only if measures are taken to ensure that no Union quarantine pests, or, where applicable, protected zone quarantine pests, are spread in the area concerned.

2a. The Commission shall be encouraged to draft a guidance document to harmonise rules of procedures across Member States and avoid undue delays for the release of plants, plant products and other objects from quarantine stations. That guidance document shall, in particular, give clear indications of when restrictions may be necessary and what risk mitigation measures may be taken. [Am. 101]

Article 60

Movement out of the Union territory

1. Where the movement of a plant, plant product or other object out of the Union is governed by a phytosanitary agreement with a third country, that movement shall comply with that agreement.
2. Where the movement of a plant, plant product or other object out of the Union is not governed by a phytosanitary agreement with a third country, that movement shall take place in accordance with the phytosanitary rules of the third country into which that plant, plant product or other object is to be moved.
3. Where the movement of a plant, plant product or other object out of the Union is neither governed by a phytosanitary agreement with a third country nor by the phytosanitary rules of the third country into which that plant, plant product or other object is to be moved, the requirements for movement of plants, plant products and other objects within the Union territory, as set out in the list referred to in Article 41(1) and (2), shall apply.

Those requirements shall, however, not apply where they concern a pest that fulfils either of the following conditions:

- (a) it is recognised by that third country as being present in its territory and not under official control;
- (b) it can be reasonably assumed that it does not qualify as a quarantine pest with respect to the territory of that third country.

Tuesday 15 April 2014

Chapter V

Registration of professional operators and traceability

Article 61

Official register of professional operators

1. The competent authority shall keep and update a register containing the professional operators who carry out the activities, listed in the second subparagraph, in the territory of the Member State concerned, and are covered by one of the following points:

- (a) they are professional operators whose activities concern plants, plant products or other objects covered by an implementing act provided for in Articles 27(1), (2) or (3), 29(1), (2) or (3), 40(1), 41(1) or (2), 47(1), 49(1) or 50(1), or subject to the provisions of Articles 43(1) or (2), 44(1), 45(1), 51, 52 or 53;
- (b) they are professional operators within the meaning of Article 3(6) of Regulation (EU) No .../... [*number of Regulation on plant reproductive material law*].

This paragraph shall apply as regards the following activities:

- (a) planting;
- (b) growing;
- (c) production;
- (d) introduction into the Union territory;
- (e) movement within the Union territory;
- (f) movement out of the Union territory;
- (g) producing and/or making available on the market in the meaning of Article 3(5) of Regulation (EU) No .../... [*number of Regulation on plant reproductive material law*];
- (h) sales through distance contracts.

That register shall be referred to as 'the register'. Professional operators registered pursuant to points (a) and (b) of the first subparagraph shall be referred to as 'registered operators'.

2. A professional operator may be registered in the register of a competent authority more than once, provided that each registration is linked to different premises, collective warehouses and dispatching centres as referred to in Article 62(2)(d). For each of those registrations, the procedure of Article 62 shall apply.

3. Paragraph 1 shall not apply to a professional operator covered by one or more of the following points:

- (a) it supplies exclusively small, as appropriate to the plants, plant products and other objects concerned, quantities of plants, plant products and other objects to final users, ~~by other means than sales through distance contracts;~~ **[Am. 102]**
- (b) its professional activity concerning plants, plant products and other objects is limited to transporting such plants, plant products or other objects for another professional operator;
- (c) its professional activity exclusively concerns the transport of objects of all kinds using wood packaging material.

Tuesday 15 April 2014

~~The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out one or more of the following:~~

- ~~(a) further categories of professional operators to be exempted from the application of paragraph 1, where that registration would constitute a disproportionate administrative burden for them compared to the phytosanitary risk of their professional activities;~~
- ~~(b) particular requirements for the registration of certain categories of professional operators;~~
- ~~(c) the maximum figure for small quantities of particular plants, plant products or other objects as referred to in point (a) of the first subparagraph. [Am. 103]~~

Article 62

Procedure of registration

1. Professional operators falling within the scope of points (a) or (b) of the first subparagraph of Article 61(1) shall submit an application to the competent authorities for inclusion in the register.
2. That application shall include the following elements:
 - (a) name, address and contact details of the professional operator;
 - (b) a statement concerning the intention of the professional operator to exercise each of the activities referred to in Article 61(1) concerning plants, plant products and other objects;
 - (c) a statement concerning the intention of the professional operator to carry out each of the following activities:
 - (i) issuing of plant passports for plants, plant products and other objects, pursuant to Article 79(1);
 - (ii) placing of the mark on wood packaging material, referred to in Article 91(1);
 - (iii) issuing of any other attestation, as referred to in Article 93(1);
 - (iv) issuing of official labels for plant reproductive material, pursuant to Article 19 of Regulation (EU) No .../....
[*number of Regulation on plant reproductive material law*];
 - (d) address of the premises, collective warehouses and dispatching centres used by the professional operator in the Member State concerned to carry out the activities referred to in Article 61(1) for the purpose of the registration;
 - (e) the genera and species of the plants and plant products, and, where appropriate, nature of other objects, concerned by the activities of the professional operator.
3. The competent authorities shall register a professional operator **without delay** where the application for registration contains the elements of paragraph 2. [Am. 104]
4. Registered professional operators shall, where appropriate, submit an application for updating the data referred to in points (a), (d) and (e) of paragraph 2, and the statements referred to in points (b) and (c) of paragraph 2.
5. Where the competent authority becomes aware that the registered operator does not carry out any more the activities of Article 61(1), or that the registered operator has submitted an application no longer complying with the requirements of paragraph 2, it shall request that operator to comply with those requirements immediately or within a specified period of time.

In case the registered operator does not comply with those requirements within the period of time set by the competent authority, the competent authority shall revoke the registration of that operator.

Tuesday 15 April 2014

Article 63

Content of the register

The register shall contain the elements set out in points (a), (b), (d) and (e) of Article 62(2) and the following elements:

- (a) the official registration number;
- (b) the two-letter code indicated in norm ISO 3166-1-alpha-2 ⁽¹⁾ for the Member State in which the professional operator is registered;
- (c) an indication whether the professional operator is authorised for each of the activities referred to in point (c) of Article 62(2).

Article 64

Availability of information of official registers

1. The Member State keeping the register shall, on request, make the information it contains available to the other Member States or the Commission.
2. The Member State keeping the register shall make available, on request, the information referred to in Article 63, with the exception of points (d) and (e) of Article 62(2), to any professional operator.

Article 65

Traceability

1. A professional operator to which plants, plant products or other objects are supplied that are subject to prohibitions, requirements or conditions pursuant to Articles 40(1), 41(1) and (2), 44(1) and (3), 45(1), 46(1) and (3), 47(1), 49(1) and (2), 50(1) and (2), 52, 53 and 54 shall keep a record for each plant, plant product or other object supplied, allowing that operator to identify the professional operators supplying it.
2. A professional operator supplying plants, plant products or other objects that are subject to prohibitions, requirements or conditions pursuant to Articles 40(1), 41(1) and (2), 44(1) and (3), 45(1), 46(1) and (3), 47(1), 49(1) and (2), 50(1) and (2), 52, 53 and 54 shall keep a record allowing that professional operator to identify, for each plant, plant product or other object it supplied, the professional operators whom it was supplied.
3. Professional operators shall keep the records referred to in paragraphs 1 and 2 for three years from the date on which the plant, plant product or other object concerned was supplied to or by them.
4. On request, they shall communicate the information in the records referred to in paragraphs 1 and 2 to the competent authorities.
5. Paragraphs 1 to 4 shall not apply to the professional operators referred to in point (b) of Article 61(3).

Article 66

Movements of plants, plant products and other objects within the premises of the professional operator

1. Professional operators shall have in place traceability systems and procedures to allow identification of the movements of their plants, plant products and other objects within their own premises.

The first subparagraph shall not apply to the professional operators referred to in point (b) of Article 61(3).

⁽¹⁾ ISO 3166-1:2006, Codes for the representation of names of countries and their subdivisions — Part 1: Country codes. International Organisation for Standardization, Geneva.

Tuesday 15 April 2014

2. The information, as identified by the systems and procedures referred to in paragraph 1, on the movement of the plants, plant products and other objects within those premises shall be made available to the competent authority on request.

Article 66a

Good plant protection practice

A professional operator which supplies or is supplied with plants, plant products or other objects that are subject to prohibitions, requirements or conditions pursuant to Articles 40(1), 41(1) and (2), 44(1) and (3), 45(1), 46(1) and (3), 47(1), 49(1) and (2), 50(1) and (2), 52, 53 or 54 shall follow good plant protection practice in order to prevent the occurrence and spread of pests. The good plant protection practice referred to in paragraph 1 shall consist, in particular, of:

- (a) identifying and monitoring critical points in the production process or in the movement of the plants, plant products and other objects which may affect their phytosanitary quality;*
- (b) ensuring that the competent authorities have access to the facilities, as well as to surveillance data and all related documents;*
- (c) taking measures, where necessary, to ensure that the phytosanitary quality of the plants, plant products and other objects is maintained. [Am. 105]*

Chapter VI

Certification of plants, plant products and other objects

Section 1

Phytosanitary certificates required for the introduction of plants, plant products and other objects into the Union territory

Article 67

Phytosanitary certificate for introduction into the Union territory

1. A phytosanitary certificate for introduction of plants, plant products and other objects into the Union territory shall be a document, issued by a third country, which fulfils the conditions of Article 71, has the contents set out in Part A of Annex V, or, where applicable, Part B of Annex V, and certifies that the plant, plant product or other object concerned complies with all of the following requirements:

- (a) it is free from Union quarantine pests;
- (b) it complies with the provisions of Article 37(1) concerning the presence of Union quality pests on plants for planting;
- (c) it complies with the requirements referred to in Article 41(1) and (2);
- (d) where applicable, it complies with rules adopted in accordance with the provisions adopted pursuant to Article 27(1) and (2) and Article 29(1).

2. Where applicable, the phytosanitary certificate shall specify under the heading 'Additional Declaration', and in accordance with the implementing acts adopted pursuant to Articles 41(1) and (2) and 50(1) and (2), which specific requirement is fulfilled, where there is a choice between several options. This specification shall include **the text of, or** a reference to the relevant option provided in those acts. [Am. 106]

Tuesday 15 April 2014

3. Where applicable, the phytosanitary certificate shall state that the plants, plant products or other objects concerned comply with phytosanitary measures recognised as equivalent, pursuant to Article 42, to the requirements of the implementing act adopted pursuant to Article 41(2).

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Parts A and B of Annex V to adapt them to the scientific and technical developments and the development of international standards.

4a. *Plant health certificates may also be used in accordance with the provisions of Council Regulation (EC) No 338/97⁽¹⁾ or Commission Regulation (EC) No 865/2006⁽²⁾. [Am. 107]*

Article 68

Plants, plant products and other objects for which phytosanitary certificates are required

1. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is required for introduction into the Union territory.

That list shall include:

- (a) the plants, plant products and other objects listed in Point I of Part B of Annex V to Directive 2000/29/EC;
- (b) plants, plant products and other objects for which requirements have been adopted pursuant to Articles 27(1) and 29(1) concerning their introduction into the Union territory;
- (c) seeds listed pursuant to Article 37(2);
- (d) plants, plant products and other objects listed pursuant to Articles 41(1) and (2).

Points (a) to (d) shall not apply, however, where the act adopted pursuant to Articles 27(1), 29(1) or 41(1) and (2) requires proof of compliance in the form of an official mark, as referred to in Article 91(1), or another official attestation, as referred to in Article 93(1).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

2. The Commission shall, by means of an implementing act, amend the implementing act referred to in paragraph 1, in the following cases:

- (a) where a plant, plant product or other object, listed in that implementing act, does not fulfil paragraph 1(b), (c) or (d);
- (b) where a plant, plant product or other object, not listed in that act, fulfils paragraph 1(b), (c) or (d).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

3. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, in accordance with the principles set out in Section 2 of Annex IV, where there is a risk that a plant, plant product or other object, not listed in that act, hosts a Union quarantine pest, or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3).

⁽¹⁾ *Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 61, 3.3.1997, p. 1).*

⁽²⁾ *Commission Regulation (EC) No 865/2006 of 4 May 2006 laying down detailed rules concerning the implementation of Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 166, 19.6.2006, p. 1).*

Tuesday 15 April 2014

4. By way of derogation from paragraphs 1, 2 and 3, no phytosanitary certificate shall be required for the plants, plant products or other objects, which are subject to Articles 44, 45, 46 and 70.

Article 69

Plants, plant products and other objects for which phytosanitary certificates are required for introduction into a protected zone

1. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is required, in addition to the cases referred to in Article 68 (1), (2) and (3), for their introduction into certain protected zones from those third countries.

That list shall include:

- (a) the plants, plant products and other objects listed in Point II of Part B of Annex V to Directive 2000/29/EC;
- (b) plants, plant products and other objects listed pursuant to Article 50(1) or (2).

Points (a) and (b) shall not apply, however, where the act adopted pursuant to Article 50(1) or (2) requires proof of compliance in the form of an official mark, as referred to in Article 91(1), or another official attestation, as referred to in Article 93(1).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

2. The Commission shall, by means of an implementing act, amend the implementing act referred to in paragraph 1, in the following cases:

- (a) where a plant, plant product or other object, listed in that implementing act, does not fulfil paragraph 1(b);
- (b) where a plant, plant product or other object, not listed in that act, fulfils paragraph 1(b).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

3. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, in accordance with the principles set out in Section 2 of Annex IV, where there is a risk that a plant, plant product or other object, not listed in that act, hosts the respective protected zone quarantine pest, or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3).

4. By way of derogation from paragraphs 1, 2 and 3, no phytosanitary certificate shall be required for the plants, plant products or other objects, which are subject to Articles 52, 53, 54 and 70.

Article 70

Exceptions for travellers' luggage, clients of postal services and internet clients

1. Small quantities of particular plants, plant products and other objects from a third country may be exempted from the requirement for a phytosanitary certificate set out in Article 68(1) and Article 69(1), if they comply with all of the following conditions:

- (a) they are introduced into the Union territory as part of travellers' personal luggage, as consignments shipped following sales through distance contracts to final users (hereinafter: 'internet clients'), or as shipments delivered by postal services to final users;
- (b) they are not to be used for professional or commercial purposes;

Tuesday 15 April 2014

(c) they are listed pursuant to paragraph 2.

That exemption shall not apply to plants for planting, other than seeds.

2. The Commission shall, by means of implementing acts, list the plants, plant products and other objects referred to in paragraph 1 and the third countries concerned, and set out the maximum quantity, as appropriate, of the plants, plant products and other objects concerned that shall be subject to the exemption of that paragraph and, where appropriate, one or more of the risk management measures set out in Section 1 of Annex IV.

That listing and the setting out of the maximum quantity concerned and, where appropriate, the risk management measures shall be decided on the basis of the phytosanitary risk posed by small quantities of those plants, plant products and other objects, in accordance with the criteria set out in Section 2 of Annex IV.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3) of this Regulation.

Article 71

Conditions to be fulfilled by a phytosanitary certificate

1. The competent authority shall only accept a phytosanitary certificate accompanying plants, plant products or other objects to be introduced from a third country, if the content of that certificate complies with Part A of Annex V. Where the plants, plant products or other objects are to be introduced from a third country from which they do not originate, the competent authority shall only accept a phytosanitary certificate complying with Part B of Annex V.

It shall not accept that phytosanitary certificate where the additional declaration referred to in Article 67(2), where applicable, is not present or not correct, and where the statement referred to in Article 67(3), where applicable, is not present.

2. The competent authority shall only accept a phytosanitary certificate if it fulfils the following requirements:

(a) it is issued in at least one of the official languages of the Union;

(b) it is addressed to the Union or one of its Member States;

(c) it has been issued no more than 14 days before the date on which the plants, plant products or other objects covered by it have left the third country, in which it was issued.

3. In the case of a third country which is party to the IPPC, the competent authority shall only accept the phytosanitary certificates issued by the official national plant protection organisation of that third country or, under its responsibility, by a public officer who is technically qualified and duly authorised by that official national plant protection organisation.

4. In the case of a third country which is not party to the IPPC, the competent authority shall only accept the phytosanitary certificates issued by the authorities competent in accordance with the national rules of that third country and notified to the Commission. The Commission shall inform the Member States and the operators, through the electronic notification system referred to in Article 97, pursuant to point (a) of Article 131 of the Regulation (EU) No .../.... [*number of Regulation on Official Controls*], of the notifications received.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, supplementing the conditions for acceptance referred to in the first subparagraph, to ensure the reliability of those certificates.

5. Electronic phytosanitary certificates shall only be accepted when provided through, or in electronic exchange with, the computerised information management system referred to in Article 130 of Regulation (EU) No .../.... [*number of Regulation on Official Controls*].

Tuesday 15 April 2014

Article 72

Invalidation of phytosanitary certificate

1. Where a phytosanitary certificate has been issued in accordance with Article 67(1), (2) and (3), and the competent authority concerned concludes that the conditions referred to in Article 71 are not fulfilled, it shall invalidate that phytosanitary certificate and ensure that it does not accompany any longer those plants, plant products or other objects concerned. In that case, and in respect of the plants, plant products or other objects concerned, the competent authority shall take one of the measures as set out in Article 64(3) of Regulation (EU) No .../.... [number of Regulation on Official Controls].
2. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where a phytosanitary certificate was invalidated pursuant to paragraph 1.

The third country which had issued that phytosanitary certificate shall also be notified.

Section 2

Plant passports required for the movement of plants, plant products and other objects within the Union territory

Article 73

Plant passports

A plant passport shall be an official label for movement of plants, plant products and other objects within the Union territory and, where applicable, into and within protected zones, which certifies compliance with all requirements set out in Article 80 and, for movement into protected zones, Article 81, and has the content and format set out in Article 78.

Article 73a

The Commission shall, not later than ...⁽¹⁾, submit a report to the European Parliament and the Council to present the experience gained from the extension of the plant passport system to all movement of plants, plant products and other objects within the Union territory including a clear costs benefits analysis for the operators, accompanied if appropriate, by a legislative proposal. [Am. 108]

Article 74

Plants, plant products and other objects for which a plant passport is required for movement within the Union territory

1. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, for which a plant passport is required for their movement within the Union territory.

That list shall include:

- (a) all plants for planting, other than seeds;
- (b) the plants, plant products and other objects listed in point (I) of Part (A) of Annex V to Directive 2000/29/EC;
- (c) plants, plant products and other objects for which requirements have been adopted pursuant to Article 27(1), (2) or (3) or 29(1), (2) or (3) concerning their movement within the Union territory;
- (d) seeds listed pursuant to Article 37(2);
- (e) plants, plant products and other objects listed pursuant to Article 41(1) and (2).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

⁽¹⁾ ***Five years after the entry into force of this Regulation.***

Tuesday 15 April 2014

2. The Commission shall, by means of an implementing act, amend the implementing act referred to in paragraph 1, in the following cases:

- (a) where a plant, plant product or other object, not listed in that act, fulfils paragraphs 1(c), (d) or (e);
- (b) where a plant, plant product or other object, listed in that implementing act, does not fulfil paragraph 1(c), (d) or (e);

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(3).

3. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, in accordance with the principles of Section 2 of Annex IV, where there is a risk that a plant, plant product or other object, not listed in that act, hosts a Union quarantine pest or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3).

4. By way of derogation from paragraphs 1, 2 and 3, no plant passport shall be required for the plants, plant products or other objects, which are subject to Articles 44, 45, 46 and 70.

4a. The Commission shall, not later than ...⁽¹⁾, submit a report to the European Parliament and the Council to present the experience gained from the extension of the plant passport system to all movement of plants, plant products and other objects within the Union territory with a clear analysis of costs and benefits for the operators. [Am. 109]

Article 75

Plants, plant products and other objects for which a plant passport is required for introduction into, and movement within, protected zones

1. The Commission shall, by means of an implementing act, establish a list of the plants, plant products and other objects, for which a plant passport is required for their introduction into certain protected zones.

That list shall include:

- (a) the plants, plant products and other objects listed in point (II) of Part A of Annex V to Directive 2000/29/EC;
- (b) other plants, plant products and other objects listed pursuant to Article 50(2).

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

2. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, in the following cases:

- (a) where a plant, plant product or other object, not listed in that act, fulfils paragraph 1(b);
- (b) where a plant, plant product or other object, listed in that implementing act, does not fulfil paragraph 1(a) or (b).

⁽¹⁾ **Five years after the entry into force of this Regulation.**

Tuesday 15 April 2014

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 99(2).

3. The Commission may, by means of an implementing act, amend the implementing act referred to in paragraph 1, and in accordance with the principles of Section 2 of Annex IV, where there is a risk that a plant, plant product or other object, not listed in that act, hosts the respective protected zone quarantine pest, or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 99(3).

4. By way of derogation from paragraphs 1, 2 and 3, no plant passport shall be required for the plants, plant products or other objects, which are subject to Articles 52, 53, 54 and 70.

Article 76

Exception for final users

No plant passport shall be required for the movement of small, as appropriate to the plants, plant products and other objects concerned, quantities of plants, plant products or other objects to a final user, **including home gardeners**. [Am. 110]

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out the maximum figure for small quantities of particular plants, plant products or other objects.

Article 77

Exceptions for movements within and between the premises of a professional operator

No plant passport shall be required for the movements of plants, plant products and other objects within and between the premises of the same professional operator.

Article 78

Content and format of the plant passport

1. The plant passport shall take the form of a distinct label, which shall be printed on any suitable substrate, provided that the plant passport is kept separate from any other information or label which may also be indicated on that substrate.

The plant passport shall be clearly legible and indelible.

2. The plant passport for movement within the Union territory shall contain the elements set out in Part A of Annex VI.

The plant passport for introduction into, and movement within, a protected zone shall contain the elements set out in Part B of Annex VI.

3. In the case of plants for planting produced, or made available on the market, in the meaning of Article 3(5) of Regulation (EU) No .../... [number of Regulation on plant reproductive material law], as pre-basic, basic or certified material in the meaning of Article 10 of that Regulation, the plant passport shall be included, in a distinct form, in the official label produced in accordance with Article 22 of that Regulation, or, where applicable, in the master certificate issued in accordance with Article 122(1) of that Regulation.

Where this paragraph applies, the plant passport for movement within the Union territory shall contain the elements set out in Part C of Annex VI.

Where this paragraph applies, the plant passport for introduction into, and movement within, a protected zone shall contain the elements set out in Part D of Annex VI.

4. The Commission shall be empowered to adopt, pursuant to Article 98, delegated acts amending Parts A, B, C and D of Annex VI, to adapt those elements, where applicable, to scientific and technical developments.

Tuesday 15 April 2014

5. Within one year from the entry into force of this Regulation, the Commission shall adopt, by means of implementing acts, the format specifications of the plant passport for movement within the Union territory and the plant passport for introduction into, and movement within, a protected zone, as regards the plant passports referred to in the first and second subparagraphs of paragraph 2 and in the second and third subparagraphs of paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

Where the nature of particular plants, plant products or other objects so requires, specific size specifications may be set out for them.

Article 79

Issuance by authorised professional operators and competent authorities

1. Plant passports shall be issued by registered operators, authorised, in accordance with Article 84, by the competent authorities to issue plant passports, hereinafter 'authorised operators', under the supervision of the competent authorities.

Authorised operators shall issue plant passports only for the plants, plant products or other objects for which they are responsible.

2. Plant passports may, however, be issued by the competent authorities where a registered operator requests so.

3. Authorised operators shall only issue plant passports in the premises, collective warehouses and dispatching centres referred to in Article 62(2)(d).

Article 80

Substantive requirements for a plant passport for movement within the Union territory

A plant passport shall be issued for movement within the Union territory for a plant, plant product or other object only where it fulfils the following requirements:

- (a) it is free from Union quarantine pests;
- (b) it complies with the provisions of Article 37(1) concerning the presence of Union quality pests on plants for planting;
- (c) it complies with the requirements referred to in Article 41(1) and (2);
- (d) where applicable, it complies with rules adopted in accordance with the provisions adopted pursuant to Article 27(1) and (2) and Article 29(1) and (2); and
- (e) where applicable, it complies with measures adopted by the competent authorities for the eradication of Union quarantine pests pursuant to Article 16(1) and the eradication of pests provisionally qualifying as Union quarantine pests pursuant to Article 28(1).

Article 81

Substantive requirements for a plant passport for movement into and within a protected zone

1. A plant passport shall be issued for introduction into, and movement within, a protected zone for a plant, plant product and other object only where it fulfils all of the requirements of Article 80, and in addition the following requirements:

- (a) it is free from the respective protected zone quarantine pest; and
- (b) it complies with the requirements referred to in Article 50(1) and (2).

2. Where Article 33(2) applies, the plant passport referred to in paragraph 1 shall not be issued.

Tuesday 15 April 2014

Article 82

Examinations for plant passports

1. A plant passport may only be issued for plants, plant products and other objects for which a meticulous examination in accordance with paragraphs 2, 3, and 4 has shown that they fulfil the requirements of Article 80, and, where applicable, Article 81.

Plants, plant products and other objects may either be examined individually or by representative samples. The examination shall also cover the packaging material of the plants, plant products or other objects concerned.

2. The examination shall be carried out by the authorised operator, or, where applicable under Article 79(2), by the competent authorities.

3. The examination shall fulfil the following conditions:

(a) it shall be carried out frequently, at appropriate times and taking into account the risks involved;

(b) it shall be carried out at the premises, collective warehouses and dispatching centres referred to in Article 62(2)(d); and

(c) it shall be made by visual examination and, in the case of suspicion of the presence of a Union quarantine pest or, in case of a protected zone, the protected zone quarantine pest concerned, by sampling and testing.

That examination shall take place without prejudice to any specific examination requirements or measures adopted in accordance with Article 27(1), (2) or (3), 29(1), (2) or (3), 41(1) and (2), and 50(1) and (2).

~~4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out detailed measures concerning visual examination, sampling and testing, and the frequency and timing of the examinations, referred to in paragraphs 1, 2 and 3, with regard to specific plants, plant products and other objects, on the basis of the particular phytosanitary risks they may present. Those examinations shall, where appropriate, concern certain plants for planting belonging to the categories referred to in Article 12(1) of Regulation (EU) No .../... (number of Regulation on the production and making available on the market of plant reproductive material), and, where appropriate, shall be carried out for any of the elements, as appropriate, set out in Part D of Annex II to that Regulation.~~

~~Where the Commission adopts such a delegated act for specific plants for planting, and those plants for planting are subject to certification schemes pursuant to Article 20(1) of Regulation (EU) No .../.... [number of Regulation on the production and making available on the market of plant reproductive material], the respective examinations shall be combined in a single certification scheme.~~

~~When adopting those delegated acts, the Commission shall take into account the technical and scientific knowledge and developments. [Am. 111]~~

Article 83

Attaching of the plants passports

Plant passports shall be attached by the authorised operators, or, where so applicable under Article 79(2), by the competent authorities, to each lot of the plants, plant products and other objects concerned before they are moved within the Union territory pursuant to Article 74 or into or within a protected zone pursuant to Article 75. Where such plants, plant products or other objects are moved in a package, bundle or container, the plant passport shall be attached to that package, bundle or container.

Article 84

Authorisation of professional operators to issue plant passports

1. The competent authority shall grant an authorisation to a professional operator to issue plant passports (hereinafter 'the authorisation to issue plant passports') where that professional operator complies with the following conditions:

Tuesday 15 April 2014

- (a) it possesses the necessary knowledge to carry out the examinations referred to in Article 82 concerning the Union quarantine pests, protected zone quarantine pests and Union quality pests that could affect the plants, plant products and other objects concerned, and concerning the signs of the presence of those pests and the symptoms caused by them, the means to prevent the presence and spread of those pests, and the means to eradicate them;
 - (b) it has in place systems and procedures enabling it to fulfil its obligations concerning traceability pursuant to Article 65 and 66.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out qualification requirements to be fulfilled by the professional operators in order for them to comply with the conditions of paragraph 1 (a).

Article 85

Obligations of authorised operators

1. Where an authorised operator intends to issue a plant passport, it shall identify and monitor the points of its production process, and the points concerning the movement of plants, plant products and other objects by that operator, which are critical as regards compliance with the rules adopted pursuant to Article 27(1), (2) and (3), Article 29(1), (2) and (3), Article 37(1), Article 41(3), Article 80 and Article 82, and, where applicable, Article 33(2), Article 50(3) and Article 81.

It shall keep records concerning the identification and monitoring of those points.

2. The authorised operator referred to in paragraph 1 shall provide appropriate training to its personnel involved in the examinations referred to in Article 82, to ensure that that personnel possesses the necessary knowledge to carry out those examinations.

Article 86

Phytosanitary risk management plans

1. The competent authority may approve, as appropriate, phytosanitary risk management plans of authorised operators, setting out the measures implemented by those operators to fulfil the obligations set out in Article 85(1).

2. The phytosanitary risk management plan shall cover, where appropriate in the form of instruction manuals, at least the following:

- (a) the information required under Article 62(2) concerning the registration of the authorised operator;
- (b) the information required under Article 65(3) and 66(1) concerning the traceability of plants, plant products and other objects;
- (c) a description of the production processes of the authorised operator and its activities as regards movement and sales of plants, plant products and other objects;
- (d) an analysis of the critical points referred to in Article 85(1) and the measures taken by the authorised operator to mitigate the phytosanitary risks associated with those critical points;
- (e) the procedures in place and actions foreseen in the case of suspicion or findings of quarantine pests, the recording of those suspicion or findings and the recording of the actions taken;
- (f) the roles and responsibilities of the personnel involved in the notifications referred to in Article 9(1), the examinations referred to in Article 82(1), and the issuance of plant passports pursuant to Article 79(1), Article 88(1) and (2) and Article 89;
- (g) the training provided to the personnel referred to in point (f).

Tuesday 15 April 2014

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending the elements referred to in paragraph 2.

Article 87

Withdrawal of authorisation

1. Where the competent authority becomes aware that an authorised operator does not comply with Article 82(1), (2), (3) or (4) or Article 84(1), or that a plant, plant product or other object, for which that professional operator has issued a plant passport, does not comply with Article 80 or, where applicable, Article 81, that authority shall without delay take the measures necessary to ensure that non-compliance with those provisions does not continue.
2. Where the competent authority has taken measures in accordance with paragraph 1, other than the withdrawal of the authorisation to issue plant passports, and non-compliance continues, that authority shall without delay withdraw that authorisation.

Article 88

Replacing a plant passport

1. An authorised operator which has received a lot of plants, plant products or other objects, for which a plant passport has been issued, or the competent authority acting on request of a professional operator, may issue a new plant passport for that lot, replacing the plant passport initially issued for that lot, provided that the conditions of paragraph 3 are fulfilled.
2. Where a lot of plants, plant products or other objects, for which a plant passport has been issued, is divided into two or more lots, the authorised operator responsible for those new lots, or the competent authority acting on request of a professional operator, shall issue a plant passport for each new lot resulting from the division, provided that the conditions set out in paragraph 3 are fulfilled. Those plant passports shall replace the plant passport issued for the initial lot.

Where two lots, for each of which a plant passport has been issued, are combined into a single lot, the authorised operator responsible for that new lot, or the competent authority acting on request of a professional operator, shall issue a plant passport for that lot. That plant passport shall replace the plant passport issued for the initial lots, provided that the conditions in paragraph 3 are fulfilled.

3. A plant passport, as provided for in paragraphs 1 and 2, may only be issued if the following conditions are fulfilled:
 - (a) the identity of the plants, plant products or other objects concerned is guaranteed; and
 - (b) the plants, plant products or other objects concerned continue to comply with the requirements referred to in Articles 80 and 81.
4. Where a plant passport is issued pursuant to paragraphs 1 or 2, the examination referred to in Article 82(1) shall not be required.
5. Following the replacement of a plant passport referred to in paragraphs 1 and 2, the authorised operator concerned shall retain the replaced plant passport for three years.

In case a plant passport is issued by the competent authority to replace a plant passport, the professional operator, on whose request it is issued, shall retain the replaced plant passport for three years.

Tuesday 15 April 2014

Article 89

Plant passports replacing phytosanitary certificates

1. By way of derogation from Article 82, where a plant, plant product or other object, introduced into the Union territory from a third country, which for movement within the Union territory requires a plant passport pursuant to the implementing acts referred to in Article 74(1) and 75(1), such a passport shall be issued where the checks pursuant to Article 47(1) of Regulation (EU) No .../...[*number of Regulation on Official Controls*] concerning the introduction of the respective plant, plant product or other object have been completed satisfactorily **and have come to the result that the plants, plant products or other objects concerned fulfil the substantive requirements for issuance of a plant passport according to Article 80 and, where appropriate, Article 81.** [Am. 112]
2. Following the issuance of a plant passport referred to in paragraph 1, the authorised operator issuing that plant passport shall, where applicable, retain the phytosanitary certificate for three years.

Where point (c) of Article 95(2) applies, that phytosanitary certificate shall be replaced by a certified copy of it.

Article 90

Obligation to remove the plant passport

1. The professional operator which has under its control a lot of plants, plant products or other objects, shall remove the plant passport from that lot, in case it becomes aware that any of the requirements of Articles 78 to 82, 84 or 85 are not fulfilled.

The professional operator shall invalidate that plant passport by drawing a clearly visible and indelible diagonal red line over it.

2. In case the professional operator fails to comply with paragraph 1, the competent authorities shall remove the plant passport from the lot concerned and shall invalidate that plant passport by drawing a clearly visible and indelible diagonal red line over it.
3. Where paragraphs 1 and 2 apply, the professional operator concerned shall retain the invalidated plant passport for three years.
4. Where paragraphs 1 and 2 apply, the professional operator concerned shall inform accordingly the authorised operator, or competent authority, who issued the invalidated plant passport.
5. Member States shall notify, through the electronic notification system referred to in Article 97, the Commission and other Member States where a plant passport was removed and invalidated pursuant to paragraph 2.

Section 3

Other attestations

Article 91

Marking of wood packaging material

1. The mark attesting that wood packaging material has been treated against Union quarantine pests and protected zone quarantine pests, in accordance with a method established pursuant to Article 27(1) or (2), Article 29(1) or (2), Article 41 (1) or (2) or Article 50(1) or (2), shall contain the elements set out in Annex VII.
2. The Commission shall be empowered, in accordance with Article 98, to adopt delegated acts amending Annex VII to adapt that mark to the development of international standards.
3. The mark shall only be applied by a professional operator authorised in accordance with Article 92.

Tuesday 15 April 2014

4. The Commission shall adopt, by means of implementing acts, the format specifications of the mark referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

Article 92

Authorisation and supervision of professional operators applying the mark of wood packaging material in the Union territory

1. An authorisation to apply the mark referred to in Article 91(3) shall be granted to a registered operator provided that it fulfils the following conditions:

- (a) it possesses the necessary knowledge to carry out the treatment of the wood packaging material required pursuant to the acts referred to in Article 91(1);
- (b) it operates appropriate facilities to carry out that treatment (hereinafter: 'treatment facilities').

The Commission shall be empowered, in accordance with Article 98, to adopt delegated acts amending the requirements for authorisation, where appropriate in view of the development of scientific and technical knowledge.

The authorisation shall be granted by the competent authority on application.

2. By way of derogation from paragraph 1, the authorisation referred to in that paragraph may be granted, concerning the marking of wood packaging material entirely composed of treated wood, where the registered operator fulfils all of the following conditions:

- (a) it exclusively uses wood from treatment facilities operated by a registered operator authorised pursuant to paragraph 1;
- (b) it ensures that the wood used for that purpose can be traced back to those treatment facilities;
- (c) where applicable pursuant to Articles 27(1) and (2), 29(1) and (2), 41(1) and (2) and 50(1) and (2), it exclusively uses wood referred to in point (a) which is accompanied by a plant passport.

3. The competent authority shall supervise the professional operators authorised pursuant to paragraph 1, to verify and ensure that they treat and mark wood packaging material in accordance with Article 91(1) and fulfil the conditions set out in paragraphs 1 and 2.

The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, supplementing the requirements set out in this paragraph concerning the supervision of professional operators by the competent authority.

4. Where the competent authority becomes aware that a professional operator does not comply with the requirements referred to in paragraphs 1, 2 or 3, that authority shall without delay take the measures necessary to ensure that non-compliance with those provisions does not continue.

Where the competent authority has taken those measures, other than the withdrawal of the authorisation referred to in paragraph 1, and non-compliance continues, that authority shall without delay withdraw the authorisation referred to in paragraph 1.

Article 93

Attestations other than the mark of wood packaging material

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out the elements to be contained in official attestations, specific for plants, plant products or other objects, other than wood packaging material, which are required by the applicable international standards as form of proof of the implementation of measures adopted pursuant to Article 27(1) or (2), Article 29(1) or (2), Article 41(1) or (2) or Article 50(1) or (2).

Tuesday 15 April 2014

2. Those delegated acts may also set out requirements concerning one or more of the following:
 - (a) the authorisation of professional operators as regards the issuance of the official attestations referred to in paragraph 1;
 - (b) the supervision by the competent authority of the professional operators authorised pursuant to point (a);
 - (c) the withdrawal of that authorisation referred to in point (a).
3. The Commission shall adopt, by means of implementing acts, the format specifications of the attestations referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

Section 4

export of plants, plant products and other objects from the Union territory

Article 94

Phytosanitary certificate for export

1. Where for the export of a plant, plant product or other object from the Union territory to a third country, a phytosanitary certificate is required by the rules of that third country (hereinafter: 'phytosanitary certificate for export'), that certificate shall be issued by the competent authority, at the request of the professional operator which has under its control the plant, plant product or other object to be exported.
2. The phytosanitary certificate for export shall be issued provided that the information available is sufficient to certify compliance with the requirements of the third country concerned. That information may originate, where applicable, from one or more of the following elements:
 - (a) a plant passport, as referred to in Article 73, accompanying the plant, plant product or other object concerned;
 - (b) the mark of wood packaging material as referred to in Article 91(1), or the attestation referred to in Article 93(1);
 - (c) the information included in the pre-export certificate referred to in Article 96;
 - (d) official information included in the phytosanitary certificate as referred to in Article 67, where the plant, plant products or other object concerned has been introduced into the Union territory from a third country;
 - (e) official inspections, sampling and testing of the plant, plant product or other object concerned.
3. The phytosanitary certificate for export shall contain the elements set out in Part A of Annex VIII.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Part A of Annex VIII to adapt it to scientific and technical developments and the development of international standards.
5. The Commission shall adopt, by means of implementing acts, the format specifications of the phytosanitary certificate as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).
6. Electronic phytosanitary certificates for export shall only be valid when provided through, or in electronic exchange with, the computerised information management system referred to in Article 130 of Regulation (EU) No .../... [number of Regulation on Official Controls].

Tuesday 15 April 2014

Article 95

Phytosanitary certificate for re-export

1. Where a plant, plant product or other object originates in a third country and has been introduced into the Union territory from that, or another, third country, a phytosanitary certificate for re-export may be issued instead of the phytosanitary certificate for export.

The phytosanitary certificate for re-export shall be issued by the competent authority at the request of the professional operator which has under its control the plant, plant product or other object to be exported.

2. The phytosanitary certificate for re-export shall be issued provided that all of the following conditions are complied with:

- (a) the plant, plant product or other object concerned has not been grown, produced or processed in the Member State from which it is exported to the third country concerned;
- (b) the plant, plant product or other object concerned has not been exposed to any risk of infestation with quarantine pests, listed as such by the third country of destination, during storage in the Member State from which it is to be exported to that third country;
- (c) where available, the phytosanitary certificate accompanying the plant, plant product or other object concerned from the third country of origin, or a certified copy of it, is attached to the phytosanitary certificate for re-export.

3. The provisions of Article 94(2), concerning the information sufficient to certify compliance with the requirements of the third country concerned, shall apply accordingly.

4. The phytosanitary certificate for re-export shall contain the elements set out in Part B of Annex VIII.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, amending Part B of Annex VIII to adapt it to scientific and technical developments and the development of international standards.

6. The Commission shall adopt, by means of implementing acts, the format specifications of the phytosanitary certificate as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

6a. The Commission shall consult the Advisory Group on the food chain and animal and plant health established under the Commission Decision 2004/613/EC⁽¹⁾. This advisory group shall provide inputs during the preparation of implementing and delegated acts. [Am. 113]

7. Electronic phytosanitary certificates for re-export shall only be valid when provided through, or in electronic exchange with, the computerised information management system referred to in Article 130 of Regulation (EU) No .../... [number of Regulation on Official Controls].

Article 96

Pre-export certificates

1. The Member State from which the plants, plant products and other objects referred to in Article 94(1) are exported and the Member State in which the plants, plant products and other objects were grown, produced or processed, shall exchange information as necessary for issuing, without delay, the phytosanitary certificate for export.

⁽¹⁾ Commission Decision 2004/613/EC of 6 August 2004 concerning the creation of an advisory group on the food chain and animal and plant health (OJ L 275, 25.8.2004, p. 17).

Tuesday 15 April 2014

2. The exchange of information referred to in paragraph 1 shall take the form of a harmonised document (hereinafter 'pre-export certificate'), in which the Member State, in which the plants, plant products and other objects were grown, produced or processed, attests compliance of those plants, plant products or other objects with specific phytosanitary requirements concerning one or more of the following:

- (a) the absence of particular pests in the plants, plants products or other objects concerned;
- (b) the origin of the plants, plant products or other objects concerned;
- (c) the phytosanitary procedures applied to the production or processing of the plants, plant products or other objects concerned.

3. The pre-export certificate shall be issued, on request of the professional operator, by the Member State, **or authorised professional operator as defined in Article 84**, in which the plants, plant products or other objects were grown, produced or processed, while those plants, plant products or other objects are on the premises of the professional operator concerned. [Am. 114]

4. The pre-export certificate shall accompany the plants, plant products and other objects concerned during their movement within the Union territory, unless the information contained in it is exchanged between the Member States concerned by electronic means.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 98, setting out the contents of the pre-export certificate.

6. The Commission shall adopt, by means of implementing acts, the format specifications of the pre-export certificate. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 99(3).

Chapter VII

Supporting measures by the Commission

Article 97

Establishment of electronic notification system

1. The Commission shall establish an electronic system for the submission of notifications by the Member States **and for informing professional operators if appropriate**. [Am. 115]

That system shall be connected to and compatible with the computerised information management system referred to in Article 130(1) of Regulation (EU) No .../.... [number of Regulation on Official Controls].

2. Where the notification concerns the presence of a pest in plants, plant products or other objects introduced into, officially presented for introduction into, or moved within, the Union territory, the notification referred to in paragraph 1 shall contain a reference to the plants, plant products and other objects concerned, the nature of the non-compliance and the measures taken.

Where the notification concerns the presence of a pest in the territory of a Member State, other than in a plant, plant product or other object introduced into, officially presented for introduction into, or moved within, the Union territory, the notification referred to in paragraph 1 shall contain a reference to the plants, plant products and other objects concerned, the name of the pest, the location and GPS coordinates of that presence, and the measures taken.

Tuesday 15 April 2014

Chapter VIII
Final provisions

Article 98
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

 2. The delegation of power referred to in Articles 1(2), **5(2), (3) and (4), 6(2)**, 7(1) and (2), 8(6), 11(3), 20, 22(3), ~~25(4), 27, 30, 32(4), 34(1), 37(3), 38, 44(2), 45(3), 46(6), 48, 61(3), 67(4), 71(4), 76, 78(4), 82(4), 84(2), 86(3), 91(2), 92(1) and (3), 93(1), 94(4), 95(5) and 96(5)~~ shall be conferred on the Commission for ~~an indeterminate~~ a period of **time five years** from ... ~~the entry into force of this Regulation~~ (*). **The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension.** [Am. 116]

 3. The delegation of power referred to in Articles 1(2), **5(2), (3) and (4), 6(2)**, 7(1) and (2), 8(6), 11(3), 20, 22(3), ~~25(4), 27, 30, 32(4), 34(1), 37(3), 38, 44(2), 45(3), 46(6), 48, 61(3), 67(4), 71(4), 76, 78(4), 82(4), 84(2), 86(3), 91(2), 92(1) and (3), 93(1), 94(4), 95(5) and 96(5)~~ may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force. [Am. 117]

 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

 5. A delegated act adopted pursuant to Articles 1(2), **5(2), (3) and (4), 6(2)**, 7(1) and (2), 8(6), 11(3), 20, 22(3), ~~25(4), 27, 30, 32(4), 34(1), 37(3), 38, 44(2), 45(3), 46(6), 48, 61(3), 67(4), 71(4), 76, 78(4), 82(4), 84(2), 86(3), 91(2), 92(1) and (3), 93(1), 94(4), 95(5) and 96(5)~~ shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.
- 5a. Four years after ...(**), the Commission shall present a report to the European Parliament and Council concerning the use of the power to adopt delegated acts provided for in paragraph 2.** [Am. 118]

(*) Date of entry into force of this Regulation.

(**) Date of entry into force of this Regulation.

Tuesday 15 April 2014

Article 98a**Urgency procedure**

1. **Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.**
2. **Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 98(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council. [Am. 119]**

Article 99

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽¹⁾. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof shall apply.

Article 100

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate **to the extent of the financial loss and phytosanitary damage incurred throughout the Union's territory**, and dissuasive. [Am. 120]

The Member States shall notify those provisions to the Commission by [date of application of this Regulation] at the latest and shall notify them without delay of any subsequent amendments affecting them.

Article 101

Repeals

1. Directive 2000/29/EC is repealed.

The following acts are also repealed:

- (a) Directive 69/464/EEC;

⁽¹⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Tuesday 15 April 2014

- (b) Directive 69/466/EEC;
- (c) Directive 74/647/EEC;
- (d) Directive 93/85/EEC;
- (e) Directive 98/57/EC;
- (f) Directive 2007/33/EC.

2. References to those repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IX hereto.

Article 102

Amendment of Regulation (EU) No 652/2014

Regulation (EU) No 652/2014 is amended as follows:

(1) In Article 1, point (e) is replaced by the following:

‘(e) on protective measures against pests of plants;’

(2) In Article 16(1), points (a), (b) and (c) are replaced by the following:

‘(a) measures to eradicate a pest from an infested area, taken by the competent authorities pursuant to Article 16(1), 27(1) or 29(1) of Regulation (EU) No ... of the European Parliament and of the Council (*);

(b) measures to contain a priority pest, listed pursuant to Article 6(2) of Regulation (EU) No [...] [...] [*Number of this Regulation — i.e. on protective measures against pests of plants*], against which Union containment measures have been adopted pursuant to Article 27(2) or Article 29(2) of that Regulation, in an infested area from which that priority pest cannot be eradicated, where those measures are essential to protect the Union territory against further spread of that priority pest. Those measures shall concern the eradication of that pest from the buffer zone surrounding that infested area in case its presence is detected in that buffer zone;

(c) prevention measures taken against the spread of a priority pest, listed pursuant to Article 6(2) of Regulation (EU) No [...] [...] [*Number of this Regulation — i.e. on protective measures against pests of plants*], against which Union measures have been adopted pursuant to Article 27(3) or Article 29(3) of that Regulation, where those measures are essential to protect the Union territory against further spread of that priority pest.

(ca) measures to rapidly eradicate invasions of alien species at an early stage, taken by the Member States pursuant to Article 15 of Regulation (EU) No [...] /2014 of the European Parliament and of the Council (),**

(*) Regulation (EU) No .../2014 of the European Parliament and of the Council of... on protective measures against pests of plants (OJ L ..., ..., p. ...) [*Number, date and, in a footnote, the publication reference of this Regulation- i.e. on protective measures against pests of plants*]

(**) **Regulation (EU) No [...] /2014 of the European Parliament and of the Council of ... on the prevention and management of the introduction and spread of invasive alien species (OJ L ..., ..., ...).** [*Number, date and, in a footnote, the publication reference of the said Regulation*][**Am. 121**]

(3) Article 17 is amended as follows:

(a) In the first paragraph, points (a) — (d) are replaced by the following:

‘(a) they concern Union quarantine pests not known to occur in the Union territory, listed pursuant to Article 5(2) of Regulation (EU) No [...] [...] [*Number of this Regulation — i.e. on protective measures against pests of plants*];

Tuesday 15 April 2014

- (b) they concern priority pests listed pursuant to Article 6(2) of Regulation (EU) No [...]/[...] [Number of this Regulation — i.e. on protective measures against pests of plants];
- (c) they concern pests, not listed as Union quarantine pests, which are covered by a measure adopted by the Commission pursuant to Article 29(1) of Regulation (EU) No [...]/[...] [Number of this Regulation — i.e. on protective measures against pests of plants];
- (ca) they concern live specimens of species, subspecies or lower taxon of plants, fungi or micro-organisms that, if introduced into the Union territory, may have a negative impact on plant health, and which are covered by early eradication measures adopted pursuant to Article 15 of Regulation (EU) No [...] /2014 [Number of Regulation on the prevention and management of the introduction and spread of invasive alien species]; [Am. 122]**

(b) The second paragraph is replaced by the following:

‘For measures fulfilling the condition laid down in point (c) of the first paragraph, the grant shall not cover costs incurred after the expiry of the measure adopted by the Commission pursuant to Article 29(1) of Regulation (EU) No [...]/[...] [Number of this Regulation — i.e. on protective measures against pests of plants].’

(4) Paragraph 1 of Article 18 is amended as follows:

(a) The following points are inserted after point (c):

- ‘(ca) costs incurred by Member States for compensation to the operators referred to in Article 2(7)(a), (b) and (c) of Regulation (EU) [...]/[...] [Number of this Regulation — i.e. on protective measures against pests of plants] for the value of the destroyed plants, plant products or other objects subject to the measures referred to in Article 16 of that Regulation, as regards priority pests, listed pursuant to Article 6(2) of that Regulation;
- (cb) costs incurred by Member States for compensation to the operators referred to in Article 2(7)(a), (b) and (c) of Regulation (EU) No [...] /2014 [Number of this Regulation — i.e. on protective measures against pests of plants] for the value of the destroyed plants, plant products or other objects covered by measures for rapid eradication at an early stage of invasion adopted pursuant to Article 15 of Regulation (EU) No [...] / [...] [Number of Regulation on the prevention and management of the introduction and spread of invasive alien species]; [Am. 123]**
- (cc) costs of compensation to operators referred to in Article 2(7)(a), (b) and (c) of Regulation (EU) [...] / [...] [Number of this Regulation — i.e. on protective measures against pests of plants] for the implementation of enhanced biosecurity measures essential to protect the Union territory against priority pests.’ [Am. 124]**

(b) Point (e) is replaced by the following:

‘(e) in exceptional and duly justified cases, taking into account the Union added value of the measures, the costs incurred in carrying out other necessary measures than those referred to in points (a) to (d), provided that such measures are set out in the grant decision referred to in Article 36(4).’

(c) The following second subparagraph is added:

‘For the purposes of point (ca), **(cb) and (cc)** of the first subparagraph, the compensation shall not exceed the market value of the plants, plant products or other objects immediately before they were destroyed and the salvage value, if any, shall be deducted from the compensation.’ [Am. 125]

Tuesday 15 April 2014

(5) Article 19 is amended as follows:

(a) In the first paragraph, points (a) and (b) are replaced by the following:

- '(a) they concern Union quarantine pests not known to occur in the Union territory, listed pursuant to Article 5(2) of Regulation (EU) No [...]/[...][Number of this Regulation — i.e. on protective measures against pests of plants];
- (b) they concern priority pests listed pursuant to Article 6(2) of Regulation (EU) [...]/[...][Number of this Regulation — i.e. on protective measures against pests of plants];
- (c) they concern pests not listed as Union quarantine pests which are covered by a measure adopted by the Commission pursuant to Article 29(1) of Regulation (EU) No [...]/[...][Number of this Regulation — i.e. on protective measures against pests of plants].'

(b) The third paragraph is replaced by the following:

'For measures fulfilling the condition laid down in point (c) of the first paragraph, the grant shall not cover costs incurred after the expiry of the measure adopted by the Commission pursuant to Article 29(1) of Regulation (EU) No [...]/[...][Number of this Regulation — i.e. on protective measures against pests of plants].'

Article 103

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply... [36 months from the entry into force].

2. Article 97(2) shall apply from the date when the systems referred to in Article 97(1) are established.

3. The acts referred to in points (a), (d), (e) and (f) of Article 101(1) shall be repealed on 31 December 2021. In case of conflict between the provisions of those acts and the provisions of this Regulation, the provisions of this Regulation shall prevail.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the European Parliament
The President

For the Council
The President

Tuesday 15 April 2014

ANNEX I

Territories for which, for the purpose of this Regulation, references to third countries shall be read as references to third countries and to those territories, and for which references to the Union territory shall be read as references to the Union territory without those territories, as referred to in Article 1(2)

The territories of:

1. Guadeloupe
 2. French Guiana
 3. Martinique
 4. Réunion
 5. Saint-Martin
 6. Mayotte
 7. Ceuta
 8. Melilla
 9. The Canary Islands
-

Tuesday 15 April 2014

ANNEX IA

List of Union quarantine pests referred to in Article 5

HARMFUL ORGANISMS NOT KNOWN TO OCCUR IN ANY PART OF THE COMMUNITY AND RELEVANT FOR THE ENTIRE COMMUNITY

(a) Insects, mites and nematodes, at all stages of their development

Acleris spp. (non-European)*Aculops fuchsiae* Keifer*Agrilus planipennis* Fairmaire*Aleurochantus* spp.*Amauromyza maculosa* (Malloch)*Anomala orientalis* Waterhouse*Anoplophora chinensis* (Thomson)*Anoplophora glabripennis* (Motschulsky)*Anoplophora malasiaca* (Forster)*Anthonomus bisignifer* (Schenkling)*Anthonomus signatus* (Say)*Aonidella citrina* Coquillet*Aphelenchoïdes besseyi* Christie*Arrhenodes minutus* Drury*Aschistonyx eppoi* Inouye*Bemisia tabaci* Genn. (non-European populations) vectors of viruses such as:

(a) Bean golden mosaic virus

(b) Cowpea mild mottle virus

(c) Lettuce infectious yellows virus

(d) Pepper mild tigré virus

(e) Squash leaf curl virus

(f) Euphorbia mosaic virus

(g) Florida tomato virus

Bursaphelenchus xylophilus (Steiner et Buher) Nickle et al.*Carposina niponensis* Walsingham*Cicadellidae* (non-European) known to be vectors of Pierce's disease (caused by *Xylella fastidiosa*), such as:(a) *Carneocephala fulgida* Nottingham(b) *Draeculacephala minerva* Bali(c) *Graphocephala atropunctata* (Signoret)*Choristoneura* spp. (non-European)*Conotrachelus nenuphar* (Herbst)*Dendrolimus sibiricus* Tschetverikov

Tuesday 15 April 2014

Diabrotica barberi Smith & Lawrence
Diabrotica undecimpunctata howardi Barber
Diabrotica undecimpunctata undecimpunctata Mannerheim
Diabrotica virgifera zae Krysan & Smith
Diaphorina citri Kuway
Enarmonia packardi (Zeller)
Enarmonia prunivora Walsh
Eotetranychus lewisi McGregor
Grapholita inopinata Heinrich
Heliothis zea (Boddie)
Hirschmanniella spp., other than *Hirschmanniella gracilis* (de Man) Luc et Goodey
Hishomonus phycitis
Leucaspis japonica Ckll.
Liriomyza sativae Blanchard
Listronotus bonariensis (Kuschel)
Longidorus diadecturus Eveleigh et Allen
Margarodes, non-European species, such as:
a) *Margarodes vitis* (Phillipi)
b) *Margarodes vredendalensis* de Klerk
c) *Margarodes prieskeansis* Jakubski
Monochamus spp. (non-European)
Myndus crudus Van Duzee
Nacobbus aberrans (Thorne) Thorne et Allen
Naupactus leucoloma Boheman
Numonia pirivorella (Matsumura)
Oligonychus perditus Pritchard et Baker
Pissodes spp. (non-European)
Premnotrypes spp. (non-European)
Pseudopityophthorus minutissimus (Zimmermann)
Pseudopityophthorus pruinus (Eichhoff)
Radopholus citrophilus Huettel Dickson et Kaplan
Rhynchophorus palmarum (L.)
Scaphoideus luteolus (Van Duzee)
Scirtothrips aurantii Faure
Scirtothrips dorsalis Hood
Scirtothrips citri (Moultext)
Scolytidae spp. (non-European)
Scrobipalpopsis solanivora Povolny

Tuesday 15 April 2014

Spodoptera eridania (Cramer)

Spodoptera frugiperda (Smith)

Spodoptera litura (Fabricus)

Tachypterellus quadrigibbus Say

Taxoptera citricida Kirk.

Thaumatotibia leucotreta

Thrips palmi Karny

Tephritidae (non-European) such as:

(a) *Anastrepha fraterculus* (Wiedemann)

(b) *Anastrepha ludens* (Loew)

(c) *Anastrepha obliqua* Macquart

(d) *Anastrepha suspensa* (Loew)

(e) *Dacus ciliatus* Loew

(f) *Dacus cucurbitae* Coquillett

(g) *Dacus dorsalis* Hendel

(h) *Dacus tryoni* (Froggatt)

(i) *Dacus tsunconis* Miyake

(j) *Dacus zonatus* Saund.

(k) *Epochra canadensis* (Loew)

(l) *Pardalaspis cyanescens* Bezzi

(m) *Pardalaspis quinaria* Bezzi

(n) *Pterandrus rosa* (Karsch)

(o) *Rhacochlaena japonica* Ito

(p) *Rhagoletis cingulata* (Loew)

(q) *Rhagoletis completa* Cresson

(r) *Rhagoletis fausta* (Osten-Sacken)

(s) *Rhagoletis indifferens* Curran

(t) *Rhagoletis mendax* Curran

(u) *Rhagoletis pomonella* Walsh

(v) *Rhagoletis ribicola* Doane

(w) *Rhagoletis suavis* (Loew)

Trioza erytreae Del Guercio

Unaspis citri Comstock

Xiphinema americanum Cobb sensu lato (non-European populations)

Xiphinema californicum Lamberti et Bleve-Zacheo

Tuesday 15 April 2014

(b) Bacteria*Citrus greening bacterium**Citrus variegated chlorosis**Erwinia stewartii* (Smith) Dye*Xanthomonas campestris* (all strains pathogenic to Citrus)*Xanthomonas campestris* pv. *oryzae* (Ishiyama) Dye and pv. *oryzicola* (Fang. et al.) Dye*Xylella fastidiosa* (Well et Raju)**(c) Fungi***Alternaria alternata* (Fr.) Keissler (non-European pathogenic isolates)*Anisogramma anomala* (Peck) E. Müller*Apiosporina morbosa* (Schwein.) v. Arx*Atropellis* spp.*Ceratocystis fagacearum* (Bretz) Hunt*Ceratocystis virescens* (Davidson) Moreau.*Cercoseptoria pini-densifloae* (Hori et Nambu) Deighton*Cercospora angolensis* Carv. et Mendes*Ciborinia camelliae* Kohn*Chrysomyxa arctostaphyli* Dietel*Cronartium* spp. (non-European)*Diaporthe vaccinii* Shaer*Endocronartium* spp. (non-European)*Elsinoe* spp. Bitanc. et Jenk. Mendes*Fusarium oxysporum* f. sp. *albedinis* (Kilian et Maire) Gordon*Guignardia citricarpa* Kiely (all strains pathogenic to Citrus)*Guignardia loricata* (Saw.) Yamamoto et Ito*Guignardia piricola* (Nosa) Yamamoto*Gymnosporangium* spp. (non-European)*Inonotus weiril* (Murril) Kotlaba et Pouzar*Melampsora farlowii* (Arthur) Davis*Monilinia fructicola* (Winter) Honey*Mycosphaerella larici-leptolepis* Ito et al.*Mycosphaerella populorum* G. E. Thompson*Phoma andina* Turkensteen*Phyllosticta solitaria* Ell. et Ev.*Puccinia pittieriana* Hennings*Septoria lycopersici* Speg. var. *malagutii* Ciccarone et Boerema*Scirrhia acicola* (Dearn.) Siggers*Stegophora ulmea* (Schweinitz: Fries) Sydow & Sydow

Tuesday 15 April 2014

Thecaphora solani Barrus

Tilletia indica Mitra

Trechispora brinkmannii (Bresad.) Rogers

Venturia nashicola Tanaka et Yamamoto

(d) Viruses and virus-like organisms

Elm phloem necrosis mycoplasma

Potato viruses and virus-like organisms, such as:

(a) Andean potato latent virus

(b) Andean potato mottle virus

(c) Arracacha virus B, oca strain

(d) Potato black ringspot virus

(e) Potato spindle tuber viroid

(f) Potato virus T

(g) Non-European isolates of potato viruses A, M, S, V, X, and Y (including Y o, Y n and Y e) and Potato leafroll virus

Tobacco ringspot virus

Tomato ringspot virus

Viruses and virus-like organisms of *Cydonia* Mill., *Fragaria* L., *Malus* Mill., *Prunus* L., *Pyrus* L., *Ribes* L., *Rubus* L. and *Vitis* L., such as:

(a) Blueberry leaf mottle virus

(b) Cherry rasp leaf virus (American)

(c) Peach mosaic virus (American)

(d) Peach phony rickettsia

(e) Peach rosette mosaic virus

(f) Peach rosette mycoplasma

(g) Peach X-disease mycoplasma

(h) Peach yellows mycoplasma

(i) Plum line pattern virus (American)

(j) Raspberry leaf curl virus (American)

(k) Strawberry latent C virus

(l) Strawberry vein banding virus

(m) Strawberry witches' broom mycoplasma

(n) Non-European viruses and virus-like organisms of *Cydonia* Mill., *Fragaria* L., *Malus* Mill., *Prunus* L., *Pyrus* L., *Ribes* L., *Rubus* L. and *Vitis* L.

Viruses transmitted by *Bemisia tabaci* Genn., such as:

(a) Bean golden mosaic virus

(b) Cowpea mild mottle virus

(c) Lettuce infectious yellows virus

(d) Pepper mild tigré virus

Tuesday 15 April 2014

(e) *Squash leaf curl virus*

(f) *Euphorbia mosaic virus*

(g) *Florida tomato virus*

Beet curly top virus (non-European isolates)

Black raspberry latent virus

Blight and blight-like

Cadang-Cadang viroid

Cherry leafroll virus

Chrysanthemum stem necrosis virus

Citrus mosaic virus

Citrus tristeza virus (non-European isolates)

Leprosis

Little cherry pathogen (non-European isolates)

Naturally spreading psorosis

Palm lethal yellowing mycoplasma

Prunus necrotic ringspot virus

Satsuma dwarf virus

Tatter leaf virus

Witches' broom (MLO)

(e) *Parasitic plants*

Arceuthobium spp. (non-European)

HARMFUL ORGANISMS KNOWN TO OCCUR IN THE COMMUNITY AND RELEVANT FOR THE ENTIRE COMMUNITY

(a) *Insects, mites and nematodes, at all stages of their development*

Diabrotica virgifera virgifera Le Conte

Globodera pallida (Stone) Behrens

Globodera rostochiensis (Wollenweber) Behrens

Meloidogyne chitwoodi Golden et al. (all populations)

Meloidogyne fallax Karssen

Opogona sacchari (Bojer)

Popillia japonica Newman

Rhizoecus hibisci Kawai & Takagi

Spodoptera littoralis (Boisduval)

(b) *Bacteria*

Clavibacter michiganensi (Smith) Davis et al. ssp. *sepedonicus* (Spieckermann et Kotthoff) Davis et al.

Pseudomonas solanacearum (Smith) Smith

Tuesday 15 April 2014

(c) **Fungi**

Melampsora medusae Thümen

Synchytrium endobioticum (Schilfersky) Percival

(d) **Viruses and virus-like organisms**

Apple proliferation mycoplasm

Apricot chlorotic leafroll mycoplasm

Pear decline mycoplasm

(e) **Other**

Pomacea spp. [Am. 126]

Tuesday 15 April 2014

ANNEX IB

List of Union priority pests referred to in Article 6(2)

(a) Insects, mites and nematodes, at all stages of their development

Anoplophora chinensis (Thomson)*Anoplophora glabripennis* (Motschulsky)*Bursaphelenchus xylophilus* (Steiner et Buher) Nickle et al.*Cicadellidae* (non-European species) known to carry Pierce's disease (caused by *Xylella fastidiosa*), such as:(a) *Carneocephala fulgida* Nottingham(b) *Draeculacephala minerva* Ball(c) *Graphocephala atropunctata* (Signoret)*Diaphorina citri* Kuway*Paysandisia archon**Pistosia dactyliferae**Rhynchophorus ferrugineus**Thaumatotibia leucotreta**Trioza erytrae* Del Guercio

(b) Bacteria

*Citrus greening bacterium**Pseudomonas solanacearum* (Smith) Smith*Pseudomonas syringae**Xanthomonas campestris* (all strains pathogenic to Citrus)*Xanthomonas campestris* pv. *oryzae* (Ishiyama) Dye and pv. *oryzicola* (Fang. et al.) Dye*Xylella fastidiosa* (Well et Raju)

(c) Fungi

Elsinoe spp. Bitanc. et Jenk. Mendes*gibberella circinata**Guignardia citricarpa* Kiely (all strains pathogenic to Citrus)*Hypoxyton mammatum**Phytophthora ramorum**Trechispora brinkmannii* (Bresad.) Rogers*Venturia nashicola* Tanaka et Yamamoto

(d) Virus and virus-like organisms

Potato viruses and virus-like organisms such as:

(a) Andean potato latent virus

(b) Andean potato mottle virus

Tuesday 15 April 2014

(c) *Arracacha virus B, oca strain*

(d) *Potato black ringspot virus*

(e) *Potato spindle tuber viroid*

(f) *Potato virus T*

(g) *Non-European isolates of potato viruses A, M, S, V, X, and Y (including Y o, Y n and Y e) and Potato leafroll virus*

Grapevine flavescence dorée MLO

(e) *other*

Pomacea spp. [Am. 127]

Tuesday 15 April 2014

ANNEX IC

List of quality pests referred to in Article 36

INSECTS

Acanthoscelides obtectus Sag.

Pelargonium flower break carmovirus

Aceria essigi.

Aculops fockeui.

Agromyzidae

Aleurodidae, particularly *Bemisia tabaci*

Aleurothrixus floccosus (Mashell)

Anarsia lineatella.

Aphelenchoides spp.

Blastophaga spp.

Bruchus affinis Froel.

Bruchus atomarius L.

Bruchus pisorum L.

Bruchus rufimanus Boh.

Cacoecimorpha pronubana

Cecidophyopsis ribis.

Circulifer haematoceps

Circulifer tenellus

Scale insects, particularly: *Epidiaspis leperii*, *Pseudaulacaspis pentagona*, *Quadraspidiotus perniciosus*.

Daktulosphaira vitifoliae (Fitch)

Diarthronomia chrysanthemi

Ditylenchus destructor Thorne

Ditylenchus dipsaci

Epichoristodes acerbella

Epidiaspis leperii.

Eriophis avellanae.

Eriophyes similis.

Eriosoma lanigerum

Eumerus spp.

Eusophera pinguis.

Eutetranychus orientalis Klein

Helicoverpa armigera (Hübner)

Lepidoptera

Tuesday 15 April 2014

Liriomyza huidobrensis (Blanchard)

Liriomyza trifolii (Burgess)

Meloidogyne spp.

Merodon equestris

Myzus ornatus

Otiorrhynchus sulcatus

Parabemisia myricae (Kuwana)

Parabemisia, myricae (Kuwana).

Parasaissetia nigra (Nietner)

Paysandisia archon (Burmeister)

Pratylenchus penetrans

Pratylenchus spp.

Pseudaulacaspis pentagona.

Quadraspidiotus perniciosus

Quadraspidiotus perniciosus

Radopholus similis (Cobb) Thorne

Rhizoglyphidae

Rhyacionia buoliana

Rhyzoglyphus spp.

Rotylenchus robustus

Salsetia oleae.

Sciara

Tarsonemidae

Tarsonemidae.

Tetranychus urticae

Thysanoptera

Tylenchulus semipenetrans

Pelargonium line pattern virus

BACTERIA

Agrobacterium rhizogenes.

Agrobacterium tumefaciens.

Agrobacterium tumefaciens

Clavibacter michiganensis spp. *insidiosus* (McCulloch) Davis et al.

Clavibacter michiganensis spp. *michiganensis* (Smith) Davis et al

Corynebacterium sepedonicum

Erwinia amylovora (Burr.) Winsl. et al

Erwinia carotovora subsp. *Carotovora*

Erwinia chrysanthemi

Tuesday 15 April 2014

Pseudomonas caryophylli (Burkholder) Starr et Burkholder

Pseudomonas marginata

Pseudomonas solanacearum.

Pseudomonas syringae pv. *glycinea*

Pseudomonas syringae pv. *mors prunorum*.

Pseudomonas syringae pv. *persicae* (Prunier et al.) Young et al

Pseudomonas syringae pv. *savastanoi*.

Pseudomonas syringae pv. *syringae*

Rhodococcus fascians

Xanthomonas campestris pv. *Begoniae*

Xanthomonas campestris pv. *corylina*.

Xanthomonas campestris pv. *juglandi*.

Xanthomonas campestris pv. *Pelargonii*

Xanthomonas campestris pv. *pruni* (Smith) Dye

Xanthomonas campestris pv. *phaseoli* (Smith) Dye

Xanthomonas campestris pv. *vesicatoria* (DoIDGE) Dye

Xanthomonas fragariae Kennedy et King

Xylophilus ampelinus Vitis (Panagopoulos) Willems. et al

FUNGI

Stem rot pathogens (*Botrytis* spp., *Pythium* spp.)

Fusarium oxisporum f. sp. *lilii*

Fusarium oxisporum sp. *gladioli*

Rhizoctonia spp.

Alternaria dianthicola

Armillariella mellea

Ceratocystis fimbriata f. sp. *platani* Walter

Chondrostereum purpureum

Claviceps purpurea

Cryphonectria parasitica (Murrill) Barr

Curvularia trifolii

Cylindrocarpon destructans

Diaporthe phaseolorum var. *caulivora* and var. *sojae*

Didymella applanata.

Didymella ligulicola (Baker, Dimock et Davis) v. Arx

Exosporium palmivorum

Fusarium fujikuroi

Fusarium oxisporum f. sp. *dianthi*

Fusarium oxisporum sp. *chrysanthemi*

Tuesday 15 April 2014

Fusarium oxysporum f. sp. *narcissi*
Fusarium spp.
Gliocladium wermoeseni
Graphiola phoenicis
Helminthosporium
Lophodermium seditiosum
Mycosphaerella dianthi
Nectria galligena
Powdery mildew
Penicillium gladioli
Peronospora rubi.
Pestalozzia Phoenicis
Phialophora cinerescens (Wollenweber) van Beyma
Phialophora gregata
Phoma tracheiphila (Petri) Kanchaveli et Gikashvili
Phyllactinia guttata.
Phytophthora cactorum.
Phytophthora fragariae var. *rubi*.
Phytophthora spp.
Plasmopara halstedii (Farlow) Berl. et de Toni
Stem rot: *Fusarium* spp. and *Pythium*
Puccinia chrysanthemi
Puccinia horiana Hennings
Puccinia pelargonii zonalis
Pythium spp.
Rhizoctonia spp.
Rhizopus spp.
Rosellinia necatrix
Scirrhia pini Funk et Parker
Sclerotinia spp.
Septoria gladioli
Slerotium bulborum
Synchytrium endobioticum
Taphrina deformans
Thielaviopsis basicola
Tilletia
Urocystis gladiolicola
Uromyces dianthi
Uromyces trasversalis

Tuesday 15 April 2014

Ustilaginaceae,

Venturia spp.

Verticillium spp

VIRUSES AND VIRUS-LIKE ORGANISMS

Narcissus white streak agent

Carnation mottle carmovirus

Carnation etched ring caulimovirus

Carnation necrotic fleck closterovirus

Aster yellow micoplasm

Corky pit agent

Anarsia lineatella

Apple mosaic virus.

Arabis mosaic virus Fragaria

Beet leaf curl virus

Black currant infecticus variegation

Black currant rever.

Cherry leaf roll virus.

Chondrostereum purpureum

Chrysanthemum stunt viroid

Citrus leaf rugose.

Citrus tristeza virus (European isolates)

Citrus vein enation woody gall

Scale insects, particularly: Epidiaspis leperii, Pseudaulacaspis pentagona, Quadraspidiotus perniciosus

Coniothyrium spp.

Tomato aspermy cucumovirus

Diplocarpon rosae

Diseases that induce in young leaves psorosis and psorosis-like symptoms such as ring-spot, cristacortis, impietratura and concave gum.

Eriosoma lanigerum

Grapevine flavescence dorée MLO

Hazel maculatura lineare MLO

Infectious variegation.

Arabis mosaic nepovirus

Peronospora sparsa

Phragmidium spp.

Plum pox virus

Potato stolbur mycoplasm

Prune dwarf virus.

Prunus necrotic ringspot virus

Tuesday 15 April 2014

Raspberry bushy dwarf virus.

Raspberry leaf curl virus.

Raspberry ringspot virus

Leaf curl

Rosellinia necatrix

Citric leaf rugose

Sphaeroteca pannosa

Spiroplasma citri Saglio. *et al.*

Strawberry crinkle virus

Strawberry green petal MLO.

Strawberry latent ringspot virus

Strawberry mild yellow edge virus

Tomato black ring virus

Tomato spotted wilt virus

Tomato yellow leaf curl virus

Pelargonium leaf curl tobusvirus

Tospovirus (tomato spotted wilt virus, Impatiens necrotic spot virus)

Infectious variegation

Venturia spp.

Verticillium spp.

Viroids such as exocortis, caquexia-xyloporosis.

Lily symptomless virus

Tulipbreaking virus

Gladiolus ringspot virus (syn. Narcissus latent virus)

Narcissus yellow stripe virus

Chrysanthemum B mosaic virus

Cucumber mosaic virus

Tobacco rattle virus

Lily virus x

NEMATODES

Heterodera rostochiensis

OTHER HARMFUL ORGANISMS

Cyperus esculentus (truffle)

Orobanche (parasitic plant) [Am. 128]

Tuesday 15 April 2014

ANNEX II

Criteria for the qualification of pests according to their risk to the Union territory

Section 1

Criteria to identify pests which qualify as a quarantine pest, as referred to in Articles 3, 7(1) and 28(2)

(1) Identity of the pest

The taxonomic identity of the pest shall be clearly defined or, alternatively, the pest shall have been shown to produce consistent symptoms and to be transmissible.

The taxonomic identity of the pest shall be defined at species level or, alternatively, a higher or lower taxonomic level, where that taxonomic level is scientifically appropriate based on its virulence, host range or vector relationships.

(2) Presence of the pest in the territory in question

One or more of the following conditions shall apply:

- (a) the pest is not known to be present in the territory in question;
- (b) the pest is not known to be present in the territory in question, except in a limited part of it;
- (c) the pest is not known to be present in the territory in question, except for scarce, irregular, isolated and infrequent presences in it.

Where points (b) or (c) apply, the pest shall be considered to be distributed to a limited extent.

(3) Capability of entry, establishment and spread of the pest in the territory in question

(a) *Capability of entry*

The pest shall be considered capable of entry into the territory in question, or, if present, into the part of that territory where it is distributed to a limited extent (hereinafter: 'endangered area'), either by natural spread, or if all of the following conditions are fulfilled:

- (i) it is associated, as regards plants, plant products or other objects which are moved into the territory in question, with those plants, plant products and other objects in the territory where they originate or from where they are moved into the territory in question;
- (ii) it survives during transport or storage;
- (iii) it may be transferred to a suitable host plant, plant product or other object in the territory in question.

(b) *Capability of establishment*

The pest shall be considered capable of perpetuating its presence for the foreseeable future (hereinafter: 'establishment') in the territory in question, or, if present, the part of that territory where it is distributed to a limited extent, if all of the following conditions are fulfilled:

- (i) hosts of the pest and, where relevant, vectors for transmission of the pest are available;
- (ii) the decisive environmental factors are favourable for the pest concerned and, where applicable, its vector, enabling it to survive periods of climatic stress and complete its life cycle;
- (iii) cultivation practices and control measures applied in that territory are favourable;

Tuesday 15 April 2014

- (iv) the survival methods, reproductive strategy, genetic adaptability of the pest and its minimum viable population size support its establishment.

(c) *Capability of spread*

The pest shall be considered capable of territorial spread in the territory in question, or, if present, the part of that territory where it is distributed to a limited extent, if one or more of the following conditions is fulfilled:

- (i) the environment is suitable for natural spread of the pest;
- (ii) barriers to natural spread of the pest are insufficient;
- (iii) commodities or conveyances allow for movement of the pest;
- (iv) hosts and, where relevant, vectors of the pest are present;
- (v) natural enemies and antagonists of the pest are not present or not sufficiently capable to suppress the pest.

(4) Potential economic, social and environmental impact

The entry, establishment and spread of the pest in the territory in question, or, if present, the part of that territory where it is distributed to a limited extent, shall have unacceptable economic, social and/or environmental impacts for that territory, or the part of that territory where it is distributed to a limited extent, as regards one or more of the following points:

- (a) crop losses in terms of yield and quality;
- (b) costs of control measures;
- (c) costs of replanting and losses due to the necessity of growing substitute crops;
- (d) effects on existing production practices;
- (e) effects on street trees, parks and public and private green;
- (f) effects on native plants, biodiversity and ecosystem services;
- (g) effects on the establishment, spread and impact of other pests, due to the capacity of the pest concerned to act as a vector for other pests;
- (h) changes to producer costs or input demands, including control costs and costs of eradication and containment;
- (i) effects on producer profits that result from changes in production costs, yields or price levels;
- (j) changes to domestic or foreign consumer demand for a product resulting from quality changes;
- (k) effects on domestic and export markets and prices paid, including effects on export market access and likelihood of phytosanitary restrictions imposed by trading partners;
- (l) resources needed for additional research and advice;
- (m) environmental and other undesired effects of control measures;
- (n) effects on Natura 2000 or other protected areas;
- (na) effects on landscape heritage and tourist areas; [Am. 129]**
- (o) changes in ecological processes and the structure, stability or processes of an ecosystem, including further effects on plant species, erosion, water table changes, fire hazards, nutrient cycling;

Tuesday 15 April 2014

- (p) costs of environmental restoration;
- (q) effects on food security;
- (r) effects on employment;
- (s) effects on water quality, recreation, tourism, animal grazing, hunting, fishing.

As regards points (a) to (g), direct effects on hosts in the endangered area shall be taken into account. Those effects shall be assessed taking account of the range of the host species, and on the basis of the types, amount and frequency of the damage suffered by those host species.

As regards points (h) to (s), indirect effects within and outside the endangered area shall be taken into account.

Section 2

Criteria to identify union quarantine pests which qualify as a priority pest as referred to in Articles 6(1) and 7(2)

A Union quarantine pest shall be considered to have most severe economic, social or environmental impact for the Union territory, if its entry, establishment and spread fulfils one or more of the following points:

- (a) Economic impacts: the pest has the potential to cause major losses in terms of the direct and indirect effects referred to in point (4) of Section 1 for crops ~~with a total annual production value for~~ **in** the Union territory ~~of at least EUR 1 billion.~~ [Am. 130]
- (aa) in case of pests affecting specialty crops, grown in the European territory on less than 200 000 hectares, the potential loss in terms of total annual Union production value shall be at least EUR 200 million.** [Am. 131]
- (b) Social impacts: the pest has the potential to cause one or more of the following effects:
 - (i) a significant employment decrease in the agriculture, horticulture or forestry sector concerned;
 - (ii) risks to food security or food safety;
 - (iii) the disappearance of, or permanent large-scale damage to, main tree species growing or cultivated in the Union territory.
- (c) Environmental impacts: the pest has the potential to cause one or more of the following effects:
 - (i) effects on species and habitats listed under the provisions of Council Directive 92/43/EEC⁽¹⁾ and Directive 2009/147/EC of the European Parliament and of the Council⁽²⁾;
 - (ii) major and permanent increases of the use of plant protection products on the crops concerned.

⁽¹⁾ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7).

⁽²⁾ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

Tuesday 15 April 2014

Section 3

Criteria for a preliminary assessment to identify pests which provisionally qualify as a Union quarantine pest requiring temporary measures as referred to in Articles 21(1), 28(1), 29(1) and 30

Subsection 1

Criteria for a preliminary assessment to identify pests which provisionally qualify as a Union quarantine pest requiring temporary measures as referred to in Article 28(1)

(1) Identity of the pest

The pest shall meet the criterion defined in point (1) of Section 1.

(2) Presence of the pest in the Member State's territory

The pest is not previously known to be present in the territory of a Member State. Based on the information available to that Member State, the pest is also not previously known to be present in Union territory, or is considered to fulfil the conditions set out in points (b) or (c) of point (2) of Section 1 as regards the Union territory.

(3) Probability of establishment and spread of the pest in the Union territory, or the specific part(s) of the Union territory where it is not present

Based on the information available to the Member State, the pest meets the criteria defined in points (3)(b) and (c) of Section 1 as regards its territory and, to the extent possible for the Member State to assess this, the Union territory.

(4) Potential economic, social and environmental impact of the pest

Based on the information available to the Member State, the pest has unacceptable economic, social and/or environmental impacts as regards its territory and, to the extent possible for the Member State to assess this, the Union territory, if it would establish and spread in that territory, as concerns one or several of the areas defined in point (4) of Section 1.

Those impacts shall include at least one or more of the direct effects listed under point (4)(a) to (g) of Section 1.

Subsection 2

Criteria for a preliminary assessment to identify pests which provisionally qualify as a Union quarantine pest requiring temporary measures as referred to in Article 29(1)

(1) Identity of the pest

The pest shall meet the criterion defined in point (1) of Section 1.

(2) Presence of the pest in the Union territory

The pest is not previously known to be present in Union territory or is considered to fulfil the conditions set out in points (b) or (c) of point (2) of Section 1 as regards the Union territory.

(3) Probability of establishment and spread of the pest in the Union territory, or the specific part(s) of the Union territory where it is not present

Based on the information available to the Union, the pest meets the criteria defined in points (3)(b) and (c) of Section 1 as regards the Union territory.

Tuesday 15 April 2014

(4) Potential economic, social and environmental impact of the pest

Based on the information available to the Union, the pest has unacceptable economic, social and/or environmental impacts as regards the Union territory, if it would establish and spread in that territory, as concerns one or several of the areas defined in point (4) of Section 1.

Those impacts shall include at least one or more of the direct effects listed under point (4)(a) to (g) of Section 1.

Section 4

Criteria to identify pests which qualify as a Union quality pest as referred to in Article 36 and 38

(1) Identity of the pest

The pest shall meet the criterion defined in point (1) of Section 1.

(2) Probability of spread in the Union territory of the pest

The spread of the pest shall be assessed to take place mainly via specific plants for planting, rather than via natural spread or via movement of plant products or other objects.

That assessment shall include, as appropriate, the following aspects:

- (a) the number of life cycles of the pest on the concerned hosts;
- (b) the biology, epidemiology and survival of the pest;
- (c) possible natural, human-assisted or other pathways for transmission of the pest to the concerned host and pathway efficiency, including mechanisms of dispersal and dispersal rate;
- (d) secondary infestation and transmission of the pest from the concerned host to other plants and vice versa;
- (e) climatological factors;
- (f) cultural practices before and after harvest;
- (g) soil types;
- (h) susceptibility of the concerned host and relevant stages of host plants;
- (i) presence of vectors for the pest;
- (j) presence of natural enemies and antagonists of the pest;
- (k) presence of other hosts susceptible to the pest;
- (l) prevalence of the pest in the Union territory;
- (m) intended use of the plants.

(3) Potential economic, social and environmental impact of the pest

Infestations of the plants for planting referred to in point (2) with the pest shall have an unacceptable economic impact on the intended use of those plants as regards one or more of the following points:

- (a) crop losses in terms of yield and quality;
- (b) extra costs of control measures;
- (c) extra costs of harvesting and grading;
- (d) costs of replanting;
- (e) losses due to the necessity of growing substitute crops;

Tuesday 15 April 2014

- (f) effects on existing production practices;
- (g) effects on other host plants at the place of production;
- (h) effects on the establishment, spread and impact of other pests, due to the capacity of the pest concerned to act as a vector for those other pests;
- (i) effects on producer costs or input demands, including control costs and costs of eradication and containment;
- (j) effects on producer profits that result from changes in production costs, yields or price levels;
- (k) changes to domestic or foreign consumer demand for a product resulting from quality changes;
- (l) effects on domestic and export markets and prices paid;
- (m) effects on employment.

As regards points (a) to (h), direct effects on hosts in the endangered area shall be taken into account. Those effects shall be assessed on the basis of the types, amount and frequency of the respective damage.

As regards points (i) to (m), indirect effects within and outside the endangered area shall be taken into account.

Tuesday 15 April 2014

ANNEX III

Elements to identify plants for planting which pose phytosanitary risks for the Union territory, as referred to in Articles 47 (2) and 48

Plants for planting from third countries shall be considered likely to pose phytosanitary risks for the Union territory, as referred to in Article 47(1), where those plants for planting fulfil at least ~~three~~ **one** of the following conditions, ~~including at least one of the conditions provided in points (1)(a), (b) and (c):~~ **[Am. 132]**

(1) Characteristics of the plants for planting

- (a) They belong to a plant genus or family known to commonly host pests regulated as quarantine pests in the Union territory or in third countries.
- (b) They belong to a plant genus or family known to commonly host polyphagous pests, or monophagous pests known to have major impact to plant species grown in the Union territory which have major economic, social or environmental importance to the Union territory.
- (c) They belong to a plant genus or family known to commonly harbour pests without signs and symptoms of those pests, or with a latent period for the expression of those signs or symptoms of at least three months, implying that the presence of pests on those plants for planting is likely to be missed during official controls at introduction into the Union territory, without recourse to sampling and testing or submission to quarantine procedures.
- (d) They are grown outdoors in the third countries of origin.
- ~~(e) They are not treated with generic plant protection products prior to or during shipment. **[Am. 133]**~~
- ~~(f) They are not subject to official export controls and certification in the third country of origin. **[Am. 134]**~~
- (g) They are not shipped in closed containers or packaging, or when shipped in such a way, the shipments because of their size cannot be opened in closed premises for purposes of official controls at introduction into the Union territory.

(2) Origin of the plants for planting

- (a) They originate from, or are moved from, a third country which is the source of frequent notifications of interceptions of quarantine pests not listed pursuant to Article 5(2).
 - (b) They originate from, or are moved from, a third country which is not a member of the IPPC.
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Tuesday 15 April 2014

ANNEX IV

Measures and principles for the management of the risks of pests

Section 1

Measures to manage the risks of quarantine pests as referred to in Articles 16(1), 20, 24(2), 27(4), 28(1), 29(4), 40(2), 41(2), 44(3), 49(2) and 50(2)

The management of the risks of quarantine pests shall consist of one or more, as appropriate, of the following measures:

(1) Measures targeting prevention and elimination of infestation of cultivated and wild plants

- (a) Restrictions as regards the identity, nature, origin, ancestry, provenance and production history of cultivated plants.
- (b) Restrictions on the cultivation, harvesting and use of plants.
- (c) Restrictions on the use of plant products, premises, land, water, soil, growing media, facilities, machinery, equipment and other objects.
- (d) Surveillance, visual examination, sampling and laboratory testing of plants, plant products, premises, land, water, soil, growing media, facilities, machinery, equipment and other objects for the presence of quarantine pests.
- (e) Surveillance for breakdown or change in the effectiveness of a resistant plant species or plant variety which relates to a change in the composition of the quarantine pest or its biotype, pathotype, race or virulence group.
- (f) Physical, chemical and biological treatment of plants, plant products, premises, land, water, soil, growing media, facilities, machinery, equipment and other objects, infested or potentially infested with quarantine pests.
- (g) Destruction of plants, plant products and other objects, infested or potentially infested with quarantine pests or for preventive purposes.
- (h) Information, data recording, communication and reporting obligations.

For the purposes of point (b), those measures may include requirements with regard to the testing of plant species and plant varieties for resistance to the quarantine pest concerned and the listing of plant species and plant varieties found to be resistant to the quarantine pest concerned.

For the purposes of point (f), those measures may include requirements with regard to:

- (a) the registration, authorisation and official supervision of professional operators applying the treatment concerned;
- (b) the issuance of a phytosanitary certificate, plant passport, label or other official attestation for the treated plants, plants products or other objects and the placing of the mark referred to in Article 91(1) following the application of the treatment concerned.

(2) Measures targeting consignments of plants, plants products and other objects

- (a) Restrictions on the identity, nature, origin, provenance, ancestry, production method, production history and traceability of plants, plant products and other objects.

Tuesday 15 April 2014

- (b) Restrictions on the introduction, movement, use, handling, processing, packaging, storage, distribution and destination of plants, plant products and other objects.
- (c) Surveillance, visual examination, sampling, laboratory testing of plants, plant products and other objects for the presence of quarantine pests, including through subjection to quarantine procedures **and pre-shipment inspections in third countries**. [Am. 135]
- (d) Physical, chemical and biological treatment and, where appropriate, destruction of plants, plant products and other objects, infested or potentially infested with quarantine pests.
- (e) Information, data recording, communication and reporting obligations.

For the purposes of points (a) to (d), those measures may include requirements with regard to:

- (a) the issuance of a phytosanitary certificate, plant passport, label or other official attestation, including the placing of the mark referred to in Article 91(1) to attest compliance with the provisions referred to in point (a) to (d);
 - (b) the registration, authorisation and official supervision of professional operators applying the treatment referred to in point (d).
- (3) Measures targeting pathways for quarantine pests, other than consignments of plants, plant products or other objects
- (a) Restrictions on the introduction and movement of quarantine pests as a commodity.
 - (b) Surveillance, visual examination, sampling and laboratory testing and where appropriate destruction of commodities of quarantine pests.
 - (c) Restrictions on plants, plant products and other objects carried by travellers.
 - (d) Surveillance, visual examination, sampling and laboratory testing and where appropriate treatment or destruction of plants, plant products and other objects carried by travellers.
 - (e) Restrictions on vehicles, packaging and other objects used in transport of commodities.
 - (f) Surveillance, visual examination, sampling and laboratory testing and where appropriate treatment or destruction of vehicles, packaging and other objects used in transport of commodities.
 - (g) Information, data recording, communication and reporting obligations.

Section 2

Principles for the management of the risks of pests as referred to in Articles 16(1), 17(2), 27(4), 28(1), 29(4), 31(1), 37(5), 44(3), 47(2), 68(3), 69(3), 70(2), 74(3) and 75(3)

The management of the risks of Union quarantine pests, protected zone quarantine pests and Union quality pests shall respect the following principles:

(1) Necessity

Measures to manage the risk of a pest shall be applied only where such measures are necessary to prevent the introduction, establishment and spread of that pest.

(2) Proportionality

Measures taken to manage the risk of a pest shall be consistent with the risk posed by the pest concerned and the level of protection that is required.

Tuesday 15 April 2014

(3) Minimal impact

Measures taken to manage the risk of a pest shall represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances.

(4) Non-discrimination

Measures taken to manage the risk of a pest shall not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade. They shall be no more stringent for third countries than measures applied to that same pest if present within the Union territory, if third countries can demonstrate that they have the same phytosanitary status and apply identical or equivalent phytosanitary measures.

(5) Technical justification

Measures taken to manage the risk of a pest shall be technically justified on the basis of conclusions reached by using an appropriate risk analysis or, where applicable, another comparable examination and **an EFSA supervised** evaluation of available scientific information. Those measures should reflect, and, where appropriate, be modified or removed to reflect new or updated risk analysis or relevant scientific information. [**Am. 136**]

(6) Feasibility

Measures taken to manage the risk of a pest should be such as to allow that the objective of those measures is likely achieved.

Tuesday 15 April 2014

ANNEX V

Contents of phytosanitary certificates for introduction into the Union territory

Part A

Phytosanitary certificates for export as referred to in Article 71(1)

Model Phytosanitary Certificate

No. _____

Plant Protection Organization of _____

TO: Plant Protection Organization(s) of _____

I. Description of Consignment

Name and address of exporter: _____

Declared name and address of consignee: _____

Number and description of packages: _____

Distinguishing marks: _____

Place of origin: _____

Declared means of conveyance: _____

Declared point of entry: _____

Name of produce and quantity declared: _____

Botanical name of plants: _____

This is to certify that the plants, plant products or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests.

They are deemed to be practically free from other pests.(*)

II. Additional Declaration

[Enter text here]

Tuesday 15 April 2014

III. Disinfestation and/or Disinfection Treatment

Date _____ Treatment _____ Chemical (active ingredient) _____

Duration and temperature _____

Concentration _____

Additional information _____

Place of issue _____

(Stamp of Organization) _____ Name of authorized officer _____

Date _____

(Signature)

No financial liability with respect to this certificate shall attach to _____ (name of Plant Protection Organization) or to any of its officers or representatives.(*)

(*) Optional clause

Tuesday 15 April 2014

Part B
Phytosanitary certificates for re-export as referred to in Article 71(1)

Model Phytosanitary Certificate for Re-Export

No. _____

Plant Protection Organization of _____ (contracting party of re-export)

TO: Plant Protection Organization(s) of _____ (contracting party(ies) of import)

I. Description of Consignment

Name and address of exporter: _____

Declared name and address of consignee: _____

Number and description of packages: _____

Distinguishing marks: _____

Place of origin: _____

Declared means of conveyance: _____

Declared point of entry: _____

Name of produce and quantity declared: _____

Botanical name of plants: _____

This is to certify that the plants, plant products or other regulated articles described above
_____ were imported into (contracting party of re-export) _____ from
_____ (contracting party of origin) covered by Phytosanitary Certificate No.
_____.

(* original (* certified true copy

of which is attached to this certificate; that they are

(* packed (* repacked

in

(* original (* new

Tuesday 15 April 2014

containers, that based on the

(*) original phytosanitary certificate

and

(*) additional inspection

they are considered to conform with the current phytosanitary requirements of the importing contracting party, and that during storage in _____ (contracting party of re-export), the consignment has not been subjected to the risk of infestation or infection.

(*) Insert tick in appropriate boxes

II. Additional Declaration

[Enter text here]

III. Disinfestation and/or Disinfection Treatment

Date _____ Treatment _____ Chemical (active ingredient) _____

Duration and temperature _____

Concentration _____

Additional information _____

(Stamp of Organization) _____ Place of issue _____

Name of authorized officer _____

Date _____

(Signature)

No financial liability with respect to this certificate shall attach to _____ (name of Plant Protection Organization) or to any of its officers or representatives. (*)

(*) Optional clause

Tuesday 15 April 2014

ANNEX VI

Plant passports

Part A

Plant passports for movement within the Union territory as referred to in the first subparagraph of Article 78(2)

- (1) The plant passport for movement within the Union territory shall contain the following elements:
 - (a) in its upper left hand corner, the words 'Plant Passport';
 - (b) in its upper right hand corner, the flag of the European Union;
 - (c) the letter 'A.', followed by the botanical name of the plant species or taxon concerned, in case of plants and plant products, or, where appropriate, the name of the object concerned;
 - (d) the letter 'B.', followed by subsequently the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator issuing the plant passport is registered, a hyphen and the registration number of the professional operator concerned;
 - (e) the letter 'C.', followed by the lot number of the plant, plant product or the other object concerned;
 - (f) the letter 'D.', optionally followed by the name of the third country of origin or two-letter code, referred to in point (b) of Article 63, for the Member State of origin.
- (2) The lot number referred to in point 1(e) may be replaced by a reference to a unique traceability barcode, hologram, chip or other data carrier, present on the lot.

Part B

Plant passports for movement into and within protected zones as referred to in the second subparagraph of Article 78(2)

- (1) The plant passport for movement into and within protected zones shall contain the following elements:
 - (a) in its upper left hand corner, the words 'Plant Passport — ZP';
 - (b) immediately underneath those words, the scientific name(s) of the protected zone quarantine pest(s) concerned;
 - (c) in the upper right hand corner, the flag of the European Union;
 - (d) the letter 'A.', followed by the botanical name of the plant species or taxon concerned, in case of plants and plant products, or, where appropriate, the name of the object concerned;
 - (e) the letter 'B.', followed by subsequently the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator issuing the plant passport is registered, a hyphen and the registration number of the professional operator concerned;
 - (f) the letter 'C.', followed by the lot number of the plant, plant product or the other object concerned;
 - (g) the letter 'D.', optionally followed by the name of the third country of origin or two-letter code, referred to in point (b) of Article 63, for the Member State of origin.
- (2) The lot number referred to in point 1(f) may be replaced by a reference to a unique traceability barcode, hologram, chip or other data carrier, present on the lot.

Tuesday 15 April 2014

Part C

Plant passports for movement within the Union territory, combined with a certification label, as referred to in the second subparagraph of Article 78(3)

(1) The plant passport for movement within the Union territory, combined in a joint label with the official label referred to in Article 19 of Regulation (EU) No .../... [*number of Regulation on plant reproductive material law*], or the master certificate referred to in Article 122 of that Regulation, shall contain the following elements:

- (a) in the upper left hand corner of the joint label, the words 'Plant Passport';
- (b) in the upper right hand corner of the joint label, the flag of the European Union.

The plant passport shall be positioned in the joint label immediately above, and have the same width as, that official label or, where applicable, that master certificate.

Where point (c), (d), (e) or (f) as referred to in point (1) of Part A is not contained in that official label or, where applicable, that master certificate, that point shall be provided in the plant passport referred to in the first subparagraph.

(2) Point (2) of Part A shall apply accordingly.

Part D

Plant passports for movement into and within protected zones, combined with a certification label, as referred to in the third subparagraph of Article 78(3)

(1) The plant passport for movement into and within protected zones, combined in a joint label with the official label referred to in Article 19 of Regulation (EU) No .../... [*number of Regulation on plant reproductive material law*], or the master certificate referred to in Article 122 of that Regulation, shall contain the following elements:

- (a) in the upper left hand corner of the joint label, the words 'Plant Passport — ZP';
- (b) immediately underneath those words, the scientific name(s) of the protected zone quarantine pest(s) concerned;
- (c) in the upper right hand corner of the joint label, the flag of the European Union.

The plant passport shall be positioned in the joint label immediately above, and have the same width as, that official label or, where applicable, that master certificate.

Where point (d), (e), (f) or (g) as referred to in point (1) of Part B is not contained in that official label or, where applicable, that master certificate, that point shall be provided in the plant passport referred to in the first subparagraph.

(2) Point (2) of Part B shall apply accordingly.

Tuesday 15 April 2014

ANNEX VII

Mark for wood packaging material referred to in Article 91(1)

The mark applied to wood packaging material pursuant to Article 91(1) shall contain the following elements:

- (a) on its left hand, the logo of the IPPC;
- (b) on its right hand, subsequently the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator applying that mark is registered, a hyphen, the registration number of the professional operator concerned, and the letters 'HT'.

No other information shall be contained within the border of the mark.

The mark shall not be hand drawn.

Tuesday 15 April 2014

ANNEX VIII

Contents of phytosanitary certificates for export and re-export as referred to in Articles 94(3) and 95(4)

Part A

Phytosanitary certificates for export as referred to in Article 94(3)

- (1) The phytosanitary certificate for movement out of the Union territory, for the purpose of export to a third country, shall contain the following elements:
 - (a) the words 'Phytosanitary certificate', followed by subsequently:
 - (i) the letters 'EU';
 - (ii) the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator requesting the issuance of the phytosanitary certificate for export is registered;
 - (iii) a slash;
 - (iv) a unique identification code for the certificate, consisting of numbers or a combination of letters and numbers, the letters representing, as applicable, the province and district of the Member State where the certificate is issued;
 - (b) the words 'Name and address of exporter', followed by the name and address of the registered operator requesting the issuance of the phytosanitary certificate for export;
 - (c) the words 'Declared name and address of consignee', followed by the declared name and address of the consignee;
 - (d) the words 'Plant protection organisation of', followed by the name of the Member State of which the plant protection organisation issues the certificate, and subsequently the words 'to the plant protection organisation(s) of', followed by the name or, as applicable, names, of the country or, as applicable, countries of destination;
 - (e) the words 'Place of origin', followed by the place of origin of the plants, plant products or other objects included in the consignment for which the certificate is issued;
 - (f) the words 'Declared means of conveyance', followed by the declared means of conveyance of that consignment;
 - (g) the words 'Declared point of entry', followed by the declared point of entry into the country of destination of that consignment;
 - (h) the words 'Distinguishing marks: number and description of packages; name of produce; botanical name of plants', followed by the number and type of packages included in the consignment;
 - (i) the words 'Quantity declared', followed by the quantity of the plants, plant products or other objects included in that consignment, expressed by number or weight;
 - (j) the words 'This is to certify that the plants, plant products or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests. They are deemed to be practically free from other pests.';
 - (k) the words 'Additional declaration', followed by the additional declaration referred to in Article 67(2) and the statement referred to in Article 67(3) and, optionally, any further phytosanitary information relevant to the consignment. If there is insufficient space for the whole of the additional declaration, the text is to be continued on the back of the form;
 - (l) the words 'Disinfestation and/or disinfection treatment';
 - (m) the word 'Treatment', followed by the treatment that has been applied to that consignment;
 - (n) the words 'Chemical (active ingredient)', followed by the active ingredient of the chemical used for the treatment referred to in point (m);

Tuesday 15 April 2014

- (o) the words 'Duration and temperature', followed by the duration and, where applicable, temperature of that treatment;
 - (p) the word 'Concentration', followed by the concentration of that chemical reached during that treatment;
 - (q) the word 'Date', followed by the date on which that treatment was applied;
 - (r) the word 'Additional information', followed by any additional information that the competent authority wishes to include in the certificate;
 - (s) the words 'Place of issue', followed by the place of issuance of the phytosanitary certificate;
 - (t) the word 'Date', followed by the date of issuance of the phytosanitary certificate;
 - (u) the words 'Name and signature of authorised officer', followed by the name and signature of the officer issuing and signing the phytosanitary certificate;
 - (v) the words 'Stamp of organisation', followed by the official stamp of the competent authority issuing the phytosanitary certificate.
- (2) The paper used shall contain the embossed seal of the competent authority that signs the certificate.

Part B

Phytosanitary certificates for re-export as referred to in Article 95(4)

- (1) The phytosanitary certificate for movement out of the Union territory, for the purpose of re-export to a third country, shall contain the following elements:
- (a) the words 'Phytosanitary certificate for re-export', followed by subsequently:
 - (i) the letters 'EU';
 - (ii) the two-letter code, referred to in point (b) of Article 63, for the Member State in which the professional operator requesting the issuance of the phytosanitary certificate for re-export is registered;
 - (iii) a slash;
 - (iv) a unique identification code for the certificate, consisting of numbers or a combination of letters and numbers, the letters representing, as applicable, the province and district of the Member State where the certificate is issued;
 - (b) the words 'Name and address of exporter', followed by the name and address of the registered operator requesting the issuance of the phytosanitary certificate for re-export;
 - (c) the words 'Declared name and address of consignee', followed by the declared name and address of the consignee;
 - (d) the words 'Plant protection organisation of', followed by the name of the Member State of which the plant protection organisation issues the certificate, and subsequently the words 'to the plant protection organisation(s) of', followed by the name or, as applicable, names, of the country or, as applicable, countries of destination;
 - (e) the words 'Place of origin', followed by the place of origin of the plants, plant products or other objects included in the consignment for which the certificate is issued;
 - (f) the words 'Declared means of conveyance', followed by the declared means of conveyance of that consignment;
 - (g) the words 'Declared point of entry', followed by the declared point of entry into the country of destination of that consignment;
 - (h) the words 'Distinguishing marks: number and description of packages; name of produce; botanical name of plants', followed by the number and type of packages included in the consignment;
 - (i) the words 'Quantity declared', followed by the quantity of the plants, plant products or other objects included in that consignment, expressed by number or weight;

Tuesday 15 April 2014

(j) the following text:

‘This is to certify

— that the plants or plant products described above were imported into (country of re-export) from (country of origin) covered by phytosanitary certificate No

*original

*certified true copy of which is attached to this certificate,

— that they are

*packed

*repacked

in

*original

*new containers,

— that based on the

*original phytosanitary certificate

and

*additional inspection,

they are considered to conform with the current phytosanitary regulation of the importing country, and

— that during storage in (country of re-export) the consignment has not been subjected to the risk of infestation or infection.

* Insert tick in appropriate boxes’,

in which text the required information shall be filled and the applicable boxes ticked;

(k) the words ‘Additional declaration’, followed by the additional declaration referred to in Article 67(2) and the statement referred to in Article 67(3) and, optionally, any further phytosanitary information relevant to the consignment. If there is insufficient space for the whole of the additional declaration, the text is to be continued on the back of the form;

(l) the words ‘Disinfestation and/or disinfection treatment’;

(m) the word ‘Treatment’, followed by the treatment that has been applied to that consignment;

(n) the words ‘Chemical (active ingredient)’, followed by the active ingredient of the chemical used for the treatment referred to in point (m);

(o) the words ‘Duration and temperature’, followed by the duration and, where applicable, temperature of that treatment;

(p) the word ‘Concentration’, followed by the concentration of that chemical reached during that treatment;

(q) the word ‘Date’, followed by the date on which that treatment was applied;

(r) the word ‘Additional information’, followed by any additional information that the competent authority wishes to include in the certificate;

(s) the words ‘Place of issue’, followed by the place of issuance of the phytosanitary certificate;

(t) the word ‘Date’, followed by the date of issuance of the phytosanitary certificate;

Tuesday 15 April 2014

- (u) the words 'Name and signature of authorised officer', followed by the name and signature of the officer issuing and signing the phytosanitary certificate;
 - (v) the words 'Stamp of organisation', followed by the official stamp of the competent authority issuing the phytosanitary certificate.
- (2) The paper used shall contain the embossed seal of the competent authority that signs the certificate.
-

Tuesday 15 April 2014

ANNEX IX

Correlation table

Council Directive 69/464/EEC	This Regulation	Regulation (EU) No .../... [number of Regulation on Official Controls]
Article 1	Article 27(1)	—
Article 2	Article 27(1)(d)	—
Articles 3, 4 and 5	Article 27(1)(c)	—
Article 6	Article 27(1)(e)	—
Article 7	—	—
Article 8	Article 8	—
Article 9	Article 31(1)	—
Articles 10 and 11	Article 27(1)(c)	—
Articles 12 and 13	—	—
Council Directive 93/85/EEC	This Regulation	Regulation (EU) No .../... [number of Regulation on Official Controls]
Article 1	Article 27(1)	—
Article 2	Article 27(1)(f)	—
Article 3	Article 9	—
Articles 4 to 8	Article 27(1)(a), (b) and (c)	—
Article 9	—	—
Article 10	Article 8	—
Article 11	Article 31(1)	—
Article 12	Article 27(1)	—
Articles 13 to 15	—	—
Annexes I to V	Article 27(1)	—
Council Directive 98/57/EC	This Regulation	Regulation (EU) No .../... [number of Regulation on Official Controls]
Article 1	Article 27(1)	—
Article 2	Article 27(1)(f)	—
Article 3	Article 9	—
Article 4 to 7	Article 27(1)(a), (b) and (c)	—
Article 8	—	—
Article 9	Article 8	—
Article 10	Article 31(1)	—

Tuesday 15 April 2014

Council Directive 98/57/EC	This Regulation	Regulation (EU) No .../.... [number of Regulation on Official Controls]
Article 11	Article 27(1)	—
Articles 12 to 14	—	—
Annexes I to VII	Article 27(1)	—
Council Directive 2007/33/EC	This Regulation	Regulation (EU) No .../.... [number of Regulation on Official Controls]
Article 1	Article 27(1)	—
Articles 2 and 3	Article 27(1) and (2)	—
Articles 4 to 8	Article 27(1)(f)	—
Articles 9 to 13	Article 27(1) and (2)	—
Article 14	Article 8	—
Article 15	Article 31(1)	—
Article 16	Article 27(1)	—
Article 17	Article 99	—
Articles 18 to 20	—	—
Annexes I to IV	Article 27(1)	—
Council Directive 2000/29/EC	This Regulation	Regulation (EU) No .../.... [number of Regulation on Official Controls]
Article 1(1), (2) and (3)	Article 1	—
Article 1(4)	—	Article 3
Article 1(5) and (6)	—	—
Article 2(1)(a)	Article 2(1)	—
Article 2(1)(b)	Article 2(2)	—
Article 2(1)(c)	—	—
Article 2(1)(d)	Article 2(3)	—
Article 2(1)(e)	Article 1(1)	—
Article 2(1)(f)	Article 73	—
Article 2(1)(g)	—	Articles 3, 25 and 36
Article 2(1)(h)	Articles 32 to 35	—
Article 2(1)(i), first subparagraph	Article 71	Article 4
Article 2(1)(i), second subparagraph	—	Articles 4 and 19
Article 2(1)(i), third subparagraph	—	Article 129
Article 2(1)(j)	—	Article 2(28)
Article 2(1)(k)	—	Article 3

Tuesday 15 April 2014

Council Directive 2000/29/EC	This Regulation	Regulation (EU) No .../... [number of Regulation on Official Controls]
Article 2(1)(l)	—	Article 3
Article 2(1)(m)	—	Article 3
Article 2(1)(n)	—	Article 3
Article 2(1)(o)	Article 2(6)	—
Article 2(1)(p)	—	Article 2(26)
Article 2(1)(q)	—	—
Article 2(1)(r)	—	Article 2(48)
Article 2(2)	Article 2(2), second subparagraph	—
Article 3(1)	Article 5(1)	—
Article 3(2) and (3)	Articles 5(1), 37(1) and 41(3)	—
Article 3(4)	—	—
Article 3(5)	Article 32(2) and 50(3)	—
Article 3(6)	Articles 5(2) and 32(3)	—
Article 3(7)	Articles 5(3), 27(1) and 37(1)	—
Articles 3(8) and (9)	Articles 8, 46 and 54	—
Article 4(1)	Article 40(1)	—
Article 4(2)	Article 49(1)	—
Article 4(3)	—	—
Article 4(4)	—	—
Article 4(5)	Articles 8, 46 and 54	—
Article 4(6)	Article 44	—
Article 5(1)	Article 40(3)	—
Article 5(2)	Article 49(3)	—
Article 5(3)	Articles 40(2) and 49(2)	—
Article 5(4)	Articles 51 and 70	—
Article 5(5)	Articles 8, 46 and 54	—
Article 5(6)	Article 44	—
Article 6(1) to (4)	Article 82(1), (2) and (3)	—
Article 6(5), first and second subparagraphs	Article 82(1), (2) and (3)	—
Article 6(5), third subparagraph	Articles 61 and 64	—

Tuesday 15 April 2014

Council Directive 2000/29/EC	This Regulation	Regulation (EU) No .../.... [number of Regulation on Official Controls]
Article 6(5), fourth subparagraph	Article 10	—
Article 6(5), fifth subparagraph	Article 76	—
Article 6(6)	Articles 61 and 65	—
Article 6(7)	Article 76	—
Article 6(8), first indent	—	—
Article 6(8), second indent	Article 53	—
Article 6(8), third indent	Article 82(4)	—
Article 6(8), fourth indent	Articles 62, 65 and 85	—
Article 6(8), fifth indent	—	—
Article 6(8), sixth indent	Article 76	—
Article 6(9)	Article 62	—
Article 10(1)	Articles 78(3), 80, 81 and 82	—
Article 10(2)	Articles 74, 75 and 76	—
Article 10(3)	Article 88	—
Article 10(4)	Article 82(4)	—
Article 11(1)	Article 82(1)	—
Article 11(2)	—	—
Article 11(3)	—	Article 19(d)
Article 11(4)	Article 87	—
Article 11(5)	Article 87	—
Article 12(1)	—	Articles 43, 134, 135 and 136
Article 12(2)	Articles 65(3), 88(5) and 90(2)	Article 4(1)(g) and (h)
Article 12(3)	—	Article 115
Article 12(4)	Articles 41(4) and 90(1) and (5)	Articles 19(d), 103, 130, 134, 135 and 136
Article 13(1) and (2)	Article 71(5)	Articles 45 and 89(1)(f)
Article 13(3) and (4)	—	—
Article 13a(1)	—	Article 47
Article 13a(2)	—	Article 52
Article 13a(3)	Article 71	—
Article 13a(4)	Article 71	—
Article 13a(5)	—	Articles 50 and 52

Tuesday 15 April 2014

Council Directive 2000/29/EC	This Regulation	Regulation (EU) No .../... [number of Regulation on Official Controls]
Article 13b(1)	—	Article 63
Article 13b(2)	—	Article 49
Article 13b(3)	—	Article 46
Article 13b(4)	—	Article 46
Article 13b(5)	—	Article 46
Article 13b(6)	—	—
Article 13c(1)(a)	—	Article 55
Article 13c(1)(b)	Article 61	—
Article 13c(1)(c)	—	Article 54, 55 and 56
Article 13c(2)(a)	—	Article 47
Article 13c(2)(b)	—	Article 51
Article 13c(2)(c)	—	Article 51
Article 13c(2)(d)	—	Article 51
Article 13c(2)(e)	—	Article 49, 50 and 51
Article 13c(2)(f)	—	Article 47
Article 13c(3)	—	Articles 55 and 130
Article 13c(4)	—	Articles 55, 58 and 62
Article 13c(5)	—	—
Article 13c(6)	Article 89	—
Article 13c(7)	Article 72	Articles 134, 135 and 136
Article 13c(8)	Articles 40(4), 41(4), 49(5), 50(4) and 97	Article 130
Article 13d(1)	—	Articles 77 and 78
Article 13d(2)	—	Article 79
Article 13d(3)	—	Articles 79 and 83
Article 13d(4)	—	Article 80
Article 13d(5)	—	Articles 78 and 79
Article 13d(6)	—	—
Article 13d(7)	—	—
Article 13e	Articles 94 and 95	—

Tuesday 15 April 2014

Council Directive 2000/29/EC	This Regulation	Regulation (EU) No .../... [number of Regulation on Official Controls]
Article 14	Articles 5(3) and (4), 32(3), 37(2) and (3), 40(2), 41(2), 49(2), 50(2), 68(2) and (3), 69(2) and (3), 74(2) and (3) and 75(2) and (3)	—
Article 15(1)	Article 41(2), first subparagraph	—
Article 15(2)	Article 41(2), second subparagraph	—
Article 15(3)	Article 67(3)	—
Article 15(4)	—	—
Article 16(1)	Article 10(1) and (2) and Article 16	—
Article 16(2), first subparagraph	Article 28	—
Article 16(2), second subparagraph	Article 14(1)	—
Article 16(2), third subparagraph	Article 14(1)	—
Article 16(2), fourth subparagraph	—	—
Article 16(3)	Article 29	—
Article 16(4)	Articles 27(1), 29(1) and 47(1)	—
Article 16(5)	Articles 27(6), 29(6) and 47(4)	—
Article 18	Article 99	—
Article 20	—	—
Article 21(1)	—	Article 115(1) and (2)
Article 21(2)	—	Article 115(4)
Article 21(3)	—	Article 115(1) and (3)
Article 21(4)	—	Article 115(1) and (3)
Article 21(5)	—	Articles 117 and 118
Article 21(6)	Article 97	Article 130
Article 21(7)	—	—
Article 21(8)	—	—
Article 22	—	—

Tuesday 15 April 2014

Council Directive 2000/29/EC	This Regulation	Regulation (EU) No .../... [number of Regulation on Official Controls]
Article 23(1)	—	—
Article 23(2)	—	—
Article 23(3)	Article 102	—
Article 23(4)	—	—
Article 23(5), first subparagraph	—	—
Article 23(5), second subparagraph	—	—
Article 23(5), third subparagraph	—	—
Article 23(5), fourth subparagraph	—	—
Article 23(5), fifth subparagraph	—	—
Article 23(6), first subparagraph	—	—
Article 23(6), second subparagraph	—	—
Article 23(6), third subparagraph	—	—
Article 23(6), fourth subparagraph	—	—
Article 23(7)	—	—
Article 23(8)	—	—
Article 23(9)	—	—
Article 23(10)	—	—
Article 24(1)	—	—
Article 24(2)	—	—
Article 24(3)	—	—
Article 25	—	—
Article 26	—	—
Article 27	—	Article 87(2)
Article 27a	—	Articles 107 to 110
Article 28	—	—
Article 29	—	—
Annex I, Part A, Section I	Article 5(2)	—
Annex I, Part A, Section II	Article 5(2)	—
Annex I, Part B	Article 32(3)	—

Tuesday 15 April 2014

Council Directive 2000/29/EC	This Regulation	Regulation (EU) No .../... [number of Regulation on Official Controls]
Annex II, Part A, section I	Article 5(2)	—
Annex II, Part A, Section II	Article 37(2)	—
Annex II, Part B	Article 32(3)	—
Annex III, Part A	Article 40(1)	—
Annex III, Part B	Article 49(1)	—
Annex IV, Part A	Article 41(1)	—
Annex IV, Part B	Article 50(1)	—
Annex V, Part A, Point I	Article 74(1)	—
Annex V, Part A, Point II	Article 75(1)	—
Annex V, Part B, Point I	Article 68(1)	—
Annex V, Part B, Point II	Article 69(1)	—
Annex VI	—	—
Annex VII	Annex VIII	—
Annex VIII	—	—
Annex VIIIa	—	—
Annex IX	—	—

Tuesday 15 April 2014

P7_TA(2014)0383

Consumer product safety *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC (COM(2013)0078 — C7-0042/2013 — 2013/0049(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/62)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0078),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0042/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 22 May 2013 ⁽¹⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinions of the Committee on International Trade, the Committee on Industry Research and Energy and the Committee on Legal Affairs, (A7-0355/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0049

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

⁽¹⁾ OJ C 271, 19.9.2013, p. 81.

Tuesday 15 April 2014

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ⁽³⁾ lays down the **fundamental** requirement **for products on the internal market** that consumer products must be safe and that Member States' market surveillance authorities must take **efficient** action against dangerous products as well as exchange information to that effect through the Community Rapid Information System (RAPEX). Directive 2001/95/EC needs to be fundamentally revised to improve its functioning and to ensure consistency with developments in Union legislation as regards market surveillance, obligations of economic operators and standardisation. In the interest of clarity, Directive 2001/95/EC should be repealed and replaced by this Regulation. [Am. 1]
- (2) A regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition **and application** by Member States. A regulation ensures that legal requirements are applicable at the same time throughout the Union. [Am. 2]
- (3) ~~This Regulation must contribute to the attainment of the objectives referred to in Article 169 of the TFEU. In particular it should aim at ensuring the functioning of the internal market as regards products intended for consumers by laying down uniform rules regarding a general~~ **In order to ensure a high level of consumer protection, the Union should contribute to protecting the health and** safety requirement, assessment criteria and obligations of economic operators. ~~Given that rules on market surveillance, including rules on RAPEX, are laid down in Regulation (EU) No [...]/... [on market surveillance of products] ⁽⁴⁾ which applies also to~~ **of consumers. In that regard, this Regulation is essential to delivering the fundamental aim of an internal market for safe** products covered by this Regulation, ~~no further provisions on market surveillance or RAPEX are needed in this Regulation, whilst contributing to the attainment of the objectives referred to in Article 169 of the Treaty on the Functioning of the European Union (TFEU).~~ [Am. 3]
- (3a) **This Regulation should aim in particular to ensure the functioning of the internal market as regards products intended for consumers, by laying down uniform rules regarding a general safety requirement, assessment of the safety of products criteria and the obligations of economic operators. Given that rules on market surveillance, including rules on RAPEX, are laid down in Regulation (EU) No .../... of the European Parliament and of the Council ⁽⁵⁾ (*), no further provisions on market surveillance or RAPEX are necessary in this Regulation.** [Am. 4]
- (3b) **The safety of consumers depends to a great extent on the active enforcement of Union product safety requirements. Market surveillance activities at national and Union level should be improved on an on-going basis and should be increasingly effective in order to meet the ever-changing challenges of a global market and a progressively complex supply chain. Failing market surveillance systems could generate a distortion of competition, jeopardise consumer safety and undermine citizens' trust in the internal market. The Member States should, therefore, establish systematic approaches to ensure the increasing effectiveness of market surveillance and other enforcement activities and should ensure their openness to the public and to interested parties.** [Am. 5]

⁽¹⁾ OJ C 271, 19.9.2013, p. 81.

⁽²⁾ Position of the European Parliament of 15 April 2014.

⁽³⁾ **Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety** (OL L 11, 15.1.2002, p. 4).

⁽⁴⁾ ~~OJ L ... p. ...~~

⁽⁵⁾ **Regulation (EU) No .../... of the European Parliament and of the Council of ... on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EC) No 764/2008, Regulation (EC) No 765/2008 and Regulation (EU) No 305/2011 of the European Parliament and of the Council (OJ L ...).**

^(*) **Number of Regulation (2013/0048(COD)) in the recital and the number, date of adoption and publication reference of the Regulation in the footnote.**

Tuesday 15 April 2014

- (4) Union legislation on food, feed and related areas sets up a specific regime ensuring the safety of the products covered by it. This Regulation should therefore not apply to those products with the exception of materials and articles intended to come into contact with food insofar as risks are concerned that are not covered by Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁽¹⁾ or by other food specific legislation which only covers chemical and biological food related risks.
- (5) Medicinal products are subject to a pre-market assessment that includes a specific risk-benefit analysis. They should therefore be excluded from the scope of this Regulation.
- (6) This Regulation should not cover services. However, in order to secure the attainment of the protection of health and safety of consumers, it should apply to **all** products that are **used**, supplied or made available to consumers in the context of the provision of services, including products to which consumers are directly exposed during the provision of a service. ~~Equipment on which consumers ride or travel which is operated by a service provider should be excluded from the scope of this Regulation since it has to be dealt with in conjunction with the safety of the service provided by a service provider.~~ [Am. 6]
- (6a) **Products which are designed exclusively for professional use but which have subsequently migrated to the consumer market should be subject to this Regulation because they can pose risks to the health and safety of consumers when used under reasonably foreseeable conditions.** [Am. 7]
- (6b) **Equipment on which consumers travel which is operated by a service provider should be excluded from the scope of this Regulation since it has to be dealt with in conjunction with the safety of the service provided.** [Am. 8]
- (7) Despite the development of sector-specific Union harmonisation legislation that addresses safety aspects of specific products or categories of products, it is practically impossible to adopt Union legislation for all consumer products that exist or may be developed. There is therefore still a need for a legislative framework of a horizontal nature to fill gaps and ensure consumer protection not otherwise ensured, in particular with a view to achieving a high level of protection of health and safety of consumers, as required by Articles 114 and 169 TFEU.
- (8) In respect of the consumer products subject to this Regulation, the scope of application of the different parts of it should be clearly delimited from sector-specific Union harmonisation legislation. Whilst the general product safety requirement and related provisions **of Chapter I of this Regulation** should be applicable to all consumer products, the obligations of economic operators should not apply where Union harmonisation legislation includes equivalent obligations, such as Union legislation on cosmetics, toys, electrical appliances or construction products. [Am. 9]
- (9) In order to ensure consistency between this Regulation and sector-specific Union harmonisation legislation with regard to specific obligations of economic operators, the provisions concerning manufacturers, authorised representatives, importers and distributors should be based on the reference provisions included in Decision No 768/2008/EC of the European Parliament and of the Council ~~of 9 July 2008 on a common framework for the marketing of products~~ ⁽²⁾. **Nevertheless, Union harmonisation legislation should not impose unnecessary administrative burdens on economic operators.** [Am. 10]
- (10) The scope of this Regulation should not be limited to any selling technique of consumer products, and should therefore also cover distance selling, **such as electronic selling, online sales and sales platforms.** [Am. 11]

⁽¹⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

⁽²⁾ **Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC** (OJ L 218, 13.8.2008, p. 82).

Tuesday 15 April 2014

- (11) This Regulation should apply to second hand products that re-enter the supply chain in the course of a commercial activity, **provided that they have been placed on the market as such, and to second-hand products originally placed on the market after the entry into force of this Regulation**, except for those second-hand products for which the consumer cannot reasonably expect that they fulfil state-of-the art safety standards, such as antiques. [Am. 12]
- (12) This Regulation should also apply to, **and thus prohibit the marketing, import, manufacture and export of**, consumer products which, although not foodstuff, resemble foodstuff and are likely to ~~be confused with foodstuff in a way that consumers, especially~~ **cause persons, in particular young children, may, to confuse them with foodstuff and consequently to** place them in their mouths, suck or ingest them, which ~~might by doing so may cause, for example, suffocation, poisoning, the perforation or obstruction of the digestive tract~~ **death or personal injury**. Those imitations of foodstuffs have so far been regulated by Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers ⁽¹⁾ which should be repealed. [Am. 13]
- (13) The safety of products should be assessed taking into account all the relevant aspects, in particular their characteristics, **composition, authenticity, materials, components**, and presentation **of the product and its packaging** as well as the categories of consumers who are likely to use the products taking into account their vulnerability, in particular children, the elderly and the disabled. [Am. 14]
- (13a) *The precautionary principle, as laid down in Article 191(2) TFEU and outlined inter alia in the Commission Communication of 2 February 2000 entitled ‘On the precautionary principle’, is a fundamental principle for the safety of products and for the safety of consumers and should be taken into due account when laying down the criteria for assessing the safety of a product.* [Am. 15]
- (13b) *This Regulation should take into account ‘child-appealing products’ whose design, packaging and characteristics in any way resemble a toy or an object appealing to or intended for use by children. Child-appealing products should furthermore be assessed for their levels of risk and appropriate action to mitigate that risk should be taken.* [Am. 16]
- (13c) *When assessing the safety of a product, special consideration should be given if the product has caused injuries notified into the Pan-European Injury Database established pursuant to Regulation (EU) No .../... (*).* [Am. 17]
- (14) To avoid overlapping safety requirements and conflicts with other Union legislation, a product which conforms to sector-specific Union harmonisation legislation that aims at the protection of health and safety of persons should be presumed to be safe under this Regulation.
- (15) Economic operators should be responsible for the compliance of products, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of the health and safety of consumers. **In that regard, there should be a strict alignment of the provisions regarding obligations of economic operators contained in Decision No 768/2008/EC, since this will provide a level playing field between the obligations on economic operators covered by Union harmonisation legislation and those covered by non-harmonised legislation under this Regulation.** [Am. 20]

⁽¹⁾ Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers (O) L 192, 11.7.1987, p. 49).

(*) Number of Regulation (2013/0048(COD)).

Tuesday 15 April 2014

- (15a) *In the case of products that are not subject to Union harmonisation legislation, European standards or national legislation on health and safety requirements, economic operators should assess the safety of products in accordance with specific criteria, on which basis they should define the level of risk associated with a product. Market surveillance authorities may assist economic operators in carrying out the safety assessment. [Am. 21]*
- (15b) *To make it easier to place safe products on the market, economic operators, in particular small and medium-sized enterprises (SMEs), should be able to meet their obligations under this Regulation by establishing consortia with the dual purpose of ensuring compliance with product safety requirements and high-quality standards and reducing the costs and 'red tape' with which individual businesses are burdened. [Am. 22]*
- (16) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market products which are safe and in conformity with this Regulation. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution process.
- (16a) *Manufacturers should ensure that the products they place on the market have been designed and manufactured in accordance with the safety requirements laid down in this Regulation. In order to clarify the obligations of the manufacturer and to minimise the related administrative burdens, the Commission should establish a Union general risk assessment methodology for products and create user-friendly electronic tools for analysing risks. That methodology should establish an efficient tool for risk assessment that the manufacturers can use when designing products, by building on best practices and input from stakeholders. [Am. 23]*
- (16b) *In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address. [Am. 24]*
- (17) Importers bear the responsibility that products originating from third countries that they place on the Union market comply with the requirements of this Regulation. The specific obligations of importers should therefore be included in this Regulation.
- (18) Distributors make products available on the market after they have been placed on the market by the manufacturer or the importer and should act with due care to ensure that their handling of the product does not adversely affect the compliance of the product with this Regulation.
- (18a) *The distributor should ensure that the manufacturer and the importer have complied with their obligations, that is to say verifying the indication on the product or on its packaging of the name, model name, brand name or address at which the manufacturer and the importer can be contacted and the affixing of the manufacturer's batch number, serial number or other element on the product for its identification. The distributor should not check each product individually, unless the distributor considers that the manufacturer or the importer have not fulfilled their obligations. [Am. 25]*
- (19) Any economic operator that either places a product on the market under his own name or trade mark or modifies a product in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (20) Ensuring product identification and the traceability of products throughout the entire supply chain helps to identify economic operators and to take effective corrective action against unsafe products, such as targeted recalls. Product identification and traceability thus ensure that consumers and economic operators obtain accurate information regarding unsafe products which enhances confidence in the market and avoids unnecessary disruption of trade. Products should therefore bear information allowing their identification and the identification of the manufacturer and, if applicable, of the importer. Manufacturers should also establish technical documentation regarding their

Tuesday 15 April 2014

products for which they may choose the most appropriate and cost-efficient way such as by electronic means. Moreover, economic operators should be required to identify the operators who supplied them and to whom they supplied a product. Directive 95/46/EC of the European Parliament and of the Council⁽¹⁾ is applicable to the processing of personal data for the purposes of this Regulation.

- (20a) *Globalisation, increased outsourcing and the growth in international trade mean that more products are being traded on markets across the world, and in that regard a close cooperation between global regulators and other stakeholders in the area of consumer product safety is essential to addressing the challenges of complex supply chains and higher volumes of trade. In particular, the Commission should be encouraged to strengthen the attention to safety by design of products through bilateral cooperation with the market surveillance authorities of third countries. [Am. 26]*
- (20b) *The current traceability systems and identification procedures already in place should be effectively enforced and improved. In that regard, assessments and evaluations on the use of the technologies in place are necessary to ensure better performance and lower the administrative burden on economic operators. One of the objectives of this Regulation is to constantly improve the traceability systems imposed on economic operators and products. [Am. 27]*
- (20c) *In order to improve traceability in the future, the Commission should assess how to facilitate the application of specific track-and-trace technologies and product authentication technologies. In that assessment, the technologies assessed should ensure inter alia consumer product safety, improve tracing mechanisms and avoid putting unnecessary administrative burdens on economic operators in order to prevent the costs thereof from being passed on to consumers. [Am. 28]*
- (20d) *Building on the establishment of national contact points pursuant to Regulation (EC) No 764/2008 of the European Parliament and of the Council⁽²⁾, Product Safety Contact Points should function as information centres in the Member States for economic operators in order for those operators to receive guidance and training on product safety requirements and legislation. [Am. 29]*
- (21) The indication of origin ~~supplements~~ **is a necessary supplement to** the basic traceability requirements **laid down in this Regulation** concerning the name and address of the manufacturer. ~~In particular~~ **Furthermore**, the indication of the country of origin helps to identify the actual place of manufacture in all those cases where the manufacturer cannot be contacted ~~or, in particular where~~ **its given address is different from the actual place of manufacture, where the name and address of the manufacturer is missing altogether or where the address was on the packaging that has been lost**. Such information can facilitate the task of market surveillance authorities in tracing the product back to the actual place of manufacture and enable contacts with the authorities of the countries of origin in the framework of bilateral or multilateral cooperation on consumer product safety for appropriate follow-up actions. [Am. 30]
- (21a) *The indication of origin of the product would make it easier for consumers to access information about the product chain, thereby increasing their level of awareness. In particular, when indicating the name of the manufacturer fulfilling the obligations of the economic operators, there is a risk of misleading the consumers since an indication of the manufacturer does not necessarily enable the consumer to establish what the country of production is. Thus, the indication of origin should be the sole means by which the consumers would be able to establish the country of production of a product. [Am. 31]*

⁽¹⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽²⁾ Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L 218, 13.8.2008, p. 21).

Tuesday 15 April 2014

- (21b) ***In several jurisdictions of the trade partners of the Union, the indication of origin is mandatory in product labelling and custom declarations. The introduction of the indication of origin pursuant to this Regulation will bring the Union into line with the international trade regime. Furthermore, since the requirement to provide an indication of origin covers all non-food products on the territory of the Union, whether imported or not, it will comply with the international trade obligations of the Union. [Am. 32]***
- (22) In order to facilitate the effective and consistent application of the general safety requirement set out in this Regulation, it is important to make use of European standards covering certain products and risks in such a way that a product which conforms to such a European standard, the reference of which has been published in the *Official Journal of the European Union*, is to be presumed to be in compliance with that requirement.
- (23) Where the Commission identifies a need for a European standard ensuring compliance of certain products with the general safety requirement under this Regulation, it should apply the relevant provisions of Regulation (EU) No 1025/2012 of the European Parliament and of the Council ⁽¹⁾ to request one or several European standardisation organisations to either draft or identify a standard which is suitable to ensure that products which conform to it are presumed to be safe. The references of such European standards should be published in the *Official Journal of the European Union*.
- (24) The procedures to request European standards in support of this Regulation, and on formal objections against them, should be laid down in this Regulation and be aligned with Regulation (EU) No 1025/2012. To ensure overall consistency in European standardisation issues, requests for European standards, or objections to a European standard, should therefore be brought before the committee set up by that Regulation, after appropriate consultation of experts of the Member States in the field of consumer product safety **and of relevant stakeholders**. [Am. 33]
- (25) European standards, the references of which have been published in accordance with Directive 2001/95/EC, should continue providing presumption of conformity with the general safety requirement. Standardisation mandates issued by the Commission in accordance with Directive 2001/95/EC should be deemed standardisation requests issued in accordance with this Regulation.
- (26) Where no relevant European standards or other recognised means to assess the safety of products exist, the assessment of product safety should take into account Commission recommendations adopted for that purpose pursuant to Article 292 TFEU.
- (26a) In order to maintain a high level of health and safety of consumers, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to determine the products, categories or groups of products for which the name, registered trade name or registered trade mark and address of the manufacturer and of the importer does not need to be indicated on the product itself due to the low level of risk related to such products, to determine the products, categories or groups of products bearing a potential serious risk to health and safety of persons and to specify the data which economic operators are to collect and store by means of traceability system. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (27) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the exemption to the obligation to inform market surveillance authorities about products presenting a risk, as regards the type of data carrier and its placement on the product for the

⁽¹⁾ Regulation (EU) No 1025/2012 of the European Parliament and the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

Tuesday 15 April 2014

purposes of the traceability system, as regards standardisation requests to European standardisation organisations and as regards decisions on formal objections to European standards. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.

- (28) The advisory procedure should be used for the adoption of implementing acts as regards decisions on formal objections to European standards and where the references to the European standard concerned have not yet been published in the *Official Journal of the European Union*, given that the relevant standard has not yet led to the presumption of conformity with the general safety requirement laid down in this Regulation.
- (30) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive **and depend on the seriousness, duration and intentional or recurring character of the infringement, as well as the size of the undertakings, in terms of the number of persons employed by and annual turnover of the economic operators concerned, with particular regard to SMEs. Infringements should entail administrative penalties that are harmonised at Union level. Member States should be encouraged to allocate the revenues collected from such penalties to market surveillance activities.** [Am. 34]
- (30a) **In order to enhance the deterrent effect of the penalties, the Commission should make them public. In addition, economic operators who are repeatedly found to have intentionally breached this Regulation should be placed on a public, Union-wide blacklist.** [Am. 35]
- (31) To allow economic operators, Member States and the Commission to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period until the requirements of this Regulation are applicable.
- (32) Since the objective of this Regulation, namely to ensure the proper functioning of the internal market as regards products intended for consumers whilst maintaining a high level of health, safety and consumer protection, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (33) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union. In particular this Regulation seeks to ensure full respect for the obligation to ensure a high level of human health protection and consumer protection as well as full respect for the freedom to conduct business,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject matter **and objective** [Am. 36]

The objective of this Regulation is to ensure the proper functioning of the internal market whilst maintaining a high level of health, safety and consumer protection. [Am. 37]

This Regulation lays down rules on the safety of consumer products placed or made available on the Union market.

The provisions of this Regulation are based on the precautionary principle. [Am. 38]

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Tuesday 15 April 2014

Article 2

Scope

1. This Regulation shall apply to products obtained through a manufacturing process placed or made available on the market, **including the online market**, whether new, used or reconditioned, and which comply with any of the following criteria: [Am. 39]

- (a) which are intended for consumers;
- (b) which are likely, under reasonably foreseeable conditions, to be used by consumers even if, **when placed on the market, they were not intended for them; products are not likely to be used by consumers if they are intended for the exclusive use by professionals and are explicitly labelled and presented as such;** [Am. 40]
- (c) ~~to which consumers are exposed~~ **are provided to a consumer** in the ~~context~~ **course** of a service provided to them, **whether or not the product is used by the consumer himself.** [Am. 41]

2. This Regulation shall not apply to products to be repaired or reconditioned prior to being used where those products are made available on the market as such, **nor to second-hand products originally placed on the market before ...** (*). [Am. 42]

3. This Regulation shall not apply to the following:

- (a) medicinal products for human or veterinary use;
- (b) food;
- (c) materials and articles intended to come into contact with food insofar as risks related to those products are covered by Regulation (EC) No 1935/2004 or other Union legislation applicable to food;
- (d) feed;
- (da) **medical devices as defined in Council Directive 90/385/EEC⁽¹⁾, Council Directive 93/42/EEC⁽²⁾ and Directive 98/79/EC of the European Parliament and of the Council⁽³⁾;** [Am. 43]
- (e) living plants and animals, genetically modified organisms and genetically modified microorganisms in contained use, as well as products of plants and animals relating directly to their future reproduction;
- (f) animal by-products and derived products;
- (g) plant protection products;
- (h) equipment on which consumers ride or travel which is operated by a service provider within the context of a service provided to consumers;
- (i) antiques;
- (ia) **construction products as defined in Regulation (EU) No 305/2011 of the European Parliament and of the Council⁽⁴⁾.** [Am. 44]

(*) **Date of entry into force of this Regulation.**

⁽¹⁾ **Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).**

⁽²⁾ **Council Directive 93/42/EEC of 14 June 1993 concerning medicinal devices (OJ L 169, 12.7.1993, p. 1).**

⁽³⁾ **Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).**

⁽⁴⁾ **Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).**

Tuesday 15 April 2014

4. Chapters II to IV of this Regulation shall not apply to products subject to requirements designed to protect human health and safety laid down in Union harmonisation legislation or pursuant to it.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) 'safe product' means any **authentic** product which **is compliant with Union harmonisation legislation relating to health and safety. In the absence of such legislation it means any product which**, under normal or reasonably foreseeable conditions of use of the product concerned, including the duration of **the** use and, where applicable, its putting into service, installation ~~and~~, maintenance, **training and supervision** requirements, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of health and safety of persons; [Am. 45]
- (1a) **'product model' means products that are considered to be distinct in terms of presenting identical or similar essential characteristics, with differences, if any, having no impact on their safety level unless otherwise proven by the manufacturer or the importer; [Am. 46]**
- (2) 'making available on the market' means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (3) 'placing on the market' means the first making available of a product on the Union market;
- (4) 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured and markets that product under his name or trade mark;
- (5) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (6) 'importer' means any natural or legal person established within the Union who places a product from a third country on the Union market;
- (7) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
- (8) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (9) 'international standard' means an international standard as defined in point (a) of Article 2(1) of Regulation (EU) No 1025/2012;
- (10) 'European standard' means a European standard as defined in point (b) of Article 2(1) of Regulation (EU) No 1025/2012;
- (11) 'national standard' means a national standard as defined in point (d) of Article 2(1) of Regulation (EU) No 1025/2012;
- (12) 'European standardisation organisation' means a European standardisation organisation as defined in Article 2(8) of Regulation (EU) No 1025/2012;
- (13) 'market surveillance authority' means a market surveillance authority as defined in point 12 of Article 3 of Regulation (EU) No .../... (*);
- (14) 'recall' means any measure aimed at achieving the return of a product that has already been made available to the end user;

(*) **Number of Regulation (2013/0048(COD)).**

Tuesday 15 April 2014

- (15) 'withdrawal' means any measure aimed at preventing a product in the supply chain from being further made available on the market;
- (16) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (17) 'serious risk' means a **any serious** risk ~~requiring rapid intervention and follow up~~, including cases where ~~those~~ the effects ~~may~~ **of which are** not be immediate, **requiring rapid intervention by the public authorities.** [Am. 47]

Article 4

General safety requirement

Economic operators shall place or make available on the Union market only safe consumer products.

Article 4a

Prohibition of marketing, import, manufacture and export of imitations of foodstuffs

Member States shall take all the measures necessary to prohibit the marketing, import, manufacture and export of consumer products which, although not foodstuff, resemble foodstuff and are likely to be confused with foodstuff due to their form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics, thereby endangering the health or safety of consumers. [Am. 48]

Article 5

Presumption of safety

For the purposes of this Regulation, a product shall be presumed to be in compliance with the general safety requirement laid down in Article 4 in the following cases:

- (a) as regards the risks covered by requirements designed to protect human health and safety laid down in or pursuant to Union harmonisation legislation, if it conforms to those requirements;
- (aa) if it is authentic, meaning that the product or any presentation of the product does not bear a trade mark without the authorisation of the trade mark owner that is identical or similar to a registered trade mark for that product, thereby misleading consumers as to the true identity of the product;** [Am. 49]
- (b) in the absence of requirements laid down in or pursuant to Union harmonisation legislation referred to in point (a) of this Article, as regards the risks covered by European standards, if it conforms to relevant European standards or parts thereof, the references of which have been published in the *Official Journal of the European Union* in accordance with Articles 16 and 17;
- (c) in the absence of requirements laid down in or pursuant to Union harmonisation legislation referred to in point (a) and European standards referred to in point (b), as regards the risks covered by health and safety requirements laid down in the law of the Member State where the product is made available on the market, if it ~~conforms to~~ **complies with** such national ~~requirements~~ **rules provided that they comply with Union law.** [Am. 50]

Article 6

Aspects for assessing the safety of products

1. In the absence of Union harmonisation legislation, European standards or health and safety requirements laid down in the law of the Member State where the product is made available on the market as referred to in points (a), (aa), (b) and (c) of Article 5, the following aspects shall be taken into account when assessing whether a product is safe, in particular:

Tuesday 15 April 2014

- (a) the characteristics of the product, including its **authenticity**, composition, packaging, instructions for assembly and, where applicable, for installation and maintenance; [Am. 51]
- (b) the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- (c) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- (d) the ~~categories~~ **characteristics** of consumers at risk when using the product **under reasonably foreseeable conditions**, in particular vulnerable consumers; [Am. 52]
- (e) the appearance of the product and in particular where a product:
 - (i) although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff due to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics; **or**
 - (ii) **although not designed or not intended for use by children, resembles an object commonly recognised as appealing to or intended for use by children, because of its design, packaging and characteristics.** [Am. 53]

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product not to be safe.

2. For the purpose of paragraph 1 of this Article, when assessing whether a product is safe, the following aspects, when available, shall be taken into account, in particular:

- ~~(a) the state of the art and technology;~~ [Am. 54]
- (aa) reasonable consumer expectations concerning safety in terms of the nature, composition and intended use of the product;** [Am. 55]
- (b) European standards other than those the references of which have been published in the *Official Journal of the European Union* in accordance with Articles 16 and 17;
- (ba) the essential requirements contained in the standardisation requests to European standardisation organisations in accordance with Article 16 as long as the Commission has not yet published the references of the harmonised standards in the Official Journal of the European Union;** [Am. 56]
- (c) international standards;
- (d) international agreements;
- (e) Commission recommendations or guidelines on product safety assessment;
- (f) national standards drawn up in the Member State in which the product is made available;
- (g) product safety codes of good practice in force in the sector concerned;
- (ga) if the product, categories or groups of products, have caused injuries notified into the Pan-European Injury Database established pursuant to Regulation (EU) No .../... (*);** [Am. 57]
- ~~(h) reasonable consumer expectations concerning safety.~~ [Am. 58]
- (ha) the state of the art and technology.** [Am. 59]

(*) *Number of Regulation (2013/0048(COD)).*

Tuesday 15 April 2014

Article 7

Indication of the origin

1. Manufacturers and importers shall ensure that products bear an indication of the country of origin of the product or, where the size or nature of the product does not allow it, that indication is to be provided on the packaging or in a document accompanying the product.
 2. For the purpose of determination of the country of origin within the meaning of paragraph 1 **of this Article**, non-preferential origin rules set out in Articles ~~23 to 25 of Council~~ **59 to 62 of Regulation (EEC) No 2913/92 establishing a Community Customs Code** ⁽¹⁾ **(EU) No 952/2013 of the European Parliament and of the Council¹, including delegated acts to be adopted pursuant to Article 62 of that Regulation**, shall apply. [Am. 61]
 3. Where the country of origin determined in accordance with paragraph 2 is a Member State of the Union, manufacturers and importers may refer to the Union or to a particular Member State.
- 3a. Manufacturers shall be authorised to indicate the country of origin in English only ('Made in [country]'), since this is readily comprehensible for consumers. [Am. 62]**

CHAPTER II

Obligations of economic operators

Article 8

Obligations of manufacturers

1. When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the general safety requirement laid down in Article 4.
 2. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with the general safety requirement laid down in Article 4.
 3. Proportionate to the possible risks of a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of **randomly picked** products made available on the market **chosen under the control of a judicial officer or any qualified person designated by each Member State**, investigate complaints and keep a register of complaints, non-conforming products and product recalls, and shall keep distributors informed of any such monitoring. **That information shall be made available to the market surveillance authorities on request. [Am. 63]**
- 3a. When the products made available on the market have been subject to a Commission decision adopted under Article 12 of Regulation (EU) No .../... (*), manufacturers or, where appropriate, importers, shall, in order to protect the health and safety of consumers and proportionate to the possible risks of a product, carry out at least once a year representative sample testing of products made available on the market chosen under the control of a judicial officer or any qualified person designated by each Member State. [Am. 64]**
4. Proportionate to the possible risks of a product, manufacturers shall draw up a technical documentation. The technical documentation shall contain, ~~as appropriate:~~ **[Am. 65]**
 - (a) a general description of the product and its essential properties relevant for assessing the product's safety;

⁽¹⁾ OJ L 302, 19.10.1992, p. 1. Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

(*) Number of Regulation (2013/0048(COD)).

Tuesday 15 April 2014

- (b) an analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any tests conducted by the manufacturer or by another party on his behalf;
- (c) where applicable, a list of the European standards referred to in point (b) of Article 5 or health and safety requirements laid down in the law of the Member State where the product is made available on the market referred to in point (c) of Article 5, or other aspects referred to in Article 6(2), applied to meet the general safety requirement laid down in Article 4.

Where any of the European standards, health and safety requirements or other aspects referred to in point (c) of the first subparagraph have been only partly applied, the parts which have been applied shall be identified.

5. Manufacturers shall keep, for a period of 10 years after the product has been placed on the market, the technical documentation ~~and make it available to~~ **in paper or electronic form at the disposal of** the market surveillance authorities **and provide it to those authorities**, upon **reasoned** request. [Am. 66]

6. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing the identification of the product which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

Where the information allowing the identification of a product is not provided directly on the product, manufacturers shall indicate in a sufficiently visible manner that the medium containing that information should be retained. [Am. 67]

6a. Manufacturers of products that are the subject of a Commission decision adopted under Article 12 of Regulation (EU) No .../... (*) shall draw up a list of product models, accompanied by a photograph, and make it available to the public and other economic operators by any appropriate means.

The manufacturer shall provide, upon request, the market surveillance authorities as well as any economic operator to whom he distributes his products with evidence supporting the existence of different essential characteristics between its models within the meaning of the definition set out in point 1a of Article 3 of this Regulation. [Am. 68]

7. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

8. Manufacturers shall ensure that their product is accompanied by instructions and safety information **addressed to the consumer in a clear and comprehensible manner** in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available, except where the product can be used safely and as intended by the manufacturer without such instructions and safety information. [Am. 69]

Member States shall inform the Commission about any provisions adopted by them determining the required language(s).

9. **Manufacturers shall ensure that they have procedures in place for taking corrective action, withdrawing or recalling their products.** Manufacturers who consider or have reason to believe that a product which they have placed on the market is not safe or is otherwise not in conformity with this Regulation shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, **and to warn consumers who are at risk caused by the non-conformity of the product.** Furthermore, where the product is not safe, manufacturers shall immediately inform the market surveillance authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk to health and safety and of any corrective action taken, **and of the results of such corrective action.** [Am. 70]

(*) Number of Regulation (2013/0048(COD)).

Tuesday 15 April 2014

Article 9

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 8(1) and (4) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) further to a **reasoned** request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product; [Am. 71]
- (b) cooperate with the market surveillance authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.

Article 10

Obligations of importers

1. Before placing a product on the market importers shall ensure that the product is compliant with the general safety requirement laid down in Article 4 and that the manufacturer has complied with the requirements set out in Article 8(4), (6) and (7).

2. Where an importer considers or has reason to believe that a product is not in conformity with this Regulation, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product is not safe, the importer shall inform the manufacturer and the market surveillance authorities of the Member State in which he is established to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. They shall ensure that any additional label does not obscure any **compulsory** information on the label or **safety-related information** provided by the manufacturer. [Am. 72]

4. Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available, except where the product can be used safely and as intended by the manufacturer without such instructions and safety information.

Member States shall inform the Commission about any provisions adopted by them determining the required language(s).

5. Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety requirement laid down in Article 4 and its conformity with Article 8(6).

6. Proportionate to the possible risks presented by a product, importers shall, to protect the health and safety of persons, carry out sample testing of **randomly picked** marketed products, investigate complaints, and keep a register of complaints, of non-conforming products and of product recalls, and shall keep the manufacturer and distributors informed of such monitoring. [Am. 73]

7. Importers who consider or have reason to believe that a product which they have placed on the market is not safe or is otherwise not in conformity with this Regulation shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, **if as** appropriate. Furthermore, where the product is not safe, importers shall immediately inform the market surveillance authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk to health and safety and of any corrective action taken, **and of the results of such corrective action**. [Am. 74]

Tuesday 15 April 2014

8. Importers shall keep, for a period of 10 years after the product has been placed on the market, the technical documentation ~~and make it available to~~ **in paper or electronic form at the disposal of** the market surveillance **authorities and provide it to those** authorities, upon **reasoned** request. [Am. 75]

Article 11

Obligations of distributors

1. When making a product available on the market, a distributor shall act with due care in relation to the requirements of this Regulation.

2. Before making a product available on the market distributors shall verify that the ~~manufacturer and the importer have complied with the requirements~~ **product bears the required information**, set out in Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable. **Distributors shall not obscure any compulsory information or safety-related information provided by the manufacturer or the importer.** [Am. 76]

3. Where a distributor considers or has a reason to believe that a product is not in conformity with this Regulation, he shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product is not safe, the distributor shall inform the manufacturer or the importer, as applicable, to that effect as well as the market surveillance authority of the Member State in which the distributor is established.

4. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety requirement laid down in Article 4 and its conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable.

4a. Depending on the risks that a product is likely to pose, distributors may, in order to protect the health and safety of consumers, test products made available on the market, taking random samples. [Am. 77]

5. Distributors who consider or have reason to believe that a product which they have made available on the market is not safe or is not in conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable, shall **immediately** make sure that the corrective action necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, is taken. Furthermore, where the product is not safe, distributors shall immediately inform the manufacturer or importer, as applicable as well as market surveillance authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk to health and safety and of any corrective action taken, **and of the results of such corrective action.** [Am. 78]

Article 12

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer under Article 8, where he places a product on the market under his name or trade mark or modifies a product already placed on the market in such a way that compliance with the requirements of this Regulation may be affected.

Article 13

Exemption from certain obligations of manufacturers, importers and distributors

1. Obligation to inform the market surveillance authorities in accordance with Article 8(9), Article 10(2) and (7) and Article 11(3) and (5) shall not apply where the following conditions are fulfilled:

- (a) only a limited number of well-identified products are not safe;
- (b) the manufacturer, importer or distributor can demonstrate that the risk has been **fully effectively** controlled ~~and cannot any more endanger~~ **so as to prevent any dangers to** the health and safety of persons; [Am. 79]
- (c) ~~the cause of the risk of the product is such that knowledge of it does not represent useful information for the authorities or the public.~~ [Am. 80]

2. The Commission may by means of implementing acts determine the situations which meet the conditions of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(3).

Tuesday 15 April 2014

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 18a determining the products, categories or groups of products for which, due to their low level of risk, the information referred to in Article 8 (7) and Article 10(3) does not need to be indicated on the product itself.

Article 14

Identification of economic operators

1. Economic operators shall, on request, ~~identify the following to~~ **provide** the market surveillance authorities **with the following information:** [Am. 81]

- (a) any economic operator who has supplied them with the product;
- (b) any economic operator to whom they have supplied the product.

2. Economic operators shall be able to present the information referred to in paragraph 1 for a period of 10 years after they have been supplied with the product and for a period of 10 years after they have supplied the product.

2a. Where economic operators provide the information referred to in paragraph 1, the market surveillance authorities shall treat that information as confidential. [Am. 82]

Article 15

Traceability of products

1. For certain products, categories or groups of products which, due to their specific characteristics or specific conditions of distribution or usage, **are** susceptible to bear a serious risk to health and safety of persons **and, after consulting relevant stakeholders, as appropriate,** the Commission may require economic operators who place and make available those products on the market to establish or adhere to a system of traceability. [Am. 83]

2. The system of traceability shall consist of the collection and storage of data by electronic means enabling the identification of the product and of the economic operators involved in its supply chain as well as of the placement of a data carrier on the product, its packaging or accompanying documents enabling access to that data.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 18a:

- (a) determining the products, categories or groups of products susceptible to bear a serious risk to health and safety of persons as referred to in paragraph 1 of this Article. **The Commission shall state in the delegated acts concerned if it has used the risk analysis methodology provided for in Commission Decision 2010/15/EU⁽¹⁾ or, if that methodology is not appropriate for the product concerned, it shall give a detailed description of the methodology used;** [Am. 84]
- (b) specifying the data which economic operators shall collect and store by means of the traceability system referred to in paragraph 2 of this Article.

4. The Commission may by means of implementing acts determine the type of data carrier and its placement as referred to in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(3).

5. When adopting the acts referred to in paragraphs 3 and 4, the Commission shall take into account the following:

- (a) the cost-effectiveness of the acts, including their impact on businesses in particular SMEs;

⁽¹⁾ *Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System RAPEX established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive) (OJ L 22, 26.1.2010, p. 1).*

Tuesday 15 April 2014

(b) the compatibility with traceability systems available at international level.

Article 15a

Product Safety Contact Points

1. Member States shall designate Product Safety Contact Points in their territories and shall communicate their contact details to the other Member States and to the Commission.
2. The Commission shall draw up and regularly update a list of Product Safety Contact Points and publish it in the Official Journal of the European Union. The Commission shall also make that information available on its website. [Am. 85]

Article 15b

Tasks of Product Safety Contact Points

1. Product Safety Contact Points shall, at the request of inter alia an economic operator or a competent authority of another Member State, provide the following information:
 - (a) the technical rules applicable to a specific type of product on the territory in which those Product Safety Contact Points are established and information as to whether that type of product is subject to a requirement for prior authorisation under the laws of their Member State, together with information concerning the principle of mutual recognition as provided for in Regulation (EC) No 764/2008 and the application of that Regulation in the territory of that Member State;
 - (b) the contact details of the competent authorities within that Member State by means of which they may be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the technical rules in question in the territory of that Member State;
 - (c) the remedies generally available in the territory of that Member State in the event of a dispute between the competent authorities and an economic operator.
2. Product Safety Contact Points shall respond within 15 working days of receiving any request referred to in paragraph 1.
3. Product Safety Contact Points in the Member State in which the economic operator concerned has lawfully marketed the product in question may provide the economic operator or the competent authority as referred to in Article 6 of Regulation (EC) No 764/2008 with any relevant information or observations.
4. The Member States shall establish offices in the framework of the Product Safety Contact Points in order to facilitate training on product safety legislation and requirements in general and transfer information across industries in order to support education of economic operators on product safety requirements.
5. Product Safety Contact Points shall not charge any fee for the provision of the information referred to in paragraph 1. [Am. 86]

CHAPTER III

European standards providing presumption of conformity

Article 16

Standardisation requests to European standardisation organisations

1. The Commission may request one or more European standardisation organisations to draft or identify a European standard, which aims at ensuring that products that conform to such standard or parts thereof comply with the general safety requirement laid down in Article 4. **The Taking into account the views of relevant stakeholders, as appropriate, the Commission shall determine the requirements as to the content to be met by the requested European standard and a deadline for its adoption. [Am. 87]**

Tuesday 15 April 2014

The Commission shall adopt the request referred to in the first subparagraph of this paragraph by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(3).

2. The relevant European standardisation organisation shall indicate, within one month following receipt of the request referred to in paragraph 1, if it accepts it.

3. Where a request for funding is made, the Commission shall inform the relevant European standardisation organisations, within two months following the receipt of the acceptance referred to in paragraph 2, about the award of a grant for drafting a European standard.

4. The European standardisation organisations shall inform the Commission about the activities undertaken for the development of the European standard referred to in paragraph 1. The Commission together with the European standardisation organisations shall assess the compliance of the European standards drafted or identified by the European standardisation organisations with its initial request.

5. Where the European standard satisfies the requirements it aims to cover and the general safety requirement laid down in Article 4, the Commission shall publish a reference to such European standard without delay in the *Official Journal of the European Union*.

Article 17

Formal objections to European standards

1. When a Member State or the European Parliament considers that a European standard referred to in Article 16 does not entirely satisfy the requirements it aims to cover and the general safety requirement laid down in Article 4, it shall inform the Commission thereof with a detailed explanation and the Commission shall decide by means of implementing acts:

(a) to publish, not to publish or to publish with restriction the references to the European standard concerned in the *Official Journal of the European Union*;

(b) to maintain, to maintain with restriction or to withdraw the references to the European standard concerned in or from the *Official Journal of the European Union*.

2. The Commission shall publish information on its website on the European standards that have been subject to a decision referred to in paragraph 1.

3. The Commission shall inform the European standardisation organisation concerned of the decision referred to in paragraph 1 and, if necessary, request the revision of the European standard concerned.

4. The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 19(2).

5. The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 19(3).

CHAPTER IV

Final provisions

Article 18

Penalties

1. The Member States shall lay down the rules on **establishing appropriate** penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. ~~The penalties provided for must be effective, proportionate and dissuasive.~~ Member States shall notify those provisions to the Commission by... (*) [insert date — 3 months prior to the date of application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them. [Am. 88]

(*) **Three months prior to the date of application of this Regulation.**

Tuesday 15 April 2014

2. **The penalties provided for shall be effective, proportionate and dissuasive.** The penalties referred to in paragraph 1 shall have regard to the size of the undertakings and in particular to the situation of small and medium-sized enterprises **seriousness, the duration and, where applicable, the intentional character of the infringement. In addition,** the penalties may be increased if **shall take into account whether** the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements. [Am. 89]

2a. **Administrative penalties applicable to infringements shall at least offset the economic advantage sought through the infringement, but shall not exceed 10 % of the annual turnover or an estimate thereof. The penalties imposed may be higher than 10 % of the annual turnover or an estimate thereof, where necessary to offset the economic advantage sought through the infringement. The penalties may include criminal sanctions for serious infringements.** [Am. 90]

2b. **The Member States shall inform the Commission of the type and the size of the penalties imposed under this Regulation, identify the actual infringements of this Regulation, and indicate the identity of economic operators upon which penalties have been imposed. The Commission shall make that information available to the public without undue delay, electronically and, where appropriate, by other means.**

The Commission shall, on the basis of the information received under the first subparagraph, publish and update a Union-wide blacklist of economic operators who are repeatedly found to intentionally infringe this Regulation. [Am. 91]

Article 18a

Exercise of the delegation

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 13(3) and Article 15(3) shall be conferred on the Commission for an indeterminate period of time from ... (*).
3. The delegation of power referred to in Article 13(3) and Article 15(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Article 13(3) and Article 15(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or of the Council.

Article 19

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

However, for the purposes of Articles 16 and 17 of this Regulation the Commission shall be assisted by the committee established by Regulation (EU) No 1025/2012. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

(*) Date of entry into force of this Regulation.

Tuesday 15 April 2014

4. Where the opinion of the committee referred to in the second subparagraph of paragraph 1 is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Article 21

Evaluation

No later than ... (*) **and every five years thereafter**, the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and the Council. That report shall assess whether this Regulation has achieved its objectives, in particular with regard to enhancing the protection of consumers against unsafe products **within the meaning of Article 4 of this Regulation**, taking into account its impact on business and in particular on ~~small and medium-sized enterprises~~ **SMEs. That report shall also assess the implications and contributions of Regulation (EU) No 1025/2012 within the scope of this Regulation.** [Am. 92]

Article 22

Repeal

1. Directive 2001/95/EC is repealed with effect from ... (**).
2. Directive 87/357/EEC is repealed with effect from ... (**).
3. References to Directive 2001/95/EC and Directive 87/357/EEC shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in the Annex.

Article 23

Transitional provisions

1. Member States shall not impede the making available on the market of products covered by Directive 2001/95/EC which are in conformity with that Directive and which were placed on the market before ... (**).
2. European standards the references of which have been published in the *Official Journal of the European Union* in accordance with Directive 2001/95/EC shall be deemed to be European standards referred to in point (b) of Article 5 of this Regulation.
3. Standardisation mandates issued by the Commission to a European standardisation organisation in accordance with Directive 2001/95/EC shall be deemed standardisation requests referred to in Article 15(1) of this Regulation.

Article 24

Entry into force

1. This Regulation shall enter into force on (***)..
2. It shall apply from ... (****).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament
The President

For the Council
The President

(*) Five years after the date of application of this Regulation.
(**) Date of application of this Regulation.
(***) Date of entry into force of Regulation (2013/0048(COD)).
(****) Date of application of Regulation (2013/0048(COD)).

Tuesday 15 April 2014

ANNEX

Correlation table

Directive 2001/95/EC	Directive 87/357/EEC	This Regulation
Article 1(1)		Article 1
First subparagraph of Article 1(2)		Article 2(1)
Second subparagraph of Article 1(2)		Article 2(4)
Article 2		Article 3
Points (b)(i)-(iv) of Article 2		Article 6(1)
Article 3(1)		Article 4
Article 3(2)		Article 5
Article 3(3)		Article 6(2)
Article 3(4)		—
Article 4		Articles 16 and 17
First subparagraph of Article 5(1)		Article 8(8)
Second subparagraph of Article 5(1)		—
Third subparagraph of Article 5(1)		Article 8(9)
Fourth subparagraph of Article 5(1)		Article 8(3), (6) and (7)
Fifth subparagraph of Article 5(1)		—
Article 5(2)		Article 11
First subparagraph of Article 5(3)		Article 8(9) and Article 11(5)
Second subparagraph of Article 5(3)		—
Article 5(4)		—
Article 6(1)		—
Article 6(2) and (3)		—
Article 7		Article 18

Tuesday 15 April 2014

Directive 2001/95/EC	Directive 87/357/EEC	This Regulation
Point (a) of Article 8(1)		—
Points (b) — (f) of Article 8(1)		—
First subparagraph of Article 8(2)		—
Second subparagraph of Article 8(2)		—
Third subparagraph of Article 8(2)		—
Article 8(3)		—
Article 8(4)		—
Article 9(1)		—
Article 9(2)		—
Article 10		—
Article 11		—
Article 12		—
Article 13		—
Article 14		—
Article 15		Article 19
Article 16		—
Article 17		—
Article 18(1)		—
Article 18(2)		—
Article 18(3)		—
Article 19(1)		—
Article 19(2)		Article 21
Article 20		—
Article 21		—
Article 22		Article 22

Tuesday 15 April 2014

Directive 2001/95/EC	Directive 87/357/EEC	This Regulation
Article 23		Article 24
Annex I, section 1		Article 8(9) and Article 11(5)
Annex I, section 2, first sentence		—
Annex I, section 2, second sentence		Article 13(1) and (2)
Annex I, section 3		—
Annex II		—
Annex III		—
Annex IV		Annex
	Article 1	Point (e) of Article 6(1)
	Articles 2 to 7	—

Tuesday 15 April 2014

P7_TA(2014)0384

Market surveillance of products ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council (COM(2013)0075 — C7-0043/2013 — 2013/0048(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/63)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0075),
 - having regard to Article 294(2) and Articles 33, 114 and 207 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0043/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 22 May 2013 ⁽¹⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinion of the Committee on International Trade (A7-0346/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0048

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EC) No 764/2008, Regulation (EC) No 765/2008 and Regulation (EU) No 305/2011 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 33, 114 and 207 thereof,

⁽¹⁾ OJ C 271, 19.9.2013, p. 86.

Tuesday 15 April 2014

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that they fulfil requirements providing a high level of protection of public interests such as health and safety of persons in general, health and safety in the workplace, consumer protection, protection of the environment and public security. Robust enforcement of those requirements is essential to the proper protection of those interests and to create the conditions in which fair competition in the Union goods market can thrive. Rules are therefore necessary on market surveillance and on controls of products entering the Union from third countries.
- (2) Market surveillance activities covered by this Regulation should not be directed exclusively towards the protection of health and safety but should also be applicable to the enforcement of Union legislation which seeks to safeguard other public interests, for example by means of regulating the accuracy of measurement, electromagnetic compatibility ~~and~~, energy efficiency **and applicable environmental legislation**. [Am. 1]
- (3) It is necessary to establish an overall framework of rules and principles in relation to market surveillance which should not affect the substantive rules of existing Union legislation designed to protect public interests such as health and safety, consumer protection and the protection of the environment, but should aim at enhancing their operation.
- (4) Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽³⁾ was adopted to establish a framework for market surveillance to complement and strengthen existing provisions in Union harmonisation legislation relating to market surveillance and the enforcement of such provisions.
- (5) For the purpose of ensuring the equivalent and consistent enforcement of Union harmonisation legislation, Regulation (EC) No 765/2008 introduced a Union market surveillance framework, defining minimum requirements against the background of the objectives to be achieved by Member States and a framework for administrative cooperation including the exchange of information among Member States.
- (6) Directive 2001/95/EC of the European Parliament and of the Council ⁽⁴⁾ established rules to ensure the safety of products intended for or likely to be used by consumers. Regulation (EC) No 765/2008 maintained the possibility for market surveillance authorities to take the more specific measures available to them under that Directive.
- (7) In its resolution of 8 March 2011 on the revision of the General Product Safety Directive and market surveillance ⁽⁵⁾ the European Parliament stated that having one single regulation is the only way to have one single market surveillance system for all products and therefore urged the Commission to establish a single market surveillance system for all products, based on one act covering both Directive 2001/95/EC and Regulation (EC) No 765/2008.
- (8) This Regulation should therefore integrate the provisions of Regulation (EC) No 765/2008, Directive 2001/95/EC and several sector-specific acts of Union harmonisation legislation relating to market surveillance into a single regulation which covers products in both the harmonised and non-harmonised areas of the Union legislation, regardless whether they are intended for use, or are likely to be used, by consumers or professionals.

⁽¹⁾ OJ C 271, 19.9.2013, p. 86.

⁽²⁾ Position of the European Parliament of 15 April 2014.

⁽³⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L 218, 13.8.2008, p. 30).

⁽⁴⁾ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

⁽⁵⁾ OJ C 199 E, 7.7.2012, p. 1.

Tuesday 15 April 2014

- (9) Union legislation applicable to products and processes of the food chain, and in particular Regulation (EC) No 882/2004 of the European Parliament and of the Council⁽¹⁾, establishes a comprehensive framework for the performance of official controls and other official activities to verify compliance with feed and food law, rules on animal health and welfare, genetically modified organisms, plant health and plant reproductive material, plant protection products, and pesticides. Those areas should therefore be excluded from the scope of this Regulation.
- (10) Union legislation concerning medicinal products, medical devices, *in vitro* diagnostic medical devices and substances of human origin contain special provisions to ensure post-market safety based in particular on sector-specific vigilance and market surveillance systems. Those products should therefore also be excluded from the scope of this Regulation, with the exception of its provisions on control of products entering the Union market which should apply to those products insofar as the relevant Union legislation does not contain specific rules relating to the organisation of border controls.
- (11) Directive 2010/35/EU of the European Parliament and of the Council⁽²⁾ applies not only to new transportable pressure equipment for the purpose of making it available on the market but also to certain other transportable pressure equipment for the purposes of its periodic inspections, intermediate inspections, exceptional checks and use. That Directive provides for specific Pi marking and for a Union safeguard procedure and particular procedures for dealing with transportable pressure equipment presenting a risk at national level, with compliant transportable pressure equipment which presents a risk to health and safety and with formal non-compliance. Therefore, the procedures for the control of products within the Union laid down in this Regulation should not apply to transportable pressure equipment subject to Directive 2010/35/EU.
- (12) This Regulation should establish a comprehensive framework for market surveillance in the Union. It should define the scope of the products covered and those excluded, impose an obligation on Member States to organise and carry out market surveillance, require Member States to appoint market surveillance authorities and to specify their powers and duties, and make Member States responsible for setting up general and sector-specific market surveillance programmes.
- (12a) *This Regulation should apply to all forms of supply of products, including distance selling. Member States and the Commission should develop a common approach for the market surveillance of products sold online and, where appropriate, produce guidance on the respective roles and responsibilities of operators involved in the e-commerce supply chain in order to strengthen enforcement of the rules for products sold online. [Am. 2]***
- (13) Some Union harmonisation legislation contains provisions on market surveillance and safeguard clauses. These may be based on the reference provisions on market surveillance and safeguard clauses contained in Decision No 768/2008/EC of the European Parliament and of the Council⁽³⁾. This Regulation should contain all of the market surveillance provisions applicable to the products falling within its scope. This Regulation should therefore include the reference provisions on market surveillance and safeguard clauses contained in Decision No 768/2008/EC. Provisions in existing Union harmonisation legislation that relate to market surveillance and safeguard clauses,

⁽¹⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁽²⁾ Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1).

⁽³⁾ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

Tuesday 15 April 2014

whether drafted before the adoption of Decision No 768/2008/EC or based on its reference provisions, should be removed from that harmonisation legislation unless there are specific sectoral reasons for retaining them. Exemptions from the safeguard clauses should be made in relation to products subject to Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁽¹⁾, certain fittings subject to Directive 2009/142/EC of the European Parliament and of the Council⁽²⁾, certain pressure equipment subject to Directive 97/23/EC of the European Parliament and of the Council⁽³⁾ and certain pressure vessels subject to Directive 2009/105/EC of the European Parliament and of the Council⁽⁴⁾.

- (14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, this Regulation should clearly set out the chronological steps of that process, from the moment when market surveillance authorities identify a product which they believe may present a risk, to the assessment of the risk presented, the corrective action to be taken by the relevant economic operator within a specified period and the measures to be taken by market surveillance authorities themselves if economic operators do not comply or in cases of urgency.
- (14a) In order to facilitate the work of market surveillance authorities, economic operators should make available all the documentation and information necessary to those authorities for the purpose of carrying out their activities. Market surveillance authorities should only require documentation and information that the relevant economic operator can be expected to possess in accordance with their role in the supply chain. [Am. 3]**
- (15) Market surveillance should be based on the assessment of the risk presented by a product taking all relevant data into account. **The methodology and criteria for assessing risks should be homogeneous in all Member States in order to ensure a level playing field for all economic operators.** A product that is subject to Union harmonisation legislation which lays down essential requirements relating to protection of certain public interests should be presumed not to present a risk to those public interests if it complies with those essential requirements. **[Am. 4]**
- (15a) Consumers can play an active and important role in contributing to market surveillance, as they are usually in direct contact with products presenting a risk, including products that are not compliant with applicable Union legislation. In that context Member States should raise consumers' awareness with regard to their right to submit complaints on issues relating to product safety and market surveillance activities and ensure that the reporting procedure is easily accessible, relatively simple and efficient. The Commission should, furthermore, explore the opportunities for making the submission of such complaints harmonised throughout the Union, for example through the creation of a central database where the complaints filed by consumers can be stored, as well as examine the possibility of making those complaints public, subject to the right of review and reply by the economic operators involved. [Am. 5]**
- (16) Products subject to Union harmonisation legislation that does not lay down essential requirements but which is designed to ensure the protection of certain public interests should be presumed not to present a risk to those public interests provided that they comply with that legislation.
- (17) Similarly, a product that is not subject to Union harmonisation legislation but which complies with national rules on the health and safety of persons or with European standards the references of which are published in the *Official Journal of the European Union* should be presumed not to present a risk to health and safety.

⁽¹⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

⁽²⁾ Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (OJ L 330, 16.12.2009, p. 10).

⁽³⁾ Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1).

⁽⁴⁾ Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels (OJ L 264, 8.10.2009, p. 12).

Tuesday 15 April 2014

- (18) For the purposes of this Regulation, risk assessment should be carried out to identify products which have the potential to affect adversely the public interests protected by Regulation (EU) No .../.... of the European Parliament and of the Council ⁽¹⁾ (*), sector-specific Union harmonisation legislation and other Union legislation on products that are subject to this Regulation. Risk assessment should include, where available, data on risks that have materialised previously with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks. The particular potential vulnerability of consumers, as opposed to professional users, and the increased vulnerability of certain categories of consumer such as children, the elderly or the disabled, should be taken into account.
- (19) Both new and second-hand products originating from outside the Union may be placed on the market only after they have been released for free circulation. Effective controls are required at the external borders of the Union to suspend the release of products that may present a risk if placed on the market in the Union pending evaluation and a final decision by market surveillance authorities.
- (20) Obliging the authorities responsible for the control of products entering the Union market to carry out checks on an adequate scale therefore contributes to a safer Union market for products. In order to increase the effectiveness of such checks, ~~cooperation and exchange of information between those authorities and market surveillance authorities~~ **those authorities and market surveillance authorities should be obliged to cooperate and exchange information** concerning products presenting a risk ~~should be enhanced~~ **and products that are non-compliant.** [Am. 6]
- (21) Market surveillance authorities should be given the power to destroy products, render inoperable or order their destruction by the relevant economic operator, if they deem it necessary and proportionate to ensure that such goods cannot pose any further threats. **The relevant economic operator should bear all the costs related to those actions, in particular the costs incurred by the market surveillance authority.** [Am. 7]
- (22) The release for free circulation of products that are imported in the physical possession of persons entering the Union for their personal, non-commercial use should not be suspended or refused under this Regulation by the authorities responsible for the control of products entering the Union market.
- (23) There should be effective, speedy and accurate exchange of information among the Member States and between the Member States and the Commission. It is therefore necessary to provide for effective tools for such exchange. The Union Rapid Information System (RAPEX) has proved its effectiveness and efficiency. RAPEX enables measures to be taken across the Union in relation to products that present a risk beyond the territory of a single Member State. To avoid unnecessary duplication, that system should be used **and constantly updated** for all alert notifications required by this Regulation relating to products presenting a risk. **RAPEX should also include notifications related to food contact materials, moved there from the Rapid Alert System for Food and Feed (RASFF) platform.** [Am. 8]
- (24) Coherent and cost-effective market surveillance activity throughout the Union also requires well-structured, comprehensive archiving and sharing among Member States of all relevant information on national activities in this context, including a reference to notifications required by this Regulation, to form a complete database of market surveillance information. The Commission has established a database called 'Information and Communication System for Market Surveillance' which is suitable for that purpose and should therefore be used.
- (25) Given the size of the Union market for goods and as there are no internal borders, it is imperative that ~~the~~ **this Regulation builds the framework for** market surveillance authorities of the Member States ~~are willing and able to~~ cooperate with each other effectively and to coordinate joint support and action. Accordingly, mechanisms for mutual assistance should be established, **enforced, verified and duly financed.** [Am. 9]

⁽¹⁾ Regulation (EU) No.../.... of the European Parliament and of the Council of... on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC (OJ L ...).

(*) Number of Regulation (2013/0049(COD)) in the recital and the number, date of adoption and the publication reference of the Regulation in the footnote.

Tuesday 15 April 2014

- (25a) *The consistent application of this Regulation should be closely monitored by the Commission, which should also, where necessary, give recommendations to Member States where it finds that the powers and resources they have given to their market surveillance authorities are insufficient to meet the requirements of this Regulation properly. [Am. 10]*
- (26) In order to facilitate market surveillance of products entering the Union market from third countries, this Regulation should provide a basis for cooperation between market surveillance authorities of Member States and the authorities of those third countries.
- (26a) *Injuries and accidents place a high social and economic burden on societies in general and on individuals. Injury and accident prevention can be enhanced primarily by improving injury surveillance. Based on the experience gained in the framework of the Joint Action on Monitoring Injuries in Europe (JAMIE) project, a genuine Pan-European Injuries Database should urgently be established, in particular given the fact that the JAMIE project expires in 2014. Moreover, political commitment is necessary to ensure that the exchange of injury data among the Member States is an absolute priority. [Am. 11]*
- (27) A European Market Surveillance Forum (EMSF) composed of representatives from market surveillance authorities should be established. The EMSF should *serve as a platform for structured cooperation between the authorities of the Member States and should* provide a *continuous and permanent* means of involving all stakeholders concerned, including professional organisations, *business organisations* and consumer organisations, in order to take advantage of available information relevant for market surveillance when establishing, implementing and updating market surveillance programmes. [Am. 12]
- (28) The Commission should provide support for cooperation between market surveillance authorities and participate in the EMSF. ~~The~~ *This* Regulation should set out a list of tasks to be performed by the EMSF. An executive secretariat should organise the EMSF's meetings and provide other operational support for the accomplishment of its tasks. *To streamline the practices of market surveillance within the Union and to make market surveillance more effective, the Commission should consider proposing, when this Regulation is next reviewed, that the EMSF is given the power to set binding recommendations as to the quality and practices of market surveillance.* [Am. 13]
- (29) Where appropriate, reference laboratories should be established with a view to providing expert, impartial technical advice and conducting tests on products required in relation to market surveillance activities.
- (29a) *In view of the conflict between the increased number of products in circulation within the internal market on the one hand, and the constraints on public resources that limit the possibility to drastically increase public market surveillance on an adequate scale on the other, the Commission should explore complementary, new and innovative, market-based solutions for more effective market surveillance on a larger scale, such as third party auditing of quality control systems and products. The Commission should include the results of those deliberations in the general evaluation report. [Am. 14]*
- (30) This Regulation should strike a balance between transparency through the release of the maximum possible amount of information to the public and maintaining confidentiality, for example for reasons of ~~personal data protection~~, commercial secrecy or the protection of investigations, in accordance with rules on confidentiality pursuant to applicable national law or, as regards the Commission, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ⁽¹⁾. *Moreover, this Regulation should respect data protection principles, such as confidential handling of personal data, requirement to process data fairly and lawfully and for specific purpose, while ensuring their*

⁽¹⁾ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Tuesday 15 April 2014

quality and allowing the individuals concerned to exercise their rights. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽¹⁾ and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ⁽²⁾ apply in the context of this Regulation. [Am. 15]

- (31) Information exchanged between competent authorities should be subject to the strictest guarantees of confidentiality and professional secrecy and be handled in such a way that investigations are not compromised and that the reputations of economic operators are not prejudiced.
- (32) Member States should provide means of redress in the competent courts and tribunals in respect of restrictive measures taken by their authorities.
- (33) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive **and depend on the seriousness, duration and intentional or recurring character of the infringement, as well as the size of the undertakings, in terms of the number of persons employed by and annual turnover of the economic operators concerned, with particular regard to small and medium-sized enterprises (SMEs). Infringements should entail administrative penalties that are harmonised at Union level. Member States should be encouraged to allocate the revenues collected from such penalties to market surveillance activities.** [Am. 16]
- (33a) **In order to enhance the deterrent effect of the penalties, the Commission should make them public. In addition, economic operators who are repeatedly found to have intentionally breached this Regulation should be placed on a public, Union-wide blacklist.** [Am. 17]
- (34) Market surveillance should be financed at least in part by fees charged to economic operators where they are required by market surveillance authorities to take corrective action or where those authorities are obliged to take action themselves. **Member States should ensure that the revenues collected from fees charged in accordance with this Regulation are allocated to market surveillance activities.** [Am. 18]
- (35) In order to achieve the objectives of this Regulation, the Union should contribute to the financing of activities required to implement policies in the field of market surveillance such as the drawing-up and updating of guidelines, preliminary or ancillary activities in connection with the implementation of Union legislation and programmes of technical assistance and cooperation with third countries as well as the enhancement of policies at Union and international level.
- (36) Union financing should be made available in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ⁽³⁾, depending on the nature of the activity to be financed, in particular for support to the executive secretariat of the EMSF.

⁽¹⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽²⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

⁽³⁾ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

Tuesday 15 April 2014

- (36a) *In order to facilitate the identification and traceability of products bearing a potential serious risk to health and safety and thus to maintain a high level of health and safety of consumers, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in order to establish a Pan-European Injuries Database. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. [Am. 19]*
- (37) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards national measures taken and notified by a Member State in relation to products subject to Union harmonisation legislation and the establishment of Union reference laboratories.
- (38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards uniform conditions for the carrying out of checks by reference to particular product categories or sectors, including the scale of checks to be carried out and the adequacy of samples to be checked. ~~Implementing powers should also be conferred as regards the modalities for the provision of information to market surveillance authorities by economic operators, as regards establishing uniform conditions for determining cases in which such information need not be provided.~~ Implementing powers should also be conferred on the Commission as regards the modalities and procedures for the exchange of information through RAPEX and as regards the adoption of temporary or permanent marketing restrictions on products presenting a serious risk, where appropriate, specifying the necessary control measures to be taken by the Member States for their effective implementation where other Union legislation does not provide a specific procedure to address the risks in question. ***In addition, implementing powers should be conferred on the Commission as regards the adoption of the general risk assessment methodology.*** Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾. [Am. 20]
- (39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to restrictive measures relating to products that present a serious risk, imperative grounds of urgency so require.
- (39a) *The precautionary principle, as laid down in Article 191(2) TFEU, and outlined inter alia in the Commission Communication of 2 February 2000 entitled ‘On the precautionary principle’, is a fundamental principle for the safety of products and for the safety of consumers and should be taken into due account by market surveillance authorities when assessing the safety of a product. [Am. 21]*

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of its implementing powers (OJ L 55, 28.2.2011, p. 44 13).

Tuesday 15 April 2014

- (40) The market surveillance provisions of Council Directive 89/686/EEC⁽¹⁾, Council Directive 93/15/EEC⁽²⁾, Directive 94/9/EC of the European Parliament and the Council⁽³⁾, Directive 94/25/EC of the European Parliament and of the Council⁽⁴⁾, Directive 95/16/EC of the European Parliament and of the Council⁽⁵⁾, Directive 97/23/EC, Directive 1999/5/EC of the European Parliament and of the Council⁽⁶⁾, Directive 2000/9/EC of the European Parliament and of the Council⁽⁷⁾, Directive 2000/14/EC of the European Parliament and of the Council⁽⁸⁾, Directive 2001/95/EC, Directive 2004/108/EC of the European Parliament and of the Council⁽⁹⁾, Directive 2006/42/EC of the European Parliament and of the Council⁽¹⁰⁾, Directive 2006/95/EC of the European Parliament and of the Council⁽¹¹⁾, Directive 2007/23/EC of the European Parliament and of the Council⁽¹²⁾, Directive 2008/57/EC of the European Parliament and of the Council⁽¹³⁾, Directive 2009/48/EC of the European Parliament and of the Council⁽¹⁴⁾, Directive 2009/105/EC, Directive 2009/142/EC, Directive 2011/65/EU of the European Parliament and of the Council⁽¹⁵⁾, Regulation (EU) No 305/2011 of the European Parliament and of the Council⁽¹⁶⁾, and Regulation (EC) No 765/2008 overlap with the provisions of this Regulation. Therefore, those provisions should be deleted. Regulation (EC) No 764/2008 of the European Parliament and of the Council⁽¹⁷⁾ should be amended accordingly.
- (40a) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 30 May 2013⁽¹⁸⁾,
- (41) Since the objective of this Regulation, namely to ensure that products on the market covered by Union legislation fulfil the requirements providing for a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market by providing a framework for coherent market surveillance in the Union, cannot be sufficiently achieved by the Member States as the attainment of that objective requires a very high degree of cooperation, interaction and uniformity of operation among all of the competent authorities of all Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

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- ⁽¹⁾ Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).
- ⁽²⁾ Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses (OJ L 121, 15.5.1993, p. 20).
- ⁽³⁾ Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 100, 19.4.1994, p. 1).
- ⁽⁴⁾ Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft (OJ L 164, 30.6.1994, p. 15).
- ⁽⁵⁾ Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213, 7.9.1995, p. 1).
- ⁽⁶⁾ Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (OJ L 91, 7.4.1999, p. 10).
- ⁽⁷⁾ Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons (OJ L 106, 3.5.2000, p. 21).
- ⁽⁸⁾ Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1).
- ⁽⁹⁾ Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (OJ L 390, 31.12.2004, p. 24).
- ⁽¹⁰⁾ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).
- ⁽¹¹⁾ Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 374, 27.12.2006, p. 10).
- ⁽¹²⁾ Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles (OJ L 154, 14.6.2007, p. 1).
- ⁽¹³⁾ Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (OJ L 191, 18.7.2008, p. 1).
- ⁽¹⁴⁾ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).
- ⁽¹⁵⁾ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).
- ⁽¹⁶⁾ Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).
- ⁽¹⁷⁾ Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L 218, 13.8.2008, p. 21).
- ⁽¹⁸⁾ OJ C 253, 3.9.2013, p. 8.

Tuesday 15 April 2014

- (42) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union. In particular this Regulation seeks to ensure full respect for the obligation to ensure a high level of human health protection and consumer protection as well as full respect for the freedom to conduct a business and the right to property,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject matter

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests.

The provisions of this Regulation are based on the precautionary principle. [Am. 22]

Article 2

Scope

1. Chapters I, II, III, V and VI of this Regulation shall apply to all products that are subject to Regulation (EU) No .../... (*) or Union harmonisation legislation, including to products assembled or manufactured for the manufacturer's own use, and to the extent that Union harmonisation legislation does not contain a specific provision with the same objective.
2. Chapters I and IV and Article 23 shall apply to all products covered by Union legislation to the extent that other Union legislation does not contain specific provisions relating to the organisation of external border controls or to cooperation between authorities in charge of external border controls.
3. Chapters II, III, V and VI shall not apply to the following products:
 - (a) medicinal products for human or veterinary use;
 - (b) medical devices and *in vitro* diagnostic medical devices;
 - (c) blood, tissues, cells, organs and other substances of human origin.
4. Chapter III of this Regulation shall not apply to transportable pressure equipment subject to Directive 2010/35/EU.
5. Articles 11 and 18 of this Regulation shall not apply to the following products:
 - (a) products subject to Regulation (EC) No 1907/2006;
 - (b) fittings as defined in point (b) of Article 1(2) of Directive 2009/142/EC;
 - (c) pressure equipment subject to the provisions of Article 3(3) of Directive 97/23/EC;
 - (d) simple pressure vessels subject to the provisions of Article 3(2) of Directive 2009/105/EC.
6. This Regulation shall not apply in the areas governed by Union legislation on official controls and other official activities carried out for the verification of compliance with the following rules:
 - (a) rules governing food and food safety, at any stage of production, processing and distribution of food, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information;
 - (b) rules governing the manufacture and use of materials and articles intended to come into contact with food;

(*) Number of Regulation (2013/0049(COD)).

Tuesday 15 April 2014

- (c) rules governing the deliberate release into the environment of genetically modified organisms;
- (d) rules governing feed and feed safety, at all stages of production, processing and distribution of feed and the use of feed, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information;
- (e) rules laying down animal health requirements;
- (f) rules aiming at preventing and minimising risks to human and animal health arising from animal by-products and derived products;
- (g) rules laying down welfare requirements for animals;
- (h) rules on protective measures against pests of plants;
- (i) rules on the production, with a view to placing on the market, and placing on the market of plant reproductive material;
- (j) rules laying down the requirements for placing on the market and the use of plant protection products and the sustainable use of pesticides;
- (k) rules governing organic production and labelling of organic products;
- (l) rules on the use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.

Article 3

Definitions

For the purposes of this Regulation the following definitions apply:

- (1) 'product' means a ~~product obtained~~ **substance, mixture, preparation or good produced** through a manufacturing process **other than food, feed, products of human origin and products of plants and animals relating directly to their future reproduction;** [Am. 23]
- (2) 'making available on the market' means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (3) 'placing on the market' means the first making available of a product on the Union market;
- (4) 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trade mark;
- (5) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks **with regard to the manufacturer's obligations under the relevant Union legislation;** [Am. 24]
- (6) 'importer' means any natural or legal person established within the Union who places a product from a third country on the Union market;
- (7) 'distributor' means any natural or legal person in the supply chain, other than a manufacturer or importer, who makes a product available on the market;
- (7a) **'intermediary service provider' means any natural or legal person who enables the placing or making available on the market of a product via electronic means, such as by operating e-commerce platforms or hosting websites;** [Am. 25]

Tuesday 15 April 2014

- (8) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (9) 'conformity assessment' means conformity assessment as defined in point 12 of Article 2 of Regulation (EC) No 765/2008;
- (10) 'conformity assessment body' means conformity assessment body as defined in point 13 of Article 2 of Regulation (EC) No 765/2008;
- (11) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that products do not endanger health, safety or any other aspect of public interest protection and, in the case of products falling within the scope of Union harmonisation legislation, that they comply with the requirements set out in that legislation;
- (12) 'market surveillance authority' means an authority of a Member State ~~responsible for carrying out market surveillance on its territory~~ **competent for exercising the regulated powers under this Regulation**; [Am. 26]
- (-13) 'non-compliant product' means a product which is not in conformity with the requirements laid down in applicable Union legislation; [Am. 27]**
- (13) 'product presenting a risk' means a product ~~having~~ **which has** the potential to affect adversely the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements; [Am. 28]
- (13a) 'product presenting an emerging risk' means a product on which there is solid scientific evidence that it presents a newly developing risk or a known risk if the product is used in new or unfamiliar conditions which cannot be reasonably foreseen by the manufacturer; [Am. 29]**
- (14) 'product presenting a serious risk' means a product presenting a serious risk requiring rapid intervention and follow-up, including cases where the effects may not be immediate;
- (15) 'recall' means any measure aimed at achieving the return of a product that has already been made available to the end user;
- (16) 'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;
- (17) 'release for free circulation' means the procedure laid down in Article 77 of Regulation (EU) No 952/2013 of the European Parliament and the Council ⁽¹⁾;
- (18) 'Union harmonisation legislation' means Union legislation harmonising the conditions for the marketing of products **by laying down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures**; [Am. 30]
- (19) 'European standard' means a European standard as defined in point (b) of Article 2(1) of Regulation (EU) No 1025/2012 of the European Parliament and the Council ⁽²⁾;
- (20) 'harmonised standard' means a harmonised standard as defined in point (c) of Article 2(1) of Regulation (EU) No 1025/2012.

⁽¹⁾ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

⁽²⁾ Regulation (EU) No 1025/2012 of the European Parliament and the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

Tuesday 15 April 2014

CHAPTER II

Union market surveillance framework

Article 4

Market surveillance obligation

1. Member States shall carry out market surveillance in respect of products covered by this Regulation.
2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk **and non-compliant products** are not **placed or** made available on the Union market and, where such products have been **placed or** made available, effective **and proportionate** measures are taken to remove the risk presented by that product **or to resolve non-compliance**. [Am. 31]
3. ~~The implementation of Member States shall report on the~~ market surveillance activities and external border controls ~~shall be monitored by the Member States which shall report on these activities and controls to the Commission every year. The information reported shall include statistics regarding the number and results of controls carried out and shall be communicated to all Member States. Member States may~~ **The Commission shall** make a summary of the results accessible **that information available** to the public **electronically and, where appropriate, by other means**. [Am. 32]
4. ~~The results of the monitoring and assessment of market surveillance activities carried out pursuant to paragraph 3 shall be made available to the public, electronically and, where appropriate, by other means.~~ [Am. 33]

Article 5

Market surveillance authorities

1. Each Member State shall establish or designate market surveillance authorities ~~and define their duties, powers and organisation~~. [Am. 34]
2. ~~Market surveillance authorities~~ **Each Member State shall be given grant market surveillance authorities** the powers and ~~entrusted~~ **entrust them** with the resources and means necessary for the proper performance of their tasks **and shall report to the Commission thereon. The Commission shall evaluate whether those powers and resources are sufficient for the proper performance of that Member State's market surveillance obligations under this Regulation, and shall make the outcomes of its evaluations available to the public electronically and, where appropriate, by other means**. [Am. 35]
3. ~~Each Member State shall establish appropriate mechanisms to ensure that the~~ Market surveillance authorities ~~that it has established or designated~~ **shall** exchange information, cooperate and coordinate their activities both among themselves and with the authorities in charge of controls of products at the external borders of the Union. [Am. 36]
4. Each Member State shall inform the Commission about its market surveillance authorities and its areas of competence, providing the necessary contact details, ~~and~~. The Commission shall ~~transmit this information~~ **make the list available to the other Member States and publish a list of market surveillance authorities public electronically and, where appropriate, by other means**. [Am. 37]
5. Member States shall inform the public of the existence, responsibilities, **powers, available resources, cooperation mechanisms** and identity of national market surveillance authorities and about the contact details of those authorities. [Am. 38]

Article 6

General obligations of market surveillance authorities

1. Market surveillance authorities shall **organise their activities in such a way that maximum effectiveness can be achieved. They shall** perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. **Market surveillance authorities shall, accordingly, carry out the sample checks on sufficient numbers of products made available on the market, enabling conformity and the real risk posed to be assessed.** They shall record those checks in the information and communication system for market surveillance referred to in Article 21. **Where appropriate, along with those traditional market sampling mechanisms, the market surveillance authorities shall endeavour to move to proactive auditing of supply chain processes at entities involved in the manufacturing, importing, trading, branding and retailing of consumer products.** [Am. 39]

Tuesday 15 April 2014

In cases of known or emerging risk related to the objectives set out in Article 1 of this Regulation and concerning a particular product or a category of products, the Commission may adopt implementing acts to establish uniform conditions for the carrying out of the checks performed by one or several market surveillance authorities in relation to that particular product or category of products, **criteria for determination of the amount of samples to be checked in relation to that particular product or category of products** and the characteristics of that known or emerging risk. ~~These~~ **Those** conditions may include requirements for a temporary increase of the scale and frequency of checks to be carried out and the adequacy of samples to be checked. ~~These~~ **Those** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2). [Am. 40]

2. ~~Where appropriate,~~ Market surveillance authorities shall alert users in their territories ~~within an adequate timeframe~~ **without delay of the identity** of products that those authorities have identified as presenting a risk. **Where available, that information shall also include data on the manufacturer, retail channel and period of sales.** [Am. 41]

~~They~~ **Market surveillance authorities** shall cooperate with economic operators **and other competent national authorities** to prevent or reduce risks caused by products made available by those **economic** operators. For that purpose, they shall encourage and promote voluntary action by economic operators including, where applicable, through the development of and adherence to codes of good practice. [Am. 42]

3. Market surveillance authorities shall carry out their duties independently, impartially and without bias and shall fulfil their obligations under this Regulation. They shall exercise their powers in relation to economic operators in accordance with the principle of proportionality.

4. Where it is necessary and justified for carrying out their duties, market surveillance authorities may enter the premises of economic operators, **check, examine and obtain copies of any relevant documents** and take any necessary samples of products. [Am. 43]

5. Market surveillance authorities shall:

(a) provide consumers and other interested parties with the opportunity to submit complaints on issues relating to product safety, market surveillance activities and risks arising in connection with products and follow up those complaints ~~as appropriate~~ **within a reasonable timeframe;** [Am. 44]

(b) verify that corrective action has been taken **in a timely manner;** [Am. 45]

(c) follow and keep up to date with developments in scientific and technical knowledge concerning the safety of products. **and compliance of products with applicable Union legislation;** [Am. 46]

(ca) **monitor accidents and damage to health which are suspected to have been caused by products;** [Am. 47]

(cb) **be encouraged to participate in national standardisation activities aimed at the development or revision of European standards requested by the Commission in accordance with Article 10 of Regulation (EU) No 1025/2012.** [Am. 48]

6. Adequate procedures shall be established and made known to the public to enable market surveillance authorities to fulfil the obligations laid down in paragraph 5.

7. Without prejudice to national legislation in the area of confidentiality, the safeguarding of confidentiality with regard to information received and collated by market surveillance authorities shall be ensured. Information exchanged between national market surveillance authorities and between them and the Commission on condition of confidentiality shall remain confidential unless the authority from which the confidential document originated has agreed to its disclosure.

8. The protection of confidentiality shall not prevent the dissemination to market surveillance authorities of information necessary to ensure effective market surveillance.

Tuesday 15 April 2014

Article 7

Market surveillance programmes

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities and take into account the specific needs of business generally, and SMEs in particular, when implementing Union harmonisation legislation and Regulation (EU) No .../... (*) and provide for guidance and assistance. It shall include the following:

- (a) the sectoral and geographical competence of the authorities designated under Article 5(1);
- (b) the financial resources, staff, technical and other means attributed to the authorities;
- (ba) the levels and methods for calculation of fees applicable to economic operators pursuant to Articles 10 and 16; [Am. 49]**
- (c) an indication of the priority areas of work of the different authorities;
- (d) the mechanisms of coordination among the different authorities and with customs authorities;
- (e) the participation of the authorities in the exchange of information under Chapter V;
- (f) the participation of the authorities in sectoral or project-oriented cooperation at Union level;
- (g) the means to fulfil the obligations laid down in Article 6(5).

2. Each Member State shall draw up sector-specific programmes **with the input of key stakeholders concerned, including professional organisations, business organisations and consumer organisations**, and shall review ~~these~~ **those** programmes, and update them if necessary, every year. ~~These~~ **Those** programmes shall cover all sectors in which authorities conduct market surveillance activities. **[Am. 50]**

3. The general and sector-specific programmes and their updates shall be communicated to the other Member States ~~and~~ **via** the Commission ~~and~~. Subject to Article 6(6), **they** shall be made accessible to the public electronically and, where appropriate, by other means. **[Am. 51]**

The Commission shall evaluate the general and sector-specific programmes and, if appropriate, make recommendations to the Member States based on that evaluation. The Commission shall make the outcomes of its evaluations and, if applicable, its recommendations to Member States available to the public electronically and, where appropriate, by other means. [Am. 52]

Article 8

General obligations of economic operators

1. ~~On~~ **Further to a reasoned** request, economic operators, **in accordance with their respective role in the supply chain** and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities ~~any~~ **all the** documentation and information that those authorities require for the purpose of carrying out their activities, ~~in a language which can be easily understood by them~~. **Such information shall include information that enables the precise identification of the product and facilitates the tracing of the product, as appropriate. Where an economic operator has previously received the documentation and information concerned from another economic operator, and where it is classified as confidential under Union and Member State trade secrecy rules, market surveillance authorities shall ensure confidentiality when that documentation and information is made available. [Am. 53]**

(*) Number of Regulation (2013/0049(COD)).

Tuesday 15 April 2014

2. Economic operators shall ~~provide all necessary information to~~ **cooperate with** market surveillance authorities ~~including information that enables the precise identification of the product and facilitates the tracing of the product~~ **at their request, on any action taken to eliminate the risks presented by or non-compliance of products that they have placed or made available on the market.** [Am. 54]

2a. All information supplied or made available to market surveillance authorities under this Article shall be clear, understandable and intelligible. [Am. 55]

2b. The obligations laid down in this Article shall also apply to intermediary service providers. [Am. 56]

CHAPTER III

Control of products within the Union

Article 9

Non-compliant products and products presenting a risk [Am. 57]

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may **be non-compliant or** present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13 **of this Regulation and in Article 6 of Regulation (EU) No .../.... (*)**. [Am. 58]

Market surveillance authorities shall take ~~due~~ into consideration any readily available **and comprehensible** test result and risk assessment that has already been carried out or issued in relation to the product by an economic operator or any other person or authority including the authorities of other Member States. [Am. 59]

2. In relation to a product ~~that is subject to Union harmonisation legislation~~, formal non-compliance with ~~that~~ **Union** legislation ~~shall~~ **may** give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases: [Am. 60]

- (a) the CE marking or other markings required by Union harmonisation legislation have not been affixed or have been affixed incorrectly;
- (aa) the product or any presentation of the product bears without authorisation a trade mark that is essentially similar to a registered trade mark for that product, thereby not allowing its authenticity or origin to be guaranteed;** [Am. 61]
- (b) the EU declaration of conformity, where required, has not been drawn up or has been drawn up incorrectly;
- (c) the technical documentation is incomplete or unavailable;
- (d) the required labelling or instructions for use are incomplete or missing.

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities ~~shall ensure that~~ **may, if appropriate, withdraw or recall** the product ~~is withdrawn or recalled~~ **in question until the non-compliance is rectified.** [Am. 62]

3. Without prejudice to Article 10(4), where market surveillance authorities find that a product presents a risk they shall without delay specify the necessary corrective action to be taken by the relevant economic operator to address the risk within a specified period. Market surveillance authorities may recommend or agree with the relevant economic operator the corrective action to be taken.

The economic operator shall ensure that all necessary corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Union.

(*) **Number of Regulation (2013/0049(COD)).**

Tuesday 15 April 2014

The economic operator shall provide all necessary information to market surveillance authorities pursuant to Article 8, and in particular the following information:

- (a) a full description of the risk presented by the product;
- (b) a description of any corrective action undertaken to address the risk.

Where possible, market surveillance authorities shall identify the manufacturer or importer of the product and take action in relation to that economic operator in addition to the distributor.

4. Corrective action to be taken ~~by economic operators~~ in relation to a product presenting a risk may include: [Am. 63]

- (a) in the case of a product subject to the requirements laid down in or pursuant to Union harmonisation legislation, taking the measures necessary to bring the product into compliance with those requirements;
- (b) in the case of a product that is liable to present a risk only in certain conditions or only to certain persons and where such risk is not addressed by requirements of Union ~~harmonisation~~ legislation: [Am. 64]
 - (i) affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks it may present, in the official language or languages of the Member State in which the product is made available on the market;
 - (ii) making the marketing of the product subject to prior conditions;
 - (iii) alerting the persons at risk to the risk, ~~in good time~~ **immediately** and in an appropriate form, including by publication of special warnings; [Am. 65]
- (c) in the case of a product that may present a serious risk, temporarily preventing the product from being placed or made available on the market pending a risk assessment;
- (d) in the case of a product that presents a serious risk:
 - (i) **immediately** preventing the product from being placed or made available on the market; [Am. 66]
 - (ii) withdrawing or recalling the product and **immediately** alerting the public, **in an appropriate form**, to the risk presented; [Am. 67]
 - (iii) destroying the product or otherwise rendering it inoperable.

~~5. The Commission may adopt implementing acts establishing the modalities for the provision of information in accordance with the third subparagraph of paragraph 3, while ensuring the effectiveness and proper functioning of the system. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32 (2). [Am. 68]~~

Article 10

Measures taken by market surveillance authorities

1. Where the identity of the relevant economic operator cannot be ascertained by the market surveillance authorities or where an economic operator has not taken the necessary corrective action pursuant to Article 9(3) within the period specified, market surveillance authorities shall take all necessary measures to deal with the risk presented by the product.
2. For the purposes of paragraph 1 of this Article, market surveillance authorities may oblige the relevant economic operators to take, inter alia, any of the corrective action referred to in Article 9(4) or take such measures themselves, as appropriate.

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. ~~They may require the relevant economic operator to bear the cost of such action.~~ [Am. 69]

Tuesday 15 April 2014

All of the expenses incurred by the market surveillance authority in the course of the application of the first subparagraph shall be borne by the relevant economic operator unless the market surveillance authority considers it to be disproportionate, in which case it may decide that the cost shall be borne only partly by that economic operator. [Am. 70]

The first subparagraph shall not prevent Member States from enabling market surveillance authorities to take other, supplementary measures.

~~3. Prior to taking any measure under paragraph 1 in relation to an economic operator who has failed to take the necessary corrective action, market surveillance authorities shall allow him at least 10 days within which to be heard.~~ [Am. 71]

4. Where market surveillance authorities consider that a product presents a serious risk, they shall take all necessary measures and may do so without first requiring the economic operator to take corrective action pursuant to Article 9(3) and without giving the operator the opportunity to be heard beforehand. In such cases the economic operator shall be heard as soon as practicable.

5. Any measure taken pursuant to paragraphs 1 or 4 shall:

- (a) be communicated without delay to the economic operator together with information about the remedies available under the law of the Member State concerned;
- (b) state the exact grounds on which it is based;
- (c) be lifted without delay where the economic operator has demonstrated that he has taken the required corrective action.

For the purposes of point (a) of the first subparagraph, where the economic operator to whom the measure has been communicated is not the economic operator concerned, the manufacturer located within the Union or the importer shall be informed of the measure, provided market surveillance authorities know his identity.

6. ***In the case of products found to present a risk***, market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. That information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities. [Am. 72]

7. Any measure taken in accordance with paragraphs 1 or 4 shall be subject to legal remedies, including recourse to the competent national courts.

8. Market surveillance authorities ~~may~~ **shall** charge fees to **the relevant** economic operators which **are caught placing or making available non-compliant products and products presenting a risk on the Union market. Such fees shall** wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraphs 1 or 4. [Am. 73]

The fees shall be calculated on the basis of the actual costs incurred for each market surveillance activity, and shall be applied to the economic operators subject to such market surveillance activities. Such fees shall not exceed the actual costs of the market surveillance activity performed and may partly or entirely reflect the time taken by the staff of the market surveillance authorities to perform the market surveillance controls. [Am. 74]

Article 11

Union assessment for products controlled within the Union and subject to harmonisation legislation

1. Within ~~60~~ **30** days of communication by the Commission to the Member States, pursuant to Article 20(4), of measures taken pursuant to ~~paragraphs 1 or 4 of Article 10(1) or (4)~~ by the original notifying Member State, a Member State may object to those measures where they relate to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question. [Am. 75]

Tuesday 15 April 2014

2. If no objection is raised by a Member State pursuant to paragraph 1 and the Commission does not consider that the national measures are contrary to Union legislation, the measures taken by the original notifying Member State shall be deemed justified and each Member State shall ensure that restrictive measures are taken without delay in respect of the product concerned.

3. Where an objection is raised by a Member State pursuant to paragraph 1 or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall without delay enter into consultation with **the notifying Member State and** the relevant economic operator or operators and shall evaluate, **within a maximum of 30 days** the national measures, taking account of all available scientific or technical evidence. [Am. 76]

3a. If an objection is raised pursuant to paragraph 1 by a Member State or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall inform all the Member States through the RAPEX contact points. [Am. 77]

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission ~~may~~ **shall** decide by means of implementing acts **within three months** whether the national measures are justified and similar measures should be taken by all Member States that have not already done so. In ~~this~~ **that** case, it shall address the decision to the Member States concerned and immediately communicate it to all Member States and the relevant economic operator or operators. [Am. 78]

5. If the Commission decides that the national measures are justified, each Member State shall take the necessary restrictive measures without delay. If it decides that the national measure is not justified, the original notifying Member State and any other Member State that has taken a similar measure shall withdraw it and the notification made under RAPEX pursuant to Article 20.

6. Where a national measure is considered justified and the product is found not to be in compliance with Union harmonisation legislation because of shortcomings in the relevant harmonised standards, the Commission shall inform the relevant European standardisation organisation and may make an appropriate request pursuant to Article 11 of Regulation (EU) No 1025/2012.

Article 12

Union action against products presenting a serious risk

1. Where it is evident that a product, or a specific category or group of products, when used in accordance with the product's intended purpose or under conditions which can be reasonably foreseeable, presents a serious risk the Commission may, by means of implementing acts, take any appropriate measures depending on the gravity of the situation, including measures prohibiting, suspending or restricting the placing or making available on the market of such products or laying down special conditions for their marketing, in order to ensure a high level of protection of the public interest, provided that the risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned or by any other procedure under Union legislation. By means of those implementing acts, the Commission may lay down the appropriate control measures to be taken by Member States to ensure their effective implementation.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 32(2).

On duly justified imperative grounds of urgency relating to the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security and other public interests, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 32(3).

2. For products ~~and risks~~ subject to Regulation (EC) No 1907/2006, **the Commission may take a decision, pursuant to paragraph 1 of this Article, only if it has justifiable grounds for believing that urgent action is essential to protect human health or the environment.** A decision taken by the Commission pursuant to paragraph 1 of this Article shall be valid for up to two years and may be extended for additional periods of up to two years. Such a decision shall be without prejudice to procedures provided in that Regulation. **The Commission shall immediately inform the Member States and the European Chemicals Agency thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based. If the provisional measure adopted by the Commission involves restricting the placing on the market or use of a substance, the Commission shall initiate a Community restrictions procedure by submitting to European Chemicals Agency a dossier, in accordance with Annex XV to Regulation (EC) No 1907/2006, within three months of the date of the Commission decision.** [Am. 79]

Tuesday 15 April 2014

3. The exportation from the Union of a product that has been prohibited to be placed or made available on the Union market pursuant to a measure adopted in accordance with paragraph 1 shall be prohibited, unless the measure expressly so permits.

4. Any Member State may submit a substantiated request to the Commission to examine the need for the adoption of a measure referred to in paragraph 1.

Article 13

Risk assessment

1. Risk assessment shall be based on available scientific or technical evidence. **Risk assessment shall be carried out in accordance with the general risk assessment methodology and, where appropriate, Commission guidelines on the application of that methodology to a specific category of products. The Commission shall, by means of implementing acts, adopt the general risk assessment methodology. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).** [Am. 80]

For products subject to Regulation (EC) No 1907/2006, risk assessment shall be carried out as appropriate in accordance with the relevant parts of Annex I to that Regulation.

2. In the context of the risk assessment, market surveillance authorities shall take into account the extent to which the product complies with the following:

(a) any requirements laid down in or pursuant to Union harmonisation legislation that apply to the product and relate to the potential risk under consideration, taking full account of test, **inspection and calibration** reports or certificates attesting conformity and issued by a conformity assessment body **accredited in accordance with Regulation (EC) No 765/2008, including assessments drawn up pursuant to Regulation (EC) No 1907/2006, for instance in connection with registration, authorisation, restrictions or reporting;** [Am. 81]

(b) in the absence of requirements laid down in or pursuant to Union harmonisation legislation, specific rules laying down health and safety requirements for such products in the national law of the Member State where it is made available on the market, provided that such rules are in accordance with Union law;

(c) any European standards the references of which have been published in the *Official Journal of the European Union*.

2a. In the absence of criteria referred to in points (a), (b) and (c) of paragraph 2 of this Article, account shall be taken of Article 6 of Regulation (EU) No .../... (*). [Am. 82]

3. Compliance with **any of** the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is new evidence that, despite such conformity or compliance, the product presents a risk. **In that case, the market surveillance authority shall demonstrate that the product presents a risk.** [Am. 83]

4. The feasibility of obtaining higher levels of protection of the public interest concerned and the availability of other products presenting a lesser risk shall not be a **sufficient** reason to consider that a product presents a risk. [Am. 84]

4a. The Commission may, on its own initiative or at the request of a market surveillance authority, have a risk assessment carried out by a Union reference laboratory, in accordance with Article 28. Such assessment shall be binding on all stakeholders. [Am. 85]

(*) Number of Regulation (2013/0049(COD)).

Tuesday 15 April 2014

4b. *In cases where Member State risk assessment practices differ and result in divergent interpretations as to the necessity of measures in respect of similar products, the Commission shall provide guidance on appropriate risk assessment practices. The Commission shall be assisted by the Scientific Committees established under Commission Decision 2004/210/EC⁽¹⁾ and shall take into account all available scientific and technical evidence relating to the risks under consideration. [Am. 86]*

CHAPTER IV

Control of products entering the Union

Article 14

Checks and suspension of release

1. The authorities of the Member States in charge of the control of products at the external borders of the Union shall have the powers and resources necessary for the proper performance of their tasks. They shall carry out appropriate documentary and, where necessary, physical and laboratory checks on products before those products are released for free circulation.
2. Where more than one authority is responsible for market surveillance or external border controls in a Member State, those authorities shall cooperate with each other, by sharing information relevant to their functions.
3. Subject to Article 17, the authorities in charge of external border controls shall suspend release of a product for free circulation on the Union market when, in the course of the checks referred to in paragraph 1 of this Article, they have reason to believe that the product may present a risk.

In relation to a product which must comply with Union harmonisation legislation when it is released for free circulation, formal non-compliance with that legislation shall give the authorities of Member States sufficient reason to believe that the product may present a risk in any of the following cases:

- (a) is not accompanied by the documentation required by the Union harmonisation legislation;
- (b) is not marked or labelled in accordance with that legislation;
- (ba) the product or any presentation of the product bears without authorisation a trade mark that is essentially similar to a registered trade mark for that product, thereby not allowing its authenticity or origin to be guaranteed; [Am. 87]**
- (c) bears a CE marking or other marking required by Union harmonisation legislation which has been affixed in a false or misleading manner.

3a. *Where products are not intended to be placed on the market in the Member State in which they are released for free circulation, the language in which the information set out in points (a), (b), (ba) and (c) of the second subparagraph of paragraph 3 is presented shall not give the authorities in charge of external border controls sufficient reason to believe that the product may present a risk. [Am. 88]*

3b. *The corrective measures of the market surveillance authorities shall be proportionate to the seriousness of the non-compliance. [Am. 89]*

4. The authorities in charge of external border controls shall immediately notify the market surveillance authorities of any suspension under paragraph 3.
5. In the case of perishable products, the authorities in charge of external border controls shall, as far as possible, ~~seek to~~ **facilitate measures to** ensure that any requirements they may impose with regard to the storage of products or the parking of vehicles used for transport are not incompatible with the preservation of those products. [Am. 90]

⁽¹⁾ *Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment (OJ L 66, 4.3.2004, p. 45).*

Tuesday 15 April 2014

6. Where, in relation to products that are not declared for free circulation, the authorities in charge of external border controls have reason to believe that those products present a risk, they shall transmit all relevant information to the authorities in charge of external border controls in the Member State of final destination.

Article 15

Release

1. A product the release of which has been suspended by the authorities in charge of external border controls pursuant to Article 14 shall be released if, within three working days of the **notification of** suspension of release, those authorities have not been requested by the market surveillance authorities to continue the suspension or they have been informed by the market surveillance authorities that the product does not present a risk, and provided that all the other requirements and formalities pertaining to such release have been fulfilled. [Am. 91]

2. If the market surveillance authorities conclude that a product the release of which was suspended due to formal non-compliance in accordance with the second subparagraph of Article 14(3) does not in fact present a risk, the economic operator shall nevertheless rectify the formal non-compliance before the product is released.

3. Compliance with the requirements of any Union harmonisation legislation that apply to the product upon its release which relate to the potential risk under consideration, taking full account of test, **inspection and calibration** reports or certificates attesting conformity and issued by a conformity assessment body **accredited in accordance with Regulation (EC) No 765/2008**, shall raise a presumption on the part of market surveillance authorities that the product does not present a risk. However, this shall not prevent those authorities from instructing the authorities in charge of external border controls not to release the product where there is evidence that, despite such compliance, the product does in fact present a risk. [Am. 92]

Article 16

Refusal to release

1. Where the market surveillance authorities conclude that a product does present a risk, they shall instruct the authorities in charge of external border controls not to release the product for free circulation and to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document:

'Product presents a risk — release for free circulation not authorised — Regulation (EU) No .../.../EU (*)'.

2. Where that product is subsequently declared for a customs procedure other than release for free circulation and provided that the market surveillance authorities do not object, the endorsement referred to in paragraph 1 shall also be included, under the conditions set out in that paragraph, on the documents used in connection with that procedure.

3. Market surveillance authorities or the authorities in charge of external border controls, as the case may be, may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. The cost of such action shall be borne by the person declaring the product for free circulation.

4. Market surveillance authorities shall provide the authorities in charge of external border controls with information on product categories in which a risk has been identified pursuant to paragraph 1.

5. Any measure taken in accordance with paragraphs 1 or 3 shall be subject to legal remedies, including recourse to the competent national courts.

6. Market surveillance authorities ~~may~~ **shall** charge fees **to the person declaring the product for free circulation** which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraph 1. [Am. 93]

(*) Number of this Regulation.

Tuesday 15 April 2014

The fees shall be calculated on the basis of the actual costs of each market surveillance activity, and applied to the person declaring the product for free circulation subject to such market surveillance activities. Such fees shall not exceed the actual costs of the market surveillance activity performed and may partly or entirely reflect the time taken by the staff of the market surveillance authorities to perform the market surveillance controls. [Am. 94]

Article 17

Personal imports

1. Where a product enters the Union accompanied by, and in the physical possession of, a natural person and reasonably appears to be destined for the personal use of that person, its release shall not be suspended pursuant to Article 14(3) except where the use of the product can endanger the health and life of persons, animals or plants.
2. A product shall be deemed to be destined for the personal use of a natural person bringing it into the Union if it is of an occasional nature and exclusively intended for use by that person or his family and does not by its nature or quantity indicate any commercial intent.

Article 18

Union assessment for products entering the Union and subject to Union harmonisation legislation

1. Within ~~60~~ **30** days of communication by the Commission to the Member States, pursuant to Article 20(4), of any refusal to release a product for free circulation by the original notifying Member State, a Member State may object to that refusal where it relates to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question. **[Am. 95]**
2. If no objection is raised by a Member State under paragraph 1 and the Commission does not consider that the national measures are contrary to Union legislation, the refusal by the original notifying Member State shall be deemed justified and each Member State shall ensure that restrictive measures are taken without delay in respect of the product concerned.
3. Where an objection is raised by a Member State under paragraph 1 or the Commission considers that the refusal may be contrary to Union legislation, the Commission shall without delay enter into consultation with **the notifying Member State and** the relevant economic operator or operators and shall, **within 30 days**, evaluate the ~~refusal~~ **national measures**, taking account of all available scientific or technical evidence. **[Am. 96]**
- 3a. If an objection is raised within 30 days pursuant to paragraph 1 by a Member State or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall inform all the Member States through the RAPEX contact points. [Am. 97]**
4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission may decide by means of implementing acts whether the refusal is justified and similar action should be taken by all Member States that have not already done so. In that case, it shall address the decision to the Member States concerned and immediately communicate it to all Member States and the relevant economic operator or operators.
5. If the Commission decides that the refusal is justified, each Member State shall take the necessary restrictive measures without delay. If it decides that the refusal is not justified, the original notifying Member State and any other Member State that has taken a similar measure shall withdraw it and the notification made under RAPEX pursuant to Article 20.
6. Where a refusal is considered justified and the product is found not to be in compliance with Union harmonisation legislation because of shortcomings in the relevant harmonised standards, the Commission shall inform the relevant European standardisation organisation and may make an appropriate request pursuant to Article 11 of Regulation (EU) No. 1025/2012.

Tuesday 15 April 2014

CHAPTER V

Exchange of information

Article 19

Union Rapid Information System — RAPEX

1. The Commission shall maintain the Union Rapid Information System (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a risk in accordance with this Regulation.
2. Each Member State shall designate a single contact point for RAPEX.
3. The Commission may, by means of implementing acts, lay down the modalities and procedures for the exchange of information through RAPEX. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).
4. Participation in RAPEX shall be open to applicant countries, third countries or international organisations within the framework of and in accordance with agreements between the Union and those countries or organisations. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Union **as well as special provisions on personal data protection, as required by Article 25 of Directive 95/46/EC and Article 9 of Regulation (EC) No 45/2001. [Am. 98]**

Article 20

Notification through RAPEX of products presenting a risk

1. The RAPEX contact point shall immediately notify to the Commission information on any of the following:
 - (a) any corrective action taken by economic operators pursuant to Article 9(3);
 - (b) any measure taken by market surveillance authorities pursuant to Article 10(1) or (4), unless it concerns a product subject to a notification pursuant to point (a) of this paragraph;
 - (c) any refusal to release a product for free circulation pursuant to Article 16.

~~The first subparagraph shall not apply where the RAPEX contact point has reason to believe that the effects of the risk presented by a product do not go beyond the territory of its Member State. [Am. 99]~~

The RAPEX contact point shall inform the Commission without delay of any relevant update, modification or withdrawal of the corrective action or measures referred to in the first subparagraph.

2. The information provided in accordance with paragraph 1 shall include all available details relating to the risk and at least the following information:
 - (a) ~~the nature and level of the risk, including a summary of the results of the risk assessment~~ **data necessary for product identification and traceability; [Am. 100]**
 - (b) ~~the nature of any non-compliance with Union harmonisation legislation~~ **and level of the risk and a summary of safety and risk assessment findings; [Am. 101]**
 - ~~(c) the data necessary to identify the product~~ **the nature of any infringement of Union legislation; [Am. 102]**
 - (d) the origin and the supply chain of the product;
 - (e) the date on which the measure or corrective action was taken and its duration;
 - (f) the nature of the measure or corrective action taken and whether voluntary, approved, required;
 - (fa) whether the product is known to be counterfeit; [Am. 103]**
 - (g) whether the economic operator has been given the opportunity to be heard.

Tuesday 15 April 2014

The information referred to in the first subparagraph shall be transmitted using the standard notification form made available by the Commission in RAPEX system.

3. Where a notification relates to a product found not to comply with Union harmonisation legislation, the information provided shall also indicate whether the non-compliance is due to any of the following:

- (a) the failure of the product to satisfy the requirements of the applicable legislation;
- (b) shortcomings in the harmonised standards referred to in that legislation which confer a presumption of conformity with those requirements.

Where a measure or corrective action referred to in paragraph 1 relates to a product that has undergone conformity assessment by a notified body, the market surveillance authorities shall ensure that the relevant notified body is informed of the corrective action or measures taken.

4. On receiving a notification, the Commission shall communicate it ~~to~~ **without delay to the relevant economic operator and** the other Member States. If the notification does not satisfy the requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it. [Am. 104]

5. The Member States shall immediately inform the Commission of the action or measures taken following receipt of a notification and shall provide any supplementary information, including the results of any tests or analyses carried out or possible differences in views. The Commission shall immediately transmit that information to other Member States.

5a. Information on a product contained in a notification in RAPEX shall be updated, where appropriate. [Am. 105]

Article 21

Information and communication system for market surveillance

1. The Commission shall maintain an information and communication system for market surveillance (ICSMS) for the collection and structured storage of information on issues relating to market surveillance. **Member States shall collect and enter into ICSMS** in particular the following information: [Am. 106]

- (a) market surveillance authorities and their areas of competence;
- (b) market surveillance programmes;
- (c) the monitoring, review and assessment of market surveillance activities;
- (d) complaints or reports about issues relating to risks arising from products;
- (da) the identification of risks and their characteristics;** [Am. 107]
- (e) any non-compliance with Union harmonisation legislation other than measures or corrective action notified under RAPEX in accordance with Article 20; [Am. 108]
- (f) any objection raised by a Member State in accordance with Article 11(1) or Article 18(1) and the follow-up.

The Commission shall provide an interface solution through which ICSMS can be connected to RAPEX for data interchange between those systems, where appropriate. [Am. 109]

ICSMS shall contain a record of references to the notifications of measures or corrective action made under RAPEX in accordance with Article 20.

ICSMS ~~may~~ **shall** also be made available, where necessary or appropriate, for use by the authorities in charge of controls at the external borders. [Am. 110]

2. For the purposes of paragraph 1 of this Article, Member States shall enter into ICSMS any information at their disposal and not already notified under Article 20 about products presenting a risk regarding, in particular, the identification of risks, results of testing carried out, restrictive measures taken, contacts with the economic operators concerned and justification for action or inaction.

Tuesday 15 April 2014

3. Market surveillance authorities shall recognise the validity and make use of test, **inspection or calibration** reports prepared by or for their counterparts in other Member States and entered into ICSMS. [Am. 111]

Article 21a

Pan-European Injuries Database

1. **The Commission shall adopt delegated acts, in accordance with Article 31a, establishing a Pan-European Injuries Database ('the Database') which would cover all types of injuries, and in particular those related to products used at home and for leisure, transportation and work activities by ... (*)**. The Database shall be coordinated and operated by the Commission.

2. **The relevant market surveillance authorities of the Member States shall contribute to the establishment of the Database and deliver comprehensive injury data. In consultation with the Member States, the Commission shall draw up and publish detailed guidance on the relevant data to be included in the Database, as well as the methods for electronic communication of the data.**

Not later than two years after the establishment of the Database, the Commission shall report to the European Parliament and to the Council on the functioning of the Database. [Am. 112]

Article 22

International exchange of confidential information

The Commission ~~and~~, **together with the** Member States, may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of **applicant countries**, third countries or international organisations with which the Commission and ~~the Member State or group of Member States~~ have concluded bilateral or multilateral confidentiality arrangements based on reciprocity. **Any such arrangements shall include provisions on confidentiality corresponding to those applicable in the Union as well as special provisions on personal data protection, as required by Article 25 of Directive 95/46/EC and Article 9 of Regulation (EC) No 45/2001.** [Am. 113]

CHAPTER VI

Cooperation

Article 23

Mutual assistance

1. There shall be efficient cooperation and exchange of information among the market surveillance authorities of the Member States, among the different authorities within ~~each~~ **and among the** Member ~~State~~ **States** and between market surveillance authorities and the Commission and the relevant Union agencies regarding market surveillance programmes and all issues relating to products presenting a risk. [Am. 114]

2. Market surveillance authorities shall, on receipt of a duly motivated request from a market surveillance authority in another Member State, provide any relevant information or documentation and carry out checks, inspections or investigations and report on them and on any follow-up action taken to the requesting authority.

The information, documentation and reporting referred to in the first subparagraph shall be used only in respect of the matter for which it was requested and shall be processed as quickly as possible, by electronic means.

Article 24

Cooperation with the competent authorities of third countries

1. Market surveillance authorities may cooperate with the competent authorities of third countries with a view to exchanging information and technical support, promoting and facilitating access to Union information exchange systems including RAPEX in accordance with Article 19(4), and promoting activities relating to conformity assessment and market surveillance.

(*) **Two years after the date of entry into force of this Regulation.**

Tuesday 15 April 2014

2. Cooperation with the competent authorities of third countries shall take the form of, inter alia, the types of activities referred to in Article 27. Member States shall ensure that their competent authorities participate in those activities.

2a. Where, in an exchange of information, personal data are exchanged, Directive 95/46/EC shall apply. [Am. 115]

Article 25

European Market Surveillance Forum

1. A European Market Surveillance Forum (EMSF) is established.
2. Each Member State shall be represented in meetings of the EMSF by a person or persons selected by the Member State having the particular knowledge and experience required in accordance with the subject matter of the meeting in question.
3. The EMSF shall meet at regular intervals and, where necessary, at the request of the Commission or a Member State.
4. The EMSF shall use its best endeavours to reach consensus. If consensus cannot be reached, the EMSF shall adopt its position by a simple majority of its members. Members may request that their positions and the grounds on which they are based are officially recorded.
5. The EMSF may invite experts and other third parties to attend meetings or provide written contributions **on a regular and continuous basis. Business organisations, SMEs, consumers, laboratories and conformity assessment bodies at Union level may be consulted on the annual market surveillance programme. [Am. 116]**
6. The EMSF may establish standing or temporary sub-groups which shall include the administrative cooperation groups for market surveillance set up for the implementation of Union harmonisation legislation. Organisations representing the interests of industry, ~~small and medium-sized enterprises~~ **SMEs**, consumers, laboratories and conformity assessment bodies at Union level ~~may~~ **shall** be invited to participate in such sub-groups as observers **on a regular and continuous basis. [Am. 117]**
7. The EMSF shall establish its rules of procedure which shall enter into force after receiving a favourable opinion from the Commission.
8. The EMSF shall cooperate with the Forum for Exchange of Information on Enforcement established by Regulation (EC) No 1907/2006.

Article 26

Commission support and EMSF executive secretariat

1. The Commission shall support cooperation between market surveillance authorities. It shall participate in the meetings of the EMSF and its sub-groups.
2. In order to perform the tasks set out in Article 27, the EMSF shall be assisted by an executive secretariat that provides technical and logistic support to the EMSF and its sub-groups.

Article 27

Tasks of the EMSF

The EMSF shall have the following tasks:

- (a) to facilitate the exchange of information on products presenting a risk, risk assessment, test methods and results, recent scientific developments and other aspects relevant to control activities;
- (b) to coordinate the preparation and implementation of the general and sector-specific market surveillance programmes referred to in Article 7;
- (c) to ~~organise~~ **facilitate the organisation of** joint market surveillance and joint testing projects; **[Am. 118]**
- (d) to exchange expertise and best practices;

Tuesday 15 April 2014

- (e) to ~~organise~~ **facilitate the organisation of** training programmes and exchanges of national officials; [Am. 119]
- (f) to assist in monitoring activities as referred to in Article 4(3);
- (g) to ~~organise~~ **facilitate the organisation of** information campaigns and joint visit programmes, **including controls at borders**; [Am. 120]
- (h) to improve cooperation at Union level with regard to the tracing, withdrawal and recall of products presenting a risk;
- (i) to ensure the easy access, retrieval and sharing of product safety information collected by market surveillance authorities, including information on complaints, accidents, injury reports and investigation and test results;
- (j) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation, taking due account of the interests of business, in particular ~~small and medium-sized enterprises~~ **SMEs, consumer protection**, and other stakeholders; [Am. 121]
- (k) to provide advice and assist the Commission, at its request, in its assessment of any issue relating to the implementation of this Regulation;
- (l) to contribute to uniform administrative practices with regard to market surveillance in the Member States;
- (la) to organise specific and regular market surveillance actions on products that are distributed on-line**; [Am. 122]
- (lb) to ensure adequate involvement of and cooperation with customs authorities**; [Am. 123]
- (lc) to contribute to a streamlining of administrative and enforcement practices with regard to market surveillance in the Member States**. [Am. 124]

Article 28

Union reference laboratories

1. For specific products or a category or group of products or for specific risks related to a category or group of products, the Commission may by means of implementing acts designate Union reference laboratories that satisfy the criteria set out in paragraph 2.
2. Each Union reference laboratory shall satisfy the following criteria:
 - (a) have suitably qualified staff with adequate training in the analytical techniques used in their area of competence and an adequate knowledge of standards and practices;
 - (b) possess the equipment and reference material needed to carry out the tasks assigned to them;
 - (c) act in the public interest in an impartial and independent manner;
 - (d) ensure that the staff respect the confidential nature of certain subjects, results or communications;
 - (da) be accredited pursuant to the provisions of Regulation (EC) No 765/2008**. [Am. 125]

Tuesday 15 April 2014

3. Within the area of their designation, Union reference laboratories shall where appropriate have the following tasks:
 - (a) carrying out product testing in relation to market surveillance activities and investigations;
 - (b) ~~contributing to the resolution of disputes between the~~ **settling any disputes arising out of a divergent risk assessment among the market surveillance** authorities of **different** Member States, ~~the~~ economic operators and ~~the~~ conformity assessment bodies; **[Am. 126]**
 - (c) providing independent technical or scientific advice to the Commission and the Member States;
 - (d) developing new techniques and methods of analysis;
 - (e) disseminating information and providing training.

CHAPTER VII

Financing

Article 29

Financing activities

1. The Union may finance the following activities in relation to the application of this Regulation:
 - (a) the drawing up and updating of contributions to guidelines on market surveillance;
 - (b) the making available to the Commission of technical or scientific expertise for the purpose of assisting the Commission in its implementation of market surveillance administrative cooperation and the Union assessment procedures referred to in Articles 11 and 18;
 - (c) the performance of preliminary or ancillary work in connection with the implementation of market surveillance activities linked to the application of Union legislation such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits, research work, the development and maintenance of databases, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work, and European market surveillance campaigns and similar activities;
 - (d) activities carried out under programmes of technical assistance, cooperation with third countries and the promotion and enhancement of European market surveillance policies and systems among interested parties at European and international levels;
 - (e) the functioning of cooperation among market surveillance authorities and the technical and logistic support by the EMSF executive secretariat and its sub-groups.
2. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012, either directly, or indirectly by entrusting budget implementation tasks to the entities listed in point (c) of Article 58(1) of Regulation (EU, Euratom) No 966/2012.
3. The appropriations allocated to activities referred to in paragraph 1 shall be determined each year by the European Parliament and the Council within the limits of the financial framework in force.
4. The appropriations determined by the European Parliament and the Council for the financing of market surveillance activities may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities which are required for the management of the activities pursuant to this Regulation and the achievement of their objectives; in particular, studies, meetings of experts, information and communication actions, including corporate communication of the political priorities of the Union as far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange, together with all other technical and administrative assistance expenses incurred by the Commission for the management of the activities pursuant to this Regulation.

Tuesday 15 April 2014

5. The Commission shall evaluate the relevance of the market surveillance activities that receive Union financing in the light of the requirements of Union policies and legislation and inform the European Parliament and the Council of the outcome of that evaluation by ... (*) and every five years thereafter.

Article 30

Protection of the financial interests of the Union

1. The Commission shall take appropriate measures to ensure that, where actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of amounts unduly paid and, where appropriate, by effective, proportionate and dissuasive penalties.

2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot checks, over all grant beneficiaries, contractors and subcontractors and other third parties who have received Union funds under this Regulation.

3. The European Anti-fraud Office (OLAF) may carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding in accordance with the procedures laid down in Council Regulation (Euratom, EC) No 2185/96 ⁽¹⁾ with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract concerning Union funding.

4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and international organisations and grant agreements and grant decisions and contracts resulting from the implementation of this Regulation shall expressly empower the Commission, the Court of Auditors and OLAF to conduct audits, on-the-spot checks and inspections.

CHAPTER VIII

Final provisions

Article 31

Penalties

1. The Member States shall lay down the rules ~~on establishing appropriate~~ **establishing appropriate** penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators and to infringements of provisions of any Union harmonisation legislation on products covered by this Regulation that impose obligations on economic operators where that legislation does not provide for penalties, and shall take all measures necessary to ensure that they are implemented. ~~The penalties provided for must be effective, proportionate and dissuasive.~~ Member States shall notify those provisions to the Commission by ~~insert date — 3 months prior to the date of application of this Regulation~~ ... (**) and shall notify it without delay of any subsequent amendment affecting them. [Am. 127]

~~The penalties provided for shall be effective, proportionate and dissuasive.~~ The penalties referred to in the first subparagraph shall have regard to the size of the undertakings and in particular to the situation of small and medium-sized enterprises: **seriousness, the duration and, where applicable, the intentional character of the infringement. In addition,** the penalties ~~may be increased if~~ **shall take into account whether** the relevant economic operator has previously committed a similar infringement ~~and may include criminal sanctions for serious infringements.~~ [Am. 128]

1a. Administrative penalties applicable to infringements shall at least offset the economic advantage sought through the infringement, but shall not exceed 10 % of the annual turnover or an estimate thereof. The penalties imposed may be higher than 10 % of the annual turnover or an estimate thereof, where it is necessary to offset the economic advantage sought through the infringement. The penalties may include criminal sanctions for serious infringements. [Am. 129]

(*) Five years following the date of application of this Regulation.

(¹) Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 14.11.1996, p. 2).

(**) **Three months prior to the date of application of this Regulation.**

Tuesday 15 April 2014

1b. *The Member States shall inform the Commission of the type and the size of the penalties imposed under this Regulation, identify the actual infringements of this Regulation, and indicate the identity of economic operators upon which penalties have been imposed. The Commission shall make that information available to the public without undue delay electronically and, where appropriate, by other means. [Am. 130]*

The Commission shall, on the basis of the information received under the first subparagraph, publish and update a Union-wide blacklist of economic operators who are repeatedly found to intentionally infringe this Regulation. [Am. 131]

Article 31a

Exercise of the delegation

- 1.** *The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.*
- 2.** *The power to adopt delegated acts referred to in Article 21a shall be conferred on the Commission for an indeterminate period of time from ... (*).*
- 3.** *The delegation of power referred to in Article 21a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.*
- 4.** *As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.*
- 5.** *A delegated act adopted pursuant to Article 21a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or of the Council. [Am. 132]*

Article 32

Committee procedure

- 1.** The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2.** Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
- 3.** Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 33

Evaluation

No later than ... (**) the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and to the Council. That report shall assess whether this Regulation has achieved its objectives, in particular with regard to ensuring more effective and efficient enforcement of product safety rules and Union harmonisation legislation, improving cooperation between market surveillance authorities, strengthening the controls of products entering the Union and better protecting the health and safety of persons in general, health and safety in the workplace, consumer protection, the protection of environment, **energy efficiency**, public security and other public interests, taking into account its impact on business and in particular on ~~small and medium-sized enterprises~~ **SMEs**. **In addition, that report shall explore new and innovative, market-based solutions that could effectively complement the market surveillance actions carried out by the market surveillance authorities, and shall include, but not be limited to, exploring the potential of compulsory third party auditing schemes.** [Am. 133]

(*) **The date of entry into force of this Regulation.**

(**) Five years after the date of application of this Regulation.

Tuesday 15 April 2014

Article 34
Amendments

1. The following provisions are deleted:

- (a) Article 7 of Council Directive 89/686/EEC;
- (b) Article 7(2) and (3) and Article 8 of Directive 93/15/EEC;
- (c) Article 7 of Directive 94/9/EC;
- (d) Article 7, Article 10(4) and Article 11 of Directive 94/25/EC;
- (e) Articles 7 and 11 of Directive 95/16/EC;
- (f) Articles 8, 16 and 18 of Directive 97/23/EC;
- (g) Article 9 of Directive 1999/5/EC;
- (h) Articles 14, 15 and 19 of Directive 2000/9/EC;
- (i) Article 5 of Directive 2000/14/EC;
- (j) Article 6(2) and (3) and Articles 8, 9, 10, 11, 12 and 13 of, and Annex II to, Directive 2001/95/EC;
- (k) Articles 10 and 11 of Directive 2004/108/EC;
- (l) Article 4(3) and (4) and Articles 11, 17 and 20 of Directive 2006/42/EC;
- (m) Article 9 of Directive 2006/95/EC;
- (n) Article 14(5) and (6) and Articles 15, 16 and 17 of Directive 2007/23/EC;
- (o) Article 13(5) and Article 14 of Directive 2008/57/EC;
- (p) Articles 39, 40, 42 to 45 of Directive 2009/48/EC;
- (q) Articles 7, 15 and 17 of Directive 2009/105/EC;
- (r) Articles 7, 11 and 12 of Directive 2009/142/EC;
- (s) Article 18 of Directive 2011/65/EU;
- (t) Articles 56 to 59 of Regulation (EU) No 305/2011.

2. Point (a) of Article 3(2) of Regulation (EC) No 764/2008 is replaced by the following:

‘(a) Article 10 of Regulation (EU) No .../... of the European Parliament and of the Council of ... (*)’.

(*) Regulation (EU) No .../... of the European Parliament and of the Council of ... on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EC) No 764/2008, Regulation (EC) No 765/2008 and Regulation (EU) No 305/2011 of the European Parliament and of the Council (OJ L ...) (+).’;

3. Regulation (EC) No 765/2008 is amended as follows:

(a) The title is replaced by the following:

‘Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 laying down the requirements for accreditation of conformity assessment bodies and general principles of CE marking and repealing Regulation (EEC) No 339/93’;

(+) Number, date of adoption and publication reference of this Regulation.

Tuesday 15 April 2014

(b) Article 1(2) and (3), points 14, 15, 17, 18 and 19 of Article 2, Chapter III and point (e) of Article 32(1) are deleted.

References to the provisions of Articles 15 to 29 of Regulation (EC) No 765/2008 shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in the Annex to this Regulation.

Article 35

Transitional provisions

Procedures initiated at national or Union level pursuant to any of the provisions referred to in Article 34 of this Regulation or to Articles 6 to 9 of Directive 2001/95/EC shall continue to be governed by those provisions.

Article 36

Entry into force

This Regulation shall enter into force on ... (*)

It shall apply from 1 January 2015.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

The President

For the Council

The President

(*) Date of entry into force of Regulation (2013/0049(COD)).

Tuesday 15 April 2014

ANNEX

Correlation table

Regulation (EC) No 765/2008	This Regulation
Article 15(1), (2) and (5)	Article 2
Article 15(3)	—
Article 15(4)	Article 3(1)
Article 16(1)	Article 4(1)
Article 16(2)	Article 4(2) read in conjunction with Article 3(12); Article 17 (1) and Article 26(5)
Article 16(3)	—
Article 16(4)	—
Article 17(1)	Article 5(4)
Article 17(2)	Article 26(1)
Article 18(1)	Article 5(3)
Article 18(2)	Article 6(6)
Article 18(3)	Article 5(2)
Article 18(4)	Article 6(4)
Article 18(5) and (6)	Article 4(3), Article 6(7)(8) and (9) and Article 26(2)
First subparagraph of Article 19(1)	Article 6(1)
Second subparagraph of Article 19(1)	Article 6(5) and Article 7
Third subparagraph of Article 19(1)	Second subparagraph of Article 8(1)
Article 19(2)	Article 6(2)
Article 19(3)	Point (a) of Article 9(5)
Article 19(4)	Article 6(3)
Article 19(5)	Article 26(5) and Article 27
Article 20(1)	Articles 9(4) and point (b) of 18(1)

Tuesday 15 April 2014

Regulation (EC) No 765/2008	This Regulation
Article 20(2)	Article 12
Article 21	Article 6(4) and Article 9
Article 22(1), (2) and (3)	Article 18(1) and (2)
Article 22(4)	Article 17
Article 23(1) and (2)	Article 19
Article 23(3)	Article 27
Article 24(1) and (2)	Article 20
Article 24(3)	Article 19(1)
Article 24(4)	Article 18(2) and Article 19(2)
Article 25	Articles 22 to 24
Article 26	Article 21
Article 27	Article 13
Article 28	Article 14
Article 29	Article 15

Tuesday 15 April 2014

P7_TA(2014)0385

Markets in financial instruments and amendment of the EMIR Regulation on OTC derivatives, central counterparties and trade repositories *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on markets in financial instruments and amending Regulation [EMIR] on OTC derivatives, central counterparties and trade repositories (COM(2011)0652 — C7-0359/2011 — 2011/0296(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/64)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0652),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0359/2011),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Central Bank of 22 March 2012 ⁽¹⁾,
 - having regard to the opinion of the European Economic and Social Committee of 22 February 2012 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 19 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Development and the Committee on Industry, Research and Energy (A7-0303/2012),
1. Adopts its position at first reading hereinafter set out ⁽³⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2011)0296**Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on markets in financial instruments and amending Regulation (EU) No 648/2012***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 600/2014.)*⁽¹⁾ OJ C 161, 7.6.2012, p. 3.⁽²⁾ OJ C 143, 22.5.2012, p. 74.⁽³⁾ This position replaces the amendments adopted on 26 October 2012 (Texts adopted P7_TA(2012)0407).

Tuesday 15 April 2014

P7_TA(2014)0386

Markets in financial instruments and repeal of Directive 2004/39/EC ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on markets in financial instruments repealing Directive 2004/39/EC of the European Parliament and of the Council (recast) (COM(2011)0656 — C7-0382/2011 — 2011/0298(COD))

(Ordinary legislative procedure — recast)

(2017/C 443/65)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0656),
 - having regard to Article 294(2) and Article 53(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0382/2011),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Central Bank of 22 March 2012 ⁽¹⁾,
 - having regard to the opinion of the European Economic and Social Committee of 25 April 2012 ⁽²⁾,
 - having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts ⁽³⁾,
 - having regard to the letter of 1 March 2012 from the Committee on Legal Affairs to the Committee on Economic and Monetary Affairs in accordance with Rule 87(3) of its Rules of Procedure,
 - having regard to the undertaking given by the Council representative by letter of 19 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 87 and 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Development and the Committee on Industry, Research and Energy (A7-0306/2012),
- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the proposal in question does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;
1. Adopts its position at first reading hereinafter set out ⁽⁴⁾, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 161, 7.6.2012, p. 3.

⁽²⁾ OJ C 191, 29.6.2012, p. 80.

⁽³⁾ OJ C 77, 28.3.2002, p. 1.

⁽⁴⁾ This position replaces the amendments adopted on 26 October 2012 (Texts adopted P7_TA(2012)0406).

Tuesday 15 April 2014

P7_TC1-COD(2011)0298

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (recast)

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/65/EU.)

Tuesday 15 April 2014

P7_TA(2014)0387

Statistics in trade ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 638/2004 on Community statistics relating to trading of goods between Member States as regards conferring of delegated and implementing powers upon the Commission for the adoption of certain measures, the communication of information by the customs administration, the exchange of confidential data between Member States and the definition of statistical value (COM(2013)0578 — C7-0242/2013 — 2013/0278(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/66)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0578),
 - having regard to Article 294(2) and Article 338(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0242/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the undertakings given by the Council representative by letter of 19 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs (A7-0457/2013),
1. Adopts its position at first reading hereinafter set out ⁽¹⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0278

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EC) No 638/2004 on Community statistics relating to trading of goods between Member States as regards conferring delegated and implementing powers on the Commission for the adoption of certain measures, the communication of information by the customs administration, the exchange of confidential data between Member States and the definition of statistical value

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 659/2014.)

⁽¹⁾ This position replaces the amendments adopted on 15 January 2014 (Texts adopted P7_TA(2014)0030).

Tuesday 15 April 2014

P7_TA(2014)0388

Securities settlement and central securities depositories *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on improving securities settlement in the European Union and on central securities depositories (CSDs) and amending Directive 98/26/EC (COM(2012)0073 — C7-0071/2012 — 2012/0029(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/67)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0073),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0071/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Central Bank of 1 August 2012 ⁽¹⁾,
 - having regard to the opinion of the European Economic and Social Committee of 11 July 2012 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 26 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinion of the Committee on Legal Affairs (A7-0039/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0029**Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 909/2014.)*⁽¹⁾ OJ C 310, 13.10.2012, p. 12.⁽²⁾ OJ C 299, 4.10.2012, p. 76.

Tuesday 15 April 2014

P7_TA(2014)0389

Marine equipment *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on marine equipment and repealing Directive 96/98/EC (COM(2012)0772 — C7-0414/2012 — 2012/0358(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/68)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0772),
 - having regard to Article 294(2) and Article 100(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0414/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 20 March 2013 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 19 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism (A7-0255/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0358

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on marine equipment and repealing Council Directive 96/98/EC

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/90/EU.)

⁽¹⁾ OJ C 161, 6.6.2013, p. 93.

Tuesday 15 April 2014

P7_TA(2014)0390

Pressure equipment *I****European Parliament legislative resolution of 15 April 2014 on the proposal for a directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to making available on the market of pressure equipment (recast) (COM(2013)0471 — C7-0203/2013 — 2013/0221(COD))****(Ordinary legislative procedure — recast)**

(2017/C 443/69)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0471),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0203/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 16 October 2013 ⁽¹⁾,
 - having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts ⁽²⁾,
 - having regard to the letter of 16 December 2013 from the Committee on Legal Affairs to the Committee on the Internal Market and Consumer Protection in accordance with Rule 87(3) of its Rules of Procedure,
 - having regard to the undertaking given by the Council representative by letter of 12 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 87 and 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection (A7-0008/2014),
- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the proposal in question does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;
1. Adopts its position at first reading hereinafter set out, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;
 2. Approves its statement annexed hereto, which will be published in the L series of the *Official Journal of the European Union* together with the final legislative act;
 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 67, 6.3.2014, p. 101.

⁽²⁾ OJ C 77, 28.3.2002, p. 1.

Tuesday 15 April 2014

P7_TC1-COD(2013)0221

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast)

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/68/EU.)

Tuesday 15 April 2014**ANNEX TO THE LEGISLATIVE RESOLUTION**

STATEMENT OF THE EUROPEAN PARLIAMENT

The European Parliament considers that only when and insofar as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

Tuesday 15 April 2014

P7_TA(2014)0391

Judgments in civil and commercial matters *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (COM(2013)0554 — C7-0239/2013 — 2013/0268(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/70)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0554),
 - having regard to Articles 294(2) and 67(4) and points (a), (c) and (e) of Article 81(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0239/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 26 February 2014 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 5 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Legal Affairs (A7-0052/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0268

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EU) No 1215/2012 as regards the rules to be applied with respect to the Unified Patent Court and the Benelux Court of Justice

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 542/2014.)

⁽¹⁾ Not yet published in the Official Journal.

Tuesday 15 April 2014

P7_TA(2014)0392

Labour force sample survey *I**

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 577/98 on the organisation of a labour force sample survey in the Community (COM(2013)0155 — C7-0086/2013 — 2013/0084(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/71)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0155),
 - having regard to Article 294(2) and Article 338(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0086/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the undertaking given by the Council representative by letter of 7 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Employment and Social Affairs and to the opinion of the Committee on Budgets (A7-0344/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0084

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 577/98 on the organisation of a labour force sample survey in the Community

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 545/2014.)

Tuesday 15 April 2014

P7_TA(2014)0393

European Maritime Safety Agency and response to pollution ***I

European Parliament legislative resolution of 15 April 2014 on the proposal for a regulation of the European Parliament and of the Council on multiannual funding for the action of the European Maritime Safety Agency in the field of response to pollution caused by ships and to marine pollution caused by oil and gas installations (COM(2013)0174 — C7-0089/2013 — 2013/0092(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/72)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0174),
 - having regard to Article 294(2) and Article 100(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0089/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 10 July 2013 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 7 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism and the opinion of the Committee on Budgets (A7-0300/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Emphasises that any decision of the legislative authority in favour of such multiannual funding for the European Maritime Safety Agency shall be without prejudice to the decisions of the budgetary authority in the context of the annual budgetary procedure;
 3. Requests the Commission to present a financial statement which fully takes into account the result of the legislative agreement between the European Parliament and the Council to meet the budgetary and staff requirements of European Maritime Safety Agency and possibly of the Commission services;
 4. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 327, 12.11.2013, p. 108.

Tuesday 15 April 2014

P7_TC1-COD(2013)0092

Position of the European Parliament adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on multiannual funding for the action of the European Maritime Safety Agency in the field of response to marine pollution caused by ships and oil and gas installations

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 911/2014.)

Wednesday 16 April 2014

P7_TA(2014)0397

Protection of species of wild fauna and flora ***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on the protection of species of wild fauna and flora by regulating trade therein (recast) (COM(2012)0403 — C7-0197/2012 — 2012/0196(COD))

(Ordinary legislative procedure — recast)

(2017/C 443/73)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0403),
 - having regard to Article 294(2) and Article 192(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0197/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 14 November 2012 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts ⁽²⁾,
 - having regard to the letter of 11 November 2013 from the Committee on Legal Affairs to the Committee on the Environment, Public Health and Food Safety in accordance with Rule 87(3) of its Rules of Procedure,
 - having regard to Rules 87 and 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0087/2014),
- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;
1. Adopts its position at first reading hereinafter set out, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 11, 15.1.2013, p. 85.

⁽²⁾ OJ C 77, 28.3.2002, p. 1.

Wednesday 16 April 2014

P7_TC1-COD(2012)0196**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the protection of species of wild fauna and flora by regulating trade therein (recast)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein ⁽³⁾ has been substantially amended several times ⁽⁴⁾. Since further amendments are to be made, that regulation should be recast in the interests of clarity.
- (2) The purpose of this Regulation is to ensure the protection of species of wild fauna and flora which are threatened by trade or likely to be so threatened.
- (3) The provisions of this Regulation do not prejudice any stricter measures which may be taken or maintained by Member States, in compliance with the Treaty, in particular with regard to the holding of specimens of species covered by this Regulation.
- (4) It is necessary to lay down objective criteria for the inclusion of species of wild fauna and flora in the Annexes to this Regulation.
- (5) The implementation of this Regulation necessitates the application of common conditions for the issue, use and presentation of documents relating to the authorisation of the introduction into the Union and the export or re-export from the Union of specimens of the species covered by this Regulation. It is necessary to lay down specific provisions relating to the transit of specimens through the Union.
- (6) It is for a management authority of the Member State of destination, assisted by the scientific authority of that Member State and, where appropriate, taking into account any opinion of the Scientific Review Group, to decide on the requests for introduction of specimens into the Union.
- (7) It is necessary to provide for a consultation procedure in the framework of the provisions on re-export, in order to limit the risk of infringement.
- (8) In order to guarantee effective protection of species of wild fauna and flora, additional restrictions may be imposed on the introduction of specimens into, and the export thereof from, the Union. With regard to live specimens, these restrictions may be supplemented by restrictions at Union level on the holding or movement of such specimens within the Union.
- (9) It is necessary to lay down specific provisions applicable to captive-born and bred, or artificially propagated specimens, to specimens which are personal or household effects, and to non-commercial loans, donations or exchanges between registered scientists and scientific institutions.

⁽¹⁾ OJ C 11, 15.1.2013, p. 85.

⁽²⁾ Position of the European Parliament of 16 April 2014.

⁽³⁾ OJ L 61, 3.3.1997, p. 1.

⁽⁴⁾ See Annex II.

Wednesday 16 April 2014

- (10) There is a need, in order to ensure the broadest possible protection for species covered by this Regulation, to lay down provisions for controlling trade and movement of specimens within the Union, and the conditions for housing specimens. The certificates issued under this Regulation, which contribute to controlling those activities, should be governed by common rules on their issue, validity and use.
- (11) Measures should be taken to minimise the adverse effects on live specimens of transport to their destination, from or within the Union.
- (12) To ensure effective controls and to facilitate customs procedures, customs offices should be designated, with trained personnel responsible for carrying out the necessary formalities and corresponding checks where specimens are introduced into the Union, in order to assign them a customs-approved treatment or use within the meaning of Council Regulation (EEC) No 2913/92 ⁽¹⁾, or where they are exported or re-exported from the Union. There should also be facilities guaranteeing that live specimens are adequately housed and cared for.
- (13) The implementation of this Regulation also calls for the designation of management and scientific authorities by the Member States.
- (14) Informing the public and making them aware of the provisions of this Regulation, particularly at border crossing points, is likely to encourage compliance with these provisions.
- (15) In order to ensure effective enforcement of this Regulation, Member States should closely monitor compliance with its provisions and, to that end, cooperate closely between themselves and with the Commission. This requires the communication of information relating to the implementation of this Regulation.
- (16) The monitoring of levels of trade in the species of wild fauna and flora covered by this Regulation is of crucial importance for assessing the effects of trade on the conservation status of species. Detailed annual reports should be drawn up in a common format.
- (17) In order to guarantee compliance with this Regulation, it is important that Member States impose sanctions for infringements in a manner which is both sufficient and appropriate to the nature and gravity of the infringement.
- (18) The multitude of biological and ecological aspects to be considered in the implementation of this Regulation requires the setting up of a Scientific Review Group, whose opinions will be forwarded by the Commission to the Committee and the management bodies of the Member States, to assist them in making their decisions.
- (19) In order to supplement or amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the adoption of certain measures regulating trade in species of wild fauna and flora, of certain amendments to the Annexes to this Regulation and of additional measures to implement resolutions of the Conference of the Parties to the Convention on international trade in endangered species of wild fauna and flora (CITES) (hereinafter referred to as 'the Convention'), decisions or recommendations of the Standing Committee of the Convention and recommendations of the Convention Secretariat. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (20) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission, **in particular for the establishment of the design, the model and the format of certain documents**. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ⁽²⁾, [Am. 1]

⁽¹⁾ Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

⁽²⁾ **Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers** (OJ L 55, 28.2.2011, p. 13).

Wednesday 16 April 2014

HAVE ADOPTED THIS REGULATION:

Article 1

Object

The object of this Regulation is to protect species of wild fauna and flora and to guarantee their conservation by regulating trade therein in accordance with Articles 2 to 22 and Annexes A to D as set out in Annex I, hereinafter referred to as 'Annex A', 'Annex B', 'Annex C' and 'Annex D'.

This Regulation shall apply in compliance with the objectives, principles and provisions of the Convention defined in Article 2(b).

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'Committee' means the Committee referred to in Article 21(1);
- (b) 'Convention' means the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES);
- (c) 'country of origin' means the country in which a specimen was taken from the wild, captive-bred or artificially propagated;
- (d) 'import notification' means the notification given by the importer or his agent or representative, at the time of the introduction into the Union of a specimen of a species included in Annexes C or D, on the form provided for in Article ~~19(2)~~ **10(1d)**; [**Am. 2**]
- (e) 'introduction from the sea' means the introduction into the Union of any specimen which was taken in, and is being introduced directly from, the marine environment not under the jurisdiction of any State, including the air-space above the sea and the sea-bed and subsoil beneath the sea;
- (f) 'issuance' means the completion of all procedures involved in preparing and validating a permit or certificate and its delivery to the applicant;
- (g) 'management authority' means a national administrative authority designated, in the case of a Member State, in accordance with Article 13(1) or, in the case of a third country party to the Convention, in accordance with Article IX of the Convention;
- (h) 'Member State of destination' means the Member State of destination mentioned in the document used to export or re-export a specimen; in the event of introduction from the sea, it shall mean the Member State within whose jurisdiction the place of destination of a specimen lies;
- (i) 'offering for sale' means offering for sale and any action that may reasonably be construed as such, including advertising or causing to be advertised for sale and invitation to treat;
- (j) 'personal or household effects' means dead specimens, parts and derivatives thereof, that are the belongings of a private individual and that form, or are intended to form, part of his normal goods and chattels;
- (k) 'place of destination' means the place at which at the time of introduction into the Union, it is intended that specimens will normally be kept; in the case of live specimens, this shall be the first place where specimens are intended to be kept following any period of quarantine or other confinement for the purposes of sanitary checks and controls;
- (l) 'population' means a biologically or geographically distinct total number of individuals;
- (m) 'primarily commercial purposes' means all purposes the non-commercial aspects of which do not clearly predominate;
- (n) 're-export from the Union' means export from the Union of any specimen that has previously been introduced;

Wednesday 16 April 2014

- (o) 're-introduction into the Union' means introduction into the Union of any specimen that has previously been exported or re-exported;
- (p) 'sale' means any form of sale. For the purposes of this Regulation, hire, barter or exchange shall be regarded as sale; cognate expressions shall be similarly construed;
- (q) 'scientific authority' means a scientific authority designated, in the case of a Member State, in accordance with Article 13(2) or, in the case of a third country party to the Convention, in accordance with Article IX of the Convention;
- (r) 'Scientific Review Group' means the consultative body established under Article 17;
- (s) 'species' means a species, subspecies or population thereof;
- (t) 'specimen' means any animal or plant, whether alive or dead, of the species listed in Annexes A to D, any part or derivative thereof, whether or not contained in other goods, as well as any other goods which appear from an accompanying document, the packaging or a mark or label, or from any other circumstances, to be or to contain parts or derivatives of animals or plants of those species, unless such parts or derivatives are specifically exempted from the provisions of this Regulation or from the provisions relating to the Annex in which the species concerned is listed by means of an indication to that effect in the Annexes concerned.

A specimen shall be considered to be a specimen of a species listed in Annexes A to D if it is, or is part of or derived from, an animal or plant at least one of whose 'parents' is of a species so listed. In cases where the 'parents' of such an animal or plant are of species listed in different Annexes, or of species only one of which is listed, the provisions of the more restrictive Annex shall apply. However, in the case of specimens of hybrid plants, if one of the 'parents' is of a species listed in Annex A, the provisions of the more restrictive Annex shall apply only if that species is annotated to that effect in the Annex;

- (u) 'trade' means the introduction into the Union, including introduction from the sea, and the export and re-export from the Union, as well as the use, movement and transfer of possession within the Union, including within a Member State, of specimens subject to the provisions of this Regulation;
- (v) 'transit' means the transport of specimens between two points outside the Union through the territory of the Union which are shipped to a named consignee and during which any interruption in the movement arises only from the arrangements necessitated by this form of traffic;
- (w) 'worked specimens that were acquired more than 50 years previously' means specimens that were significantly altered from their natural raw state for jewellery, adornment, art, utility, or musical instruments, before 3 March 1947 and that have been, to the satisfaction of the management authority of the Member State concerned, acquired in such conditions. Such specimens shall be considered as worked only if they are clearly in one of the aforementioned categories and require no further carving, crafting or manufacture to effect their purpose;
- (x) 'checks at the time of introduction, export, re-export and transit' means documentary checks on the certificates, permits and notifications provided for in this Regulation and, in cases where Union provisions so provide or in other cases by representative sampling of the consignments, examination of the specimens, where appropriate accompanied by the taking of samples with a view to analysis or more detailed checks.

Article 3**Scope****1. Annex A shall contain:**

- (a) the species listed in Appendix I to the Convention for which the Member States have not entered a reservation;
- (b) any species:
 - (i) which is, or may be, in demand for utilisation in the Union or for international trade and which is either threatened with extinction or so rare that any level of trade would imperil the survival of the species,

or

Wednesday 16 April 2014

- (ii) which is in a genus of which most of the species or which is a species of which most of the subspecies are listed in Annex A in accordance with the criteria in point (a) or (b)(i) and whose listing in that Annex is essential for the effective protection of those taxa.
2. Annex B shall contain:
- (a) the species listed in Appendix II to the Convention, other than those listed in Annex A, for which the Member States have not entered a reservation;
- (b) the species listed in Appendix I to the Convention for which a reservation has been entered;
- (c) any other species not listed in Appendices I or II to the Convention:
- (i) which is subject to levels of international trade that might not be compatible:
- with its survival or with the survival of populations in certain countries, or
 - with the maintenance of the total population at a level consistent with the role of the species in the ecosystems in which it occurs;
- or
- (ii) whose listing in the Annex for reasons of similarity in appearance to other species listed in Annex A or B, is essential in order to ensure the effectiveness of controls on trade in specimens of such species;
- (d) species in relation to which it has been established that the introduction of live specimens into the natural habitat of the Union would constitute an ecological threat to wild species of fauna and flora indigenous to the Union.
3. Annex C shall contain:
- (a) the species listed in Appendix III to the Convention, other than those listed in Annex A or B, for which the Member States have not entered a reservation;
- (b) the species listed in Appendix II to the Convention for which a reservation has been entered.
4. Annex D shall contain:
- (a) species not listed in Annexes A, B and C which are imported into the Union in such numbers as to warrant monitoring;
- (b) the species listed in Appendix III to the Convention for which a reservation has been entered.
5. Where the conservation status of species covered by this Regulation warrants their inclusion in one of the Appendices to the Convention, the Member States shall contribute to the necessary amendments.

Article 4

Introduction into the Union

1. The introduction into the Union of specimens of the species listed in Annex A shall be subject to completion of the necessary checks and the prior presentation, at the border customs office at the point of introduction, of an import permit issued by a management authority of the Member State of destination.

The import permit may be issued only in accordance with the restrictions established pursuant to paragraph 6 and when the following conditions have been met:

- (a) the competent scientific authority, after considering any opinion of the Scientific Review Group, has advised that the introduction into the Union:
- (i) would not have a harmful effect on the conservation status of the species or on the extent of the territory occupied by the relevant population of the species,

Wednesday 16 April 2014

(ii) is taking place:

- for one of the purposes referred to in Article 8(3)(e), (f) and (g), or
- for other purposes which are not detrimental to the survival of the species concerned;

- (b) (i) the applicant provides documentary evidence that the specimens have been obtained in accordance with the legislation on the protection of the species concerned which, in the case of import from a third country of specimens of a species listed in the Appendices to the Convention, shall be an export permit or re-export certificate, or copy thereof, issued in accordance with the Convention by a competent authority of the country of export or re-export,
- (ii) however, the issuance of import permits for species listed in Annex A in accordance with Article 3(1)(a) shall not require such documentary evidence, but the original of any such import permit shall be withheld from the applicant pending presentation of the export permit or re-export certificate;
- (c) the competent scientific authority is satisfied that the intended accommodation for a live specimen at the place of destination is adequately equipped to conserve and care for it properly;
- (d) the management authority is satisfied that the specimen is not to be used for primarily commercial purposes;
- (e) the management authority is satisfied, following consultation with the competent scientific authority, that there are no other factors relating to the conservation of the species which militate against issuance of the import permit; and
- (f) in the case of introduction from the sea, the management authority is satisfied that any live specimen will be so prepared and shipped as to minimise the risk of injury, damage to health or cruel treatment.

2. The introduction into the Union of specimens of the species listed in Annex B shall be subject to completion of the necessary checks and the prior presentation, at the border customs office at the point of introduction, of an import permit issued by a management authority of the Member State of destination.

The import permit may be issued only in accordance with the restrictions established pursuant to paragraph 6 and when:

- (a) the competent scientific authority, after examining available data and considering any opinion of the Scientific Review Group, is of the opinion that the introduction into the Union would not have a harmful effect on the conservation status of the species or on the extent of the territory occupied by the relevant population of the species, taking account of the current or anticipated level of trade. This opinion shall be valid for subsequent imports as long as the abovementioned aspects have not changed significantly;
- (b) the applicant provides documentary evidence that the intended accommodation for a live specimen at the place of destination is adequately equipped to conserve and care for it properly;
- (c) the conditions referred to in paragraph 1(b)(i), (e) and (f) have been met.

3. The introduction into the Union of specimens of the species listed in Annex C shall be subject to completion of the necessary checks and the prior presentation, at the border customs office at the point of introduction, of an import notification and:

- (a) in the case of export from a country mentioned in relation to the species concerned in Annex C, the applicant shall provide documentary evidence, by means of an export permit issued in accordance with the Convention by an authority of that country competent for the purpose, that the specimens have been obtained in accordance with the national legislation on the conservation of the species concerned; or
- (b) in the case of export from a country not mentioned in relation to the species concerned in Annex C or re-export from any country, the applicant shall present an export permit, a re-export certificate or a certificate of origin issued in accordance with the Convention by an authority of the exporting or re-exporting country competent for the purpose.

Wednesday 16 April 2014

4. The introduction into the Union of specimens of the species listed in Annex D shall be subject to completion of the necessary checks and the prior presentation of an import notification at the border customs office at the point of introduction.

5. The conditions for the issuance of an import permit as referred to in paragraph 1(a) and (d) and in paragraph 2(a), (b) and (c) shall not apply to specimens for which the applicant provides documentary evidence:

(a) that they had previously been legally introduced into or acquired in the Union and that they are, modified or not, being reintroduced into the Union; or

(b) that they are worked specimens that were acquired more than 50 years previously.

6. ~~In consultation with~~ **The Commission shall be empowered, after consulting** the countries of origin concerned and taking account of any opinion of the Scientific Review Group, ~~the Commission may, by means of implementing acts, establish~~ **to adopt delegated acts in accordance with Article 20 establishing** general restrictions, or restrictions relating to certain countries of origin, on the introduction into the Union: **[Am. 3]**

(a) on the basis of the conditions referred to in paragraph 1(a)(i) or (e), of specimens of species listed in Annex A;

(b) on the basis of the conditions referred to in paragraph 1(e) or paragraph 2(a), of specimens of species listed in Annex B; and

(c) of live specimens of species listed in Annex B which have a high mortality rate during shipment or for which it has been established that they are unlikely to survive in captivity for a considerable proportion of their potential life span; or

(d) of live specimens of species for which it has been established that their introduction into the natural environment of the Union presents an ecological threat to wild species of fauna and flora indigenous to the Union.

~~The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 21(2).~~ **[Am. 4]**

The Commission shall on a quarterly basis publish a list of restrictions established in accordance with the first subparagraph, if any, in the *Official Journal of the European Union*.

7. Where special cases of transshipment, air transfer or rail transport occur following the introduction into the Union, the Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning the granting of derogations from the completion of the checks and the presentation of import documents at the border customs office at the point of introduction which are referred to in paragraphs 1 to 4 of this Article, in order to permit such checks and the presentation to be carried out at another customs office designated in accordance with Article 12(1).

Article 5

Export or re-export from the Union

1. The export or re-export from the Union of specimens of the species listed in Annex A shall be subject to completion of the necessary checks and the prior presentation, at the customs office at which the export formalities are completed, of an export permit or re-export certificate issued by a management authority of the Member State in which the specimens are located.

2. An export permit for specimens of the species listed in Annex A may be issued only when the following conditions have been met:

(a) the competent scientific authority has advised in writing that the capture or collection of the specimens in the wild or their export will not have a harmful effect on the conservation status of the species or on the extent of the territory occupied by the relevant population of the species;

(b) the applicant provides documentary evidence that the specimens have been obtained in accordance with the legislation in force on the protection of the species in question; where the application is made to a Member State other than the Member State of origin, such documentary evidence shall be furnished by means of a certificate stating that the specimen was taken from the wild in accordance with the legislation in force on its territory;

Wednesday 16 April 2014

(c) the management authority is satisfied that:

- (i) any live specimen will be so prepared and shipped as to minimise the risk of injury, damage to health or cruel treatment, and
- (ii) — the specimens of species not listed in Appendix I to the Convention will not be used for primarily commercial purposes, or
 - in the case of export to a State party to the Convention of specimens of the species referred to in Article 3(1)(a) of this Regulation, an import permit has been issued;

and

(d) the management authority of the Member State is satisfied, following consultation with the competent scientific authority, that there are no other factors relating to the conservation of the species which militate against issuance of the export permit.

3. A re-export certificate may be issued only when the conditions referred to in paragraph 2(c) and (d) have been met and when the applicant provides documentary evidence that the specimens:

- (a) were introduced into the Union in accordance with the provisions of this Regulation;
- (b) if introduced into the Union before 3 March 1997, were introduced in accordance with the provisions of Council Regulation (EEC) No 3626/82 ⁽¹⁾; or if introduced into the Union before the entry into force of this Regulation but after 3 March 1997, were introduced into the Union in accordance with the provisions of Regulation (EC) No 338/97; or
- (c) if introduced into the Union before 1984, entered international trade in accordance with the provisions of the Convention; or
- (d) were legally introduced into the territory of a Member State before the provisions of the Regulations referred to in (a) and (b) or of the Convention became applicable to them, or became applicable in that Member State.

4. The export or re-export from the Union of specimens of the species listed in Annexes B and C shall be subject to completion of the necessary checks and the prior presentation, at the customs office at which the export formalities are completed, of an export permit or re-export certificate issued by a management authority of the Member State in whose territory the specimens are located.

An export permit may be issued only when the conditions referred to in paragraph 2(a), (b), (c)(i) and (d) have been met.

A re-export certificate may be issued only when the conditions referred to in paragraph 2(c)(i) and (d) and in paragraph 3(a) to (d) have been met.

5. Where an application for a re-export certificate concerns specimens introduced into the Union under an import permit issued by another Member State, the management authority must first consult the management authority which issued the permit. The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning the establishment of the consultation procedures and of the cases in which consultation is necessary.

6. The conditions for the issuance of an export permit or re-export certificate as referred to in paragraph 2(a) and (c)(ii) shall not apply to:

- (a) worked specimens that were acquired more than 50 years previously; or
- (b) dead specimens and parts and derivatives thereof for which the applicant provides documentary evidence that they were legally acquired before the provisions of this Regulation, of Regulation (EC) No 338/97 or of Regulation (EEC) No 3626/82 or of the Convention became applicable to them.

⁽¹⁾ Council Regulation (EEC) No 3626/82 of 3 December 1982 on the implementation in the Community of the Convention on international trade in endangered species of wild fauna and flora (OJ L 384, 31.12.1982, p. 1).

Wednesday 16 April 2014

7. The competent scientific authority in each Member State shall monitor the issuance of export permits by that Member State for specimens of species listed in Annex B and actual exports of such specimens. Whenever such a scientific authority determines that the export of specimens of any such species should be limited in order to maintain that species throughout its range at a level consistent with its role in the ecosystem in which it occurs, and well above the level at which that species might become eligible for inclusion in Annex A in accordance with Article 3(1)(a) or (b)(i), the scientific authority shall advise the competent management authority, in writing, of suitable measures to be taken to limit the issuance of export permits for specimens of that species.

Whenever a management authority is advised of the measures referred to in the first subparagraph, it shall inform and send comments to the Commission. If appropriate, the Commission shall, by means of implementing acts, recommend restrictions on exports of the species concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).

Article 6

Rejection of applications for permits and certificates referred to in Articles 4, 5 and 10

1. When a Member State rejects an application for a permit or certificate in a case of significance in respect of the objectives of this Regulation, it shall immediately inform the Commission of the rejection and of the reasons for rejection.
2. The Commission shall communicate information received in accordance with paragraph 1 to the other Member States in order to ensure the uniform application of this Regulation.
3. When an application is made for a permit or certificate relating to specimens for which such an application has previously been rejected, the applicant must inform the competent authority to which the application is submitted of the previous rejection.
4. Member States shall recognise the rejection of applications by the competent authorities of the other Member States, where such rejection is based on the provisions of this Regulation.

However, the first subparagraph shall not apply where the circumstances have significantly changed or where new evidence to support an application has become available. In such cases, if a management authority issues a permit or certificate, it shall inform the Commission thereof, stating the reasons for issuance.

Article 7

Derogations

1. Specimens born and bred in captivity or artificially propagated

Save where Article 8 applies, specimens of species listed in Annex A that have been born and bred in captivity or artificially propagated shall be treated in accordance with the provisions applicable to specimens of species listed in Annex B.

In the case of artificially propagated plants, the provisions of Articles 4 and 5 may be waived under special conditions.

The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning:

- (a) the criteria for determining whether a specimen has been born and bred in captivity or artificially propagated and whether for commercial purposes;
- (b) the special conditions referred to in the second subparagraph of this paragraph relating to:
 - (i) the use of phytosanitary certificates;
 - (ii) trade by registered commercial traders and by the scientific institutions referred to in paragraph 4 of this Article; and

Wednesday 16 April 2014

(iii) trade in hybrids.

2. Transit

By way of derogation from Article 4, where a specimen is in transit through the Union, checks and presentation at the border customs office at the point of introduction of the prescribed permits, certificates and notifications shall not be required.

In the case of species listed in the Annexes in accordance with Article 3(1) and Article 3(2)(a) and (b), the derogation referred to in the first subparagraph of this paragraph shall apply only where a valid export or re-export document provided for by the Convention, relating to the specimens that it accompanies and specifying the destination of the specimens, has been issued by the competent authorities of the exporting or re-exporting third country.

If the document referred to in the second subparagraph has not been issued before export or re-export, the specimen must be seized and may, where applicable, be confiscated unless the document is submitted retrospectively in compliance with special conditions.

The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning the special conditions for submitting an export or re-export document retrospectively.

3. Personal and household effects

By way of derogation from Articles 4 and 5, the provisions of those Articles shall not apply to dead specimens, parts and derivatives of species listed in Annexes A to D which are personal or household effects being introduced into the Union, or exported or re-exported from the Union, in compliance with special provisions.

The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning the special provisions regarding the introduction, export or re-export of personal or household effects.

4. Scientific institutions

The documents referred to in Articles 4, 5, 8 and 9 shall not be required in the case of non-commercial loans, donations and exchanges between scientists and scientific institutions, registered by the management authorities of the States in which they are located, of herbarium specimens and other preserved, dried or embedded museum specimens, and of live plant material, bearing a label, the model of which has been established in accordance with the second subparagraph of this paragraph or a similar label issued or approved by a management authority of a third country.

The Commission shall, by means of implementing acts, establish a model for a label for live plant material. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).

Article 8

Provisions relating to the control of commercial activities

1. The purchase, offer to purchase, acquisition for commercial purposes, display to the public for commercial purposes, use for commercial gain and sale, keeping for sale, offering for sale or transporting for sale of specimens of the species listed in Annex A shall be prohibited.

2. Member States may prohibit the holding of specimens, in particular live animals of the species listed in Annex A.

3. In accordance with the requirements of other Union legislation on the conservation of wild fauna and flora, exemptions from the prohibitions referred to in paragraph 1 may be granted by the issuance of a certificate to that effect by a management authority of the Member State in which the specimens are located, on a case-by-case basis where the specimens:

(a) were acquired in, or were introduced into, the Union before the provisions relating to species listed in Appendix I to the Convention or in Annex C1 to Regulation (EEC) No 3626/82 or in Annex A to Regulation (EC) No 338/97 or to this Regulation became applicable to the specimens; or

(b) are worked specimens that were acquired more than 50 years previously; or

(c) were introduced into the Union in compliance with the provisions of Regulation (EC) No 338/97 or of this Regulation and are to be used for purposes which are not detrimental to the survival of the species concerned; or

Wednesday 16 April 2014

- (d) are captive-born and bred specimens of an animal species or artificially propagated specimens of a plant species or are parts or derivatives of such specimens; or
- (e) are required under exceptional circumstances for the advancement of science or for essential biomedical purposes pursuant to Council Directive 86/609/EEC ⁽¹⁾ where the species in question proves to be the only one suitable for those purposes and where there are no specimens of the species which have been born and bred in captivity; or
- (f) are intended for breeding or propagation purposes from which conservation benefits will accrue to the species concerned; or
- (g) are intended for research or education aimed at the preservation or conservation of the species; or
- (h) originate in a Member State and were taken from the wild in accordance with the legislation in force in that Member State.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning general derogations from the prohibitions referred to in paragraph 1 of this Article based on the conditions referred to in paragraph 3, as well as general derogations with regard to species listed in Annex A in accordance with point (ii) of Article 3 (1)(b). Any such derogations must be in accordance with the requirements of other Union legislation on the conservation of wild fauna and flora.

5. The prohibitions referred to in paragraph 1 shall also apply to specimens of the species listed in Annex B except where it can be proved to the satisfaction of the competent authority of the Member State concerned that such specimens were acquired and, if they originated outside the Union, were introduced into it, in accordance with the legislation in force for the conservation of wild fauna and flora.

6. The competent authorities of the Member States shall have discretion to sell any specimen of the species listed in Annexes B, C and D they have confiscated under this Regulation, provided that it is not thus returned directly to the person or entity from whom it was confiscated or who was party to the offence. Such specimens may then be treated for all purposes as if they had been legally acquired.

Article 9

Movement of live specimens

1. Any movement within the Union of a live specimen of a species listed in Annex A from the location indicated in the import permit or in any certificate issued in compliance with this Regulation shall require prior authorisation from a management authority of the Member State in which the specimen is located. In other cases of movement, the person responsible for moving the specimen must be able, where applicable, to provide proof of the legal origin of the specimen.

2. Such authorisation shall:

- (a) be granted only when the competent scientific authority of such Member State or, where the movement is to another Member State, the competent scientific authority of the latter, is satisfied that the intended accommodation for a live specimen at the place of destination is adequately equipped to conserve and care for it properly;
- (b) be confirmed by issuance of a certificate; and
- (c) where applicable, be immediately communicated to a management authority of the Member State in which the specimen is to be located.

3. However, no such authorisation shall be required if a live animal must be moved for the purpose of urgent veterinary treatment and is returned directly to its authorised location.

4. Where a live specimen of a species listed in Annex B is moved within the Union, the holder of the specimen may relinquish it only after ensuring that the intended recipient is adequately informed of the accommodation, equipment and practices required to ensure the specimen will be properly cared for.

⁽¹⁾ Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ L 358, 18.12.1986, p. 1).

Wednesday 16 April 2014

5. When any live specimens are transported into, from or within the Union or are held during any period of transit or transshipment, they shall be prepared, moved and cared for in a manner such as to minimise the risk of injury, damage to health or cruel treatment and, in the case of animals, in conformity with Union legislation on the protection of animals during transport.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning restrictions on the holding or movement of live specimens of such species in relation to which restrictions on introduction into the Union have been established in accordance with Article 4(6).

Article 10

Permits, notifications and certificates to be issued [Am. 5]

1. On receiving an application, together with all the requisite supporting documents, from the person concerned and provided that all the conditions governing their issuance have been fulfilled, a management authority of a Member State may issue a certificate for the purposes referred to in Article 5(2)(b), Article 5(3) and (4), Article 8(3) and Article 9(2)(b).

1a. The Commission shall adopt implementing acts in order to determine the design of the certificates referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2). [Am. 6]

1b. On receiving an application and the requisite supporting documents from the person concerned and provided that all the requirements for their issuance have been fulfilled, the management authority of a Member State may issue a permit for the purposes of Article 4(1) and (2) and Article 5(1) and (4). [Am. 7]

1c. The Commission shall adopt implementing acts in order to determine the design of the permit referred to in paragraph 1b. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2). [Am. 8]

1d. The Commission shall adopt implementing acts in order to determine the design of the import notification referred to in Article 4(3) and (4). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2). [Am. 9]

Article 11

Validity of and special conditions for permits and certificates

1. Without prejudice to stricter measures which the Member States may adopt or maintain, permits and certificates issued by the competent authorities of the Member States in accordance with this Regulation shall be valid throughout the Union.

2. Any such permit or certificate, as well as any permit or certificate issued on the basis of it, shall be deemed void if a competent authority or the Commission, in consultation with the competent authority which issued the permit or certificate, establishes that it was issued on the false premise that the conditions for its issuance were met.

Specimens situated in the territory of a Member State and covered by such documents shall be seized by the competent authorities of that Member State and may be confiscated.

3. Any permit or certificate issued in accordance with this Regulation may stipulate conditions and requirements imposed by the issuing authority to ensure compliance with the provisions thereof. Where such conditions or requirements need to be incorporated in the design of permits or certificates, Member States shall inform the Commission thereof.

4. Any import permit issued on the basis of a copy of the corresponding export permit or re-export certificate shall be valid for the introduction of specimens into the Union only when accompanied by the original of the valid export permit or re-export certificate.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning the time limits for the issuance of permits and certificates.

Wednesday 16 April 2014

Article 12

Places of introduction and export

1. Member States shall designate customs offices for carrying out the checks and formalities for the introduction into and export from the Union, in order to assign to them a customs-approved treatment or use, within the meaning of Regulation (EEC) No 2913/92, of specimens of species covered by this Regulation and shall state which offices are specifically intended to deal with live specimens.
2. All offices designated in accordance with paragraph 1 shall be provided with sufficient and adequately trained staff. Member States shall ensure that accommodation is provided in accordance with relevant Union legislation as regards the transport and accommodation of live animals and that, where necessary, adequate steps are taken for live plants.
3. All offices designated in accordance with paragraph 1 shall be notified to the Commission which shall publish a list of them in the *Official Journal of the European Union*.
4. In exceptional cases and in accordance with special criteria, a management authority may authorise the introduction into the Union or the export or re-export from the Union at a customs office other than one designated in accordance with paragraph 1.

The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning the special criteria in accordance with which the introduction, export or re-export at another customs office may be authorised.

5. Member States shall ensure that at border crossing-points the public are informed of the provisions adopted pursuant to this Regulation.

Article 13

Management and scientific authorities and other competent authorities

1. Each Member State shall designate a management authority with primary responsibility for the implementation of this Regulation and for communication with the Commission.

Each Member State may also designate additional management authorities and other competent authorities to assist in the implementation, in which case the primary management authority shall be responsible for providing the additional authorities with all the information required for the correct application of this Regulation.

2. Each Member State shall designate one or more scientific authorities with appropriate qualifications whose duties shall be separate from those of any designated management authority.
3. Not later than 3 March 1997 Member States shall forward the names and addresses of the designated management authorities, other authorities competent to issue permits or certificates and scientific authorities to the Commission, which shall publish this information in the *Official Journal of the European Union*.

Each management authority referred to in the first subparagraph of paragraph 1 shall, if so requested by the Commission, communicate to it within two months the names and specimen signatures of the persons authorised to sign permits or certificates, and impressions of the stamps, seals or other devices used to authenticate permits or certificates.

Member States shall communicate to the Commission any changes in the information already provided, not later than two months after the implementation of such change.

Article 14

Monitoring of compliance and investigation of infringements

1. The competent authorities of the Member States shall monitor compliance with the provisions of this Regulation.

If, at any time, the competent authorities have reason to believe that these provisions are being infringed, they shall take the appropriate steps to ensure compliance or to instigate legal action.

Wednesday 16 April 2014

Member States shall inform the Commission and, in the case of species listed in the Appendices to the Convention, the Convention Secretariat of any steps taken by the competent authorities in relation to significant infringements of this Regulation, including seizures and confiscations.

2. The Commission shall draw the attention of the competent authorities of the Member States to matters whose investigation it considers necessary under this Regulation. Member States shall inform the Commission and, in the case of species listed in the Appendices to the Convention, the Convention Secretariat of the outcome of any subsequent investigation.

3. An enforcement group shall be established consisting of the representatives of each Member State's authorities with responsibility for ensuring the implementation of the provisions of this Regulation. The group shall be chaired by the representative of the Commission.

The enforcement group shall examine any technical question relating to the enforcement of this Regulation raised by the chairman, either on his own initiative or at the request of the members of the group or the Committee.

The Commission shall convey the opinions expressed in the enforcement group to the Committee.

Article 15

Communication of information

1. The Member States and the Commission shall communicate to one another the information necessary for implementing this Regulation.

The Member States and the Commission shall ensure that the necessary steps are taken to make the public aware and inform it of the provisions regarding the implementation of the Convention and of this Regulation and of measures adopted pursuant to this Regulation.

2. The Commission shall communicate with the Convention Secretariat so as to ensure that the Convention is effectively implemented throughout the territory to which this Regulation applies.

3. The Commission shall immediately communicate any opinion of the Scientific Review Group to the management authorities of the Member States concerned.

4. The management authorities of the Member States shall communicate to the Commission before 15 June each year all the information relating to the preceding year required for drawing up the reports referred to in Article VIII.7(a) of the Convention and equivalent information on international trade in all specimens of species listed in Annexes A, B and C and on introduction into the Union of specimens of species listed in Annex D. The Commission shall, by means of implementing acts, specify the information to be communicated and the format for its presentation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).

On the basis of the information referred to in the first subparagraph, the Commission shall publish before 31 October each year a statistical report on the introduction into, and the export and re-export from, the Union of specimens of the species to which this Regulation applies and shall forward to the Convention Secretariat information on the species to which the Convention applies.

Without prejudice to Article 22, the management authorities of the Member States shall, before 15 June of each second year, and for the first time in 1999, communicate to the Commission all the information relating to the preceding two years required for drawing up the reports referred to in Article VIII.7(b) of the Convention and equivalent information on the provisions of this Regulation that fall outside the scope of the Convention. The Commission shall, by means of implementing acts, specify the information to be communicated and the format for its presentation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).

On the basis of the information referred to in the third subparagraph, the Commission shall, before 31 October of each second year, and for the first time in 1999, draw up a report on the implementation and enforcement of this Regulation.

Wednesday 16 April 2014

5. With a view to the preparation of amendments to the Annexes, the competent authorities of the Member States shall forward all relevant information to the Commission. The Commission shall, by means of implementing acts, specify the information required. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).

6. Without prejudice to Directive 2003/4/EC of the European Parliament and of the Council ⁽¹⁾, the Commission shall take appropriate measures to protect the confidentiality of information obtained in the implementation of this Regulation.

Article 16

Sanctions

1. Member States shall take appropriate measures to ensure the imposition of sanctions for at least the following infringements of this Regulation:

- (a) introduction into, or export or re-export from, the Union of specimens without the appropriate permit or certificate or with a false, falsified or invalid permit or certificate or one altered without authorisation by the issuing authority;
- (b) failure to comply with the stipulations specified on a permit or certificate issued in accordance with this Regulation;
- (c) making a false declaration or knowingly providing false information in order to obtain a permit or certificate;
- (d) using a false, falsified or invalid permit or certificate or one altered without authorisation as a basis for obtaining a Union permit or certificate or for any other official purpose in connection with this Regulation;
- (e) failure to make an import notification or making a false import notification;
- (f) shipment of live specimens not properly prepared so as to minimise the risk of injury, damage to health or cruel treatment;
- (g) use of specimens of species listed in Annex A other than in accordance with the authorisation given at the time of issuance of the import permit or subsequently;
- (h) trade in artificially propagated plants contrary to the provisions laid down in accordance with the second subparagraph of Article 7(1);
- (i) shipment of specimens into or out of or in transit through the territory of the Union without the appropriate permit or certificate issued in accordance with this Regulation and, in the case of export or re-export from a third country party to the Convention, in accordance therewith, or without satisfactory proof of the existence of such permit or certificate;
- (j) purchase, offer to purchase, acquisition for commercial purposes, use for commercial gain, display to the public for commercial purposes, sale, keeping for sale, offering for sale or transporting for sale of specimens in breach of Article 8;
- (k) use of a permit or certificate for any specimen other than one for which it was issued;
- (l) falsification or alteration of any permit or certificate issued in accordance with this Regulation;
- (m) failure to disclose the rejection of an application for a Union import, export or re-export permit or certificate, in accordance with Article 6(3).

2. The measures referred to in paragraph 1 shall be appropriate to the nature and gravity of the infringement and shall include provisions relating to the seizure and, where appropriate, confiscation of specimens.

⁽¹⁾ Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

Wednesday 16 April 2014

3. Where a specimen is confiscated, it shall be entrusted to a competent authority of the Member State of confiscation which:

- (a) following consultation with a scientific authority of that Member State, shall place or otherwise dispose of the specimen under conditions which it deems to be appropriate and consistent with the purposes and provisions of the Convention and this Regulation; and
- (b) in the case of a live specimen which has been introduced into the Union, may, after consultation with the State of export, return the specimen to that State at the expense of the convicted person.

4. Where a live specimen of a species listed in Annex B or C arrives at a point of introduction into the Union without the appropriate valid permit or certificate, the specimen must be seized and may be confiscated or, if the consignee refuses to acknowledge the specimen, the competent authorities of the Member State responsible for the point of introduction may, if appropriate, refuse to accept the shipment and require the carrier to return the specimen to its place of departure.

Article 17**The Scientific Review Group**

1. A Scientific Review Group is hereby established, consisting of the representatives of each Member State's scientific authority or authorities and chaired by the representative of the Commission.

2. The Scientific Review Group shall examine any scientific question relating to the application of this Regulation — in particular concerning Article 4(1)(a), (2)(a) and (6) — raised by the chairman, either on his own initiative or at the request of the members of the Group or the Committee.

3. The Commission shall convey the opinions of the Scientific Review Group to the Committee.

Article 18**Further delegated powers**

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 20 concerning the uniform conditions and criteria for:

- (a) the issue, validity and use of the documents referred to in Article 4, Article 5, Article 7(4) and Article 10;
- (b) the use of phytosanitary certificates referred to in point (a) of the second subparagraph of Article 7(1);
- (c) the establishment of procedures, where necessary, for marking specimens in order to facilitate identification and ensure enforcement of the provisions of this Regulation.

2. The Commission shall be empowered to adopt, where necessary, delegated acts in accordance with Article 20 concerning additional measures to implement resolutions of the Conference of the Parties to the Convention, decisions or recommendations of the Standing Committee of the Convention and recommendations of the Convention Secretariat.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 20 for the purpose of amending Annexes A to D, except in the case of amendments to Annex A which do not result from decisions of the Conference of the Parties to the Convention.

Article 19**Further implementing powers**

~~1. The Commission shall, by means of implementing acts, determine the design of the documents referred to in Article 4, Article 5, Article 7(4) and Article 10. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).~~

Wednesday 16 April 2014

~~2. The Commission shall, by means of implementing acts, prescribe a form for the presentation of the import notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2). [Am. 10]~~

Article 20

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article ~~4(6)~~, 4(7), Article 5(5), Article 7(1), (2) and (3), Article 8(4), Article 9(6), Article 11(5), Article 12(4) and Article 18(1), (2) and (3) shall be conferred on the Commission for an indeterminate period of time from [the date of entry into force of the basic legislative act or from any other date set by the legislator].**[Am. 11]**
3. The delegation of powers referred to in Article ~~4(6)~~, 4(7), Article 5(5), Article 7(1), (2) and (3), Article 8(4), Article 9(6), Article 11(5), Article 12(4) and Article 18(1), (2) and (3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force. **[Am. 12]**
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Article ~~4(6)~~, 4(7), Article 5(5), Article 7(1), (2) and (3), Article 8(4), Article 9(6), Article 11(5), Article 12(4) and Article 18(1), (2) and (3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of [two months] of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by [two months] at the initiative of the European Parliament or the Council. **[Am. 13]**

Article 21

Committee procedure

1. The Commission shall be assisted by a Committee which shall be referred to as the Committee on Trade in Wild Fauna and Flora. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 22

Final provisions

Each Member State shall notify the Commission and the Convention Secretariat of the provisions which it adopts specifically for the implementation of this Regulation and of all legal instruments used and measures taken for its implementation and enforcement.

The Commission shall communicate that information to the other Member States.

Article 23

Repeal

Regulation (EC) No 338/97 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Wednesday 16 April 2014

Article 24

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

The President

For the Council

The President

Wednesday 16 April 2014

ANNEX I**Notes on interpretation of Annexes A, B, C and D**

1. Species included in these Annexes A, B, C and D are referred to:
 - (a) by the name of the species; or
 - (b) as being all of the species included in a higher taxon or designated part thereof.
2. The abbreviation 'spp.' is used to denote all species of a higher taxon.
3. Other references to taxa higher than species are for the purposes of information or classification only.
4. Species printed in bold in Annex A are listed there in consistency with their protection as provided for by Directive 2009/147/EC of the European Parliament and of the Council⁽¹⁾ or Council Directive 92/43/EEC⁽²⁾.
5. The following abbreviations are used for plant taxa below the level of species:
 - (a) 'ssp.' is used to denote subspecies;
 - (b) 'var(s)।' is used to denote variety (varieties); and
 - (c) 'fa.' is used to denote forma.
6. The symbols '(I)', '(II)' and '(III)' placed against the name of a species or higher taxon refer to the Appendices to the Convention in which the species concerned are listed as indicated in notes 7 to 9. Where none of these annotations appears, the species concerned are not listed in the Appendices to the Convention.
7. (I) against the name of a species or higher taxon indicates that the species or higher taxon concerned is included in Appendix I to the Convention.
8. (II) against the name of a species or higher taxon indicates that the species or higher taxon concerned is included in Appendix II to the Convention.
9. (III) against the name of a species or higher taxon indicates that it is included in Appendix III to the Convention. In this case the country with respect to which the species or higher taxon is included in Appendix III is also indicated.
10. 'Cultivar' means, following the definition of the 8th edition of the *International Code of Nomenclature for Cultivated Plants*, an assemblage of plants that (a) has been selected for a particular character or combination of characters, (b) is distinct, uniform, and stable in these characters, and (c) when propagated by appropriate means, retains those characters. No new taxon of a cultivar can be regarded as such until its category name and circumscription has been formally published in the latest edition of the *International Code of Nomenclature for Cultivated Plants*.
11. Hybrids may be specifically included in the Appendices but only if they form distinct and stable populations in the wild. Hybrid animals that have in their previous four generations of the lineage one or more specimens of species included in Annexes A or B shall be subject to the provisions of this Regulation just as if they were full species, even if the hybrid concerned is not specifically included in the Annexes.

⁽¹⁾ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

⁽²⁾ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7).

Wednesday 16 April 2014

12. When a species is included in Annex A, B or C, all parts and derivatives of the species are also included in the same Annex unless the species is annotated to indicate that only specific parts and derivatives are included. In accordance with Article 2(t) of this Regulation, the symbol '#' followed by a number placed against the name of a species or higher taxon included in Annex B or C designates parts or derivatives which are specified in relation thereto for the purposes of the Regulation as follows:

#1	Designates all parts and derivatives, except: (a) seeds, spores and pollen (including pollinia); (b) seedling or tissue cultures obtained <i>in vitro</i> , in solid or liquid media, transported in sterile containers; (c) cut flowers of artificially propagated plants; and (d) fruits and parts and derivatives thereof of artificially propagated plants of the genus <i>Vanilla</i> .
#2	Designates all parts and derivatives, except: (a) seeds and pollen; and (b) finished products packaged and ready for retail trade.
#3	Designates whole and sliced roots and parts of roots.
#4	Designates all parts and derivatives, except: (a) seeds (including seedpods of Orchidaceae), spores and pollen (including pollinia). The exemption does not apply to seeds from Cactaceae spp. exported from Mexico, and to seeds from <i>Beccariophoenix madagascariensis</i> and <i>Neodypsis decaryi</i> exported from Madagascar; (b) seedling or tissue cultures obtained <i>in vitro</i> , in solid or liquid media, transported in sterile containers; (c) cut flowers of artificially propagated plants; (d) fruits and parts and derivatives thereof of naturalized or artificially propagated plants of the genus <i>Vanilla</i> (Orchidaceae) and of the family Cactaceae; (e) stems, flowers, and parts and derivatives thereof of naturalized or artificially propagated plants of the genera <i>Opuntia</i> subgenus <i>Opuntia</i> and <i>Selenicereus</i> (Cactaceae); and (f) finished products of <i>Euphorbia antisyphilitica</i> packaged and ready for retail trade.
#5	Designates logs, sawn wood and veneer sheets.
#6	Designates logs, sawn wood, veneer sheets and plywood.
#7	Designates logs, wood-chips, powder and extracts.
#8	Designates underground parts (i.e. roots, rhizomes): whole, parts and powdered.
#9	Designates all parts and derivatives, except those bearing a label 'Produced from <i>Hoodia</i> spp. material obtained through controlled harvesting and production in collaboration with the CITES Management Authorities of Botswana/Namibia/South Africa under agreement no. BW/NA/ZA xxxxxx'.

Wednesday 16 April 2014

#10	Designates logs, sawn wood, veneer sheets, including unfinished wood articles used for the fabrication of bows for stringed musical instruments.
#11	Designates logs, sawn wood, veneer sheets, plywood, powder and extracts.
#12	Designates logs, sawn wood, veneer sheets, plywood and essential oil, excluding finished products packaged and ready for retail trade.
#13	Designates the kernel (also known as 'endosperm', 'pulp' or 'copra') and any derivative thereof.

13. As none of the species or higher taxa of FLORA included in Annex A is annotated to the effect that its hybrids shall be treated in accordance with the provisions of Article 4(1) of this Regulation, this means that artificially propagated hybrids produced from one or more of these species or taxa may be traded with a certificate of artificial propagation, and that seeds and pollen (including pollinia), cut flowers, seedling or tissue cultures obtained *in vitro*, in solid or liquid media, transported in sterile containers of these hybrids are not subject to the provisions of this Regulation.
14. Urine, faeces and ambergris which are waste products and gained without the manipulation of the animal concerned are not subject to the provisions of this Regulation.
15. In respect of fauna species listed in Annex D, the provisions shall apply only to live specimens and whole, or substantially whole, dead specimens except for taxa which are annotated as follows to show that other parts and derivatives are also covered:

§ 1	Any whole, or substantially whole, skins, raw or tanned.
§ 2	Any feathers or any skin or other part with feathers on it.

16. In respect of flora species listed in Annex D, the provisions shall apply only to live specimens except for taxa which are annotated as follows to show that other parts and derivatives are also covered:

§ 3	Dried and fresh plants, including, where appropriate; leaves, roots/rootstock, stems, seeds/spores, bark and fruits.
§ 4	Logs, sawn wood and veneer sheets.

	Annex A	Annex B	Annex C	Common name
FAUNA				
CHORDATA (CHORDATES)				
MAMMALIA				Mammals
ARTIODACTYLA				
<i>Antilocapridae</i>				Pronghorn
	<i>Antilocapra americana</i> (I) (Only the population of Mexico; no other population is included in the Annexes to this Regulation)			Mexican pronghorn

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
Bovidae				Antelopes, cattle, duikers, gazelles, goats, sheep etc.
	<i>Addax nasomaculatus</i> (I)			Addax
		<i>Ammotragus lervia</i> (II)		Barbary sheep
			<i>Antilope cervicapra</i> (III Nepal)	Blackbuck
		<i>Bison bison athabascae</i> (II)		Wood bison
	<i>Bos gaurus</i> (I) (Excludes the domesticated form referenced as <i>Bos frontalis</i> which is not subject to the provisions of this Regulation)			Gaur
	<i>Bos mutus</i> (I) (Excludes the domesticated form referenced as <i>Bos grunniens</i> which is not subject to the provisions of this Regulation)			Wild yak
	<i>Bos sauveli</i> (I)			Kouprey
			<i>Bubalus arnee</i> (III Nepal) (Excludes the domesticated form referenced as <i>Bubalus bubalis</i> , which is not subject to the provisions of this Regulation)	Wild Asiatic buffalo
	<i>Bubalus depressicornis</i> (I)			Lowland anoa
	<i>Bubalus mindorensis</i> (I)			Tamarau
	<i>Bubalus quarlesi</i> (I)			Mountain anoa
		<i>Budorcas taxicolor</i> (II)		Takin
	<i>Capra falconeri</i> (I)			Markhor
	<i>Capricornis milneedwardsii</i> (I)			Chinese serow
	<i>Capricornis rubidus</i> (I)			Red serow
	<i>Capricornis sumatraensis</i> (I)			Sumatran serow
	<i>Capricornis thar</i> (I)			Himalayan serow
		<i>Cephalophus brookei</i> (II)		Brooke's duiker
		<i>Cephalophus dorsalis</i> (II)		Bay duiker

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Cephalophus jentinki</i> (I)			Jentink's duiker
		<i>Cephalophus ogilbyi</i> (II)		Ogilby's duiker
		<i>Cephalophus silvicultor</i> (II)		Yellow-backed duiker
		<i>Cephalophus zebra</i> (II)		Zebra duiker
		<i>Damaliscus pygargus pygargus</i> (II)		Bontebok
	<i>Gazella cuvieri</i> (I)			Cuvier's gazelle
			<i>Gazella dorcas</i> (III Algeria / Tunisia)	Dorcas gazelle
	<i>Gazella leptoceros</i> (I)			Slender-horned gazelle
	<i>Hippotragus niger variani</i> (I)			Giant sable antelope
		<i>Kobus leche</i> (II)		Lechwe
	<i>Naemorhedus baileyi</i> (I)			Red goral
	<i>Naemorhedus caudatus</i> (I)			Long-tailed goral
	<i>Naemorhedus goral</i> (I)			Himalayan goral
	<i>Naemorhedus griseus</i> (I)			Chinese goral
	<i>Nanger dama</i> (I)			Dama gazelle
	<i>Oryx dammah</i> (I)			Scimitar-horned oryx
	<i>Oryx leucoryx</i> (I)			Arabian oryx
		<i>Ovis ammon</i> (II) (Except for the subspecies included in Annex A)		Argali
	<i>Ovis ammon hodgsonii</i> (I)			Tibetan argali
	<i>Ovis ammon nigrimontana</i> (I)			Kara Tau argali
		<i>Ovis canadensis</i> (II) (Only the population of Mexico; no other population is included in the Annexes to this Regulation)		Mexican bighorn sheep
	<i>Ovis orientalis ophion</i> (I)			Cyprus mouflon
		<i>Ovis vignei</i> (II) (Except for the subspecies included in Annex A)		Urial

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Ovis vignei vignei</i> (I)			Ladakh urial
	<i>Pantholops hodgsonii</i> (I)			Chiru
		<i>Philantomba monticola</i> (II)		Blue duiker
	<i>Pseudoryx nghetinhensis</i> (I)			Siola
	<i>Rupicapra pyrenaica ornata</i> (I)			Abruzzo chamois
		<i>Saiga borealis</i> (II)		Mongolian saiga
		<i>Saiga tatarica</i> (II)		Steppe saiga
			<i>Tetracerus quadricornis</i> (III Nepal)	Four-horned antelope
Camelidae				Camels, guanaco, vicuña
		<i>Lama guanicoe</i> (II)		Guanaco
	<i>Vicugna vicugna</i> (I) (Except for the populations of: Argentina [the populations of the Provinces of Jujuy and Catamarca and the semi-captive populations of the Provinces of Jujuy, Salta, Catamarca, La Rioja and San Juan]; Bolivia [the whole population]; Chile [population of the Primera Región]; and Peru [the whole population]; which are included in Annex B)	<i>Vicugna vicugna</i> (II) (Only the populations of Argentina ⁽¹⁾ [the populations of the Provinces of Jujuy and Catamarca and the semi-captive populations of the Provinces of Jujuy, Salta, Catamarca, La Rioja and San Juan]; Bolivia ⁽²⁾ [the whole population]; Chile ⁽³⁾ [population of the Primera Región]; Peru ⁽⁴⁾ [the whole population]; all other populations are included in Annex A)		Vicuña

⁽¹⁾ Population of Argentina (listed in Annex B):For the exclusive purpose of allowing international trade in wool sheared from live vicuñas of the populations included in Annex B, in cloth and in derived manufactured products and other handicraft artefacts. The reverse side of the cloth must bear the logotype adopted by the range States of the species, which are signatories to the Convenio para la Conservación y Manejo de la Vicuña, and the selvages the words 'VICUÑA-ARGENTINA'. Other products must bear a label including the logotype and the designation 'VICUÑA-ARGENTINA-ARTESANÍA'. All other specimens shall be deemed to be specimens of species included in Annex A and the trade in them shall be regulated accordingly.

⁽²⁾ Population of Bolivia (listed in Annex B):For the exclusive purpose of allowing international trade in wool sheared from live vicuñas and in cloth and items made thereof, including luxury handicrafts and knitted articles. The reverse side of the cloth must bear the logotype adopted by the range States of the species, which are signatories to the Convenio para la Conservación y Manejo de la Vicuña, and the selvages the words 'VICUÑA-BOLIVIA'. Other products must bear a label including the logotype and the designation 'VICUÑA-BOLIVIA-ARTESANÍA'. All other specimens shall be deemed to be specimens of species included in Annex A and the trade in them shall be regulated accordingly.

⁽³⁾ Population of Chile (listed in Annex B):For the exclusive purpose of allowing international trade in wool sheared from live vicuñas of the populations included in Annex B, and in cloth and items made thereof, including luxury handicrafts and knitted articles. The reverse side of the cloth must bear the logotype adopted by the range States of the species, which are signatories to the Convenio para la Conservación y Manejo de la Vicuña, and the selvages the words 'VICUÑA-CHILE'. Other products must bear a label including the logotype and the designation 'VICUÑA-CHILE-ARTESANÍA'. All other specimens shall be deemed to be specimens of species included in Annex A and the trade in them shall be regulated accordingly.

⁽⁴⁾ Population of Peru (listed in Annex B):For the exclusive purpose of allowing international trade in wool sheared from live vicuñas and in the stock extant at the time of the ninth meeting of the Conference of the Parties (November 1994) of 3249 kg of wool, and in cloth and items made thereof, including luxury handicrafts and knitted articles. The reverse side of the cloth must bear the logotype adopted by the range States of the species, which are signatories to the Convenio para la Conservación y Manejo de la Vicuña, and the selvages the words 'VICUÑA-PERU'. Other products must bear a label including the logotype and the designation 'VICUÑA-PERU-ARTESANÍA'. All other specimens shall be deemed to be specimens of species included in Annex A and the trade in them shall be regulated accordingly.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
Cervidae				Deer, huemuls, muntjacs, pudus
	<i>Axis calamianensis</i> (I)			Calamian deer
	<i>Axis kuhlii</i> (I)			Bawean deer
	<i>Axis porcinus annamiticus</i> (I)			Indochina hog deer
	<i>Blastocerus dichotomus</i> (I)			Marsh deer
		<i>Cervus elaphus bactrianus</i> (II)		Bactrian deer
			<i>Cervus elaphus barbarus</i> (III Algeria / Tunisia)	Barbary deer
	<i>Cervus elaphus hanglu</i> (I)			Hangul
	<i>Dama dama mesopotamica</i> (I)			Persian fallow deer
	<i>Hippocamelus</i> spp. (I)			Huemuls
			<i>Mazama temama cerasina</i> (III Guatemala)	Central American red brocket
	<i>Muntiacus crinifrons</i> (I)			Black muntjac
	<i>Muntiacus vuquangensis</i> (I)			Giant muntjac
			<i>Odocoileus virginianus mayensis</i> (III Guatemala)	Guatemalan white-tailed deer
	<i>Ozotoceros bezoarticus</i> (I)			Pampas deer
		<i>Pudu mephistophiles</i> (II)		Northern pudu
	<i>Pudu puda</i> (I)			Southern pudu
	<i>Rucervus duvaucelii</i> (I)			Barasingha
	<i>Rucervus eldii</i> (I)			Eld's deer
Hippopotamidae				Hippopotamuses
		<i>Hexaprotodon liberiensis</i> (II)		Pygmy hippopotamus
		<i>Hippopotamus amphibius</i> (II)		Common hippopotamus

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
Moschidae				Musk deer
	Moschus spp. (I) (Only the populations of Afghanistan, Bhutan, India, Myanmar, Nepal and Pakistan; all other populations are included in Annex B)	Moschus spp. (II) (Except for the populations of Afghanistan, Bhutan, India, Myanmar, Nepal and Pakistan, which are included in Annex A)		Musk deer
Suidae				Babirusa, hogs, pigs
	<i>Babyrousa babyrussa</i> (I)			Buru babirusa
	<i>Babyrousa bolabatuensis</i> (I)			Bola Batu babirusa
	<i>Babyrousa celebensis</i> (I)			North Sulawesi babirusa
	<i>Babyrousa togeanensis</i> (I)			Malenge babirusa
	<i>Sus salvanius</i> (I)			Pygmy hog
Tayassuidae				Peccaries
		Tayassuidae spp. (II) (Except for the species included in Annex A and excluding the populations of <i>Pecari tajacu</i> of Mexico and the United States, which are not included in the Annexes to this Regulation)		Peccaries
	<i>Catagonus wagneri</i> (I)			Chacoan peccary
CARNIVORA				
Ailuridae				
	<i>Ailurus fulgens</i> (I)			Red panda
Canidae				Dogs, foxes, wolves
			<i>Canis aureus</i> (III India)	Golden jackal
	<i>Canis lupus</i> (I/II) (All populations except those of Spain north of the Duero and Greece north of the 39th parallel. Populations of Bhutan, India, Nepal and Pakistan are listed in Appendix I; all other populations are listed in Appendix II. Excludes the domesticated form and the dingo which are referenced as <i>Canis lupus familiaris</i> and <i>Canis lupus dingo</i>)	<i>Canis lupus</i> (II) (Populations of Spain north of the Duero and Greece north of the 39th parallel. Excludes the domesticated form and the dingo which are referenced as <i>Canis lupus familiaris</i> and <i>Canis lupus dingo</i>)		Grey wolf

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Canis simensis</i>			Ethiopian wolf
		<i>Cerdocyon thous</i> (II)		Crab-eating fox
		<i>Chrysocyon brachyurus</i> (II)		Maned wolf
		<i>Cuon alpinus</i> (II)		Dhole
		<i>Lycalopex culpaeus</i> (II)		Culpeo
		<i>Lycalopex fulvipes</i> (II)		Darwin's fox
		<i>Lycalopex griseus</i> (II)		South American grey fox
		<i>Lycalopex gymnocercus</i> (II)		Pampas fox
	<i>Speothos venaticus</i> (I)			Bush dog
			<i>Vulpes bengalensis</i> (III India)	Bengal fox
		<i>Vulpes cana</i> (II)		Blanford's fox
		<i>Vulpes zerda</i> (II)		Fennec fox
<i>Eupleridae</i>				
		<i>Cryptoprocta ferox</i> (II)		Fossa
		<i>Eupleres goudotii</i> (II)		Falanouc
		<i>Fossa fossana</i> (II)		Malagasy civet
<i>Felidae</i>				Cats, cheetahs, leopards, lions, tigers etc.
		Felidae spp. (II) (Except for the species included in Annex A. Specimens of the domesticated form are not subject to the provisions of this Regulation)		Cats
	<i>Acinonyx jubatus</i> (I) (Annual export quotas for live specimens and hunting trophies are granted as follows: Botswana: 5; Namibia: 150; Zimbabwe: 50. The trade in such specimens is subject to the provisions of Article 4.1 of this Regulation)			Cheetah
	<i>Caracal caracal</i> (I) (Only the population of Asia; all other populations are included in Annex B)			Asian Caracal

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Catopuma temminckii</i> (I)			Asian golden cat
	<i>Felis nigripes</i> (I)			Black-footed cat
	<i>Felis silvestris</i> (II)			Wild cat
	<i>Leopardus geoffroyi</i> (I)			Geoffroy's cat
	<i>Leopardus jacobitus</i> (I)			Andean mountain cat
	<i>Leopardus pardalis</i> (I)			Ocelot
	<i>Leopardus tigrinus</i> (I)			Oncilla
	<i>Leopardus wiedii</i> (I)			Margay
	<i>Lynx lynx</i> (II)			Eurasian lynx
	<i>Lynx pardinus</i> (I)			Iberian lynx
	<i>Neofelis nebulosa</i> (I)			Clouded leopard
	<i>Panthera leo persica</i> (I)			Asiatic lion
	<i>Panthera onca</i> (I)			Jaguar
	<i>Panthera pardus</i> (I)			Leopard
	<i>Panthera tigris</i> (I)			Tiger
	<i>Pardofelis marmorata</i> (I)			Marbled cat
	<i>Prionailurus bengalensis bengalensis</i> (I) (Only the populations of Bangladesh, India and Thailand; all other populations are included in Annex B)			Bengal leopard cat
	<i>Prionailurus iriomotensis</i> (II)			Iriomote cat
	<i>Prionailurus planiceps</i> (I)			Flat-headed cat
	<i>Prionailurus rubiginosus</i> (I) (Only the population of India; all other populations are included in Annex B)			Rusty-spotted cat

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Puma concolor coryi</i> (I)			Florida cougar
	<i>Puma concolor costaricensis</i> (I)			Costa Rican cougar
	<i>Puma concolor cougar</i> (I)			Eastern cougar
	<i>Puma yagouaroundi</i> (I) (Only the populations of Central and North America; all other populations are included in Annex B)			Jaguarundi
	<i>Uncia uncia</i> (I)			Snow leopard
<i>Herpestidae</i>				Mongoose
			<i>Herpestes fuscus</i> (III India)	Indian brown mongoose
			<i>Herpestes edwardsi</i> (III India)	Indian grey mongoose
			<i>Herpestes javanicus auro-punctatus</i> (III India)	Small Indian mongoose
			<i>Herpestes smithii</i> (III India)	Ruddy mongoose
			<i>Herpestes urva</i> (III India)	Crab-eating mongoose
			<i>Herpestes vitticollis</i> (III India)	Stripe-necked mongoose
<i>Hyaenidae</i>				Aardwolf, hyenas
			<i>Proteles cristata</i> (III Botswana)	Aardwolf
<i>Mephitidae</i>				Skunks
		<i>Conepatus humboldtii</i> (II)		Humboldt's hog-nosed skunk
<i>Mustelidae</i>				Badgers, martens, weasels etc.
<i>Lutrinae</i>				Otters
		Lutrinae spp. (II) (Except for the species included in Annex A)		Otters
	<i>Aonyx capensis microdon</i> (I) (Only the populations of Cameroon and Nigeria; all other populations are included in Annex B)			Cameroon clawless otter

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Enhydra lutris nereis</i> (I)			Southern sea otter
	<i>Lontra felina</i> (I)			Marine otter
	<i>Lontra longicaudis</i> (I)			Neotropical otter
	<i>Lontra provocax</i> (I)			Southern river otter
	<i>Lutra lutra</i> (I)			European otter
	<i>Lutra nippon</i> (I)			Japanese otter
	<i>Pteronura brasiliensis</i> (I)			Giant otter
Mustelinae				Grisons, martens, tayra, weasels
			<i>Eira barbara</i> (III Honduras)	Tayra
			<i>Galictis vittata</i> (III Costa Rica)	Greater grison
			<i>Martes flavigula</i> (III India)	Yellow-throated marten
			<i>Martes foina intermedia</i> (III India)	Stone marten
			<i>Martes gwatkinsii</i> (III India)	Nilgiri marten
			<i>Mellivora capensis</i> (III Botswana)	Honey badger
	<i>Mustela nigripes</i> (I)			Black-footed ferret
Odobenidae				Walrus
		<i>Odobenus rosmarus</i> (III Canada)		Walrus
Otariidae				Fur seals, sealions
		<i>Arctocephalus</i> spp. (II) (Except for the species included in Annex A)		Fur seals
	<i>Arctocephalus philippii</i> (II)			Juan Fernández fur seal
	<i>Arctocephalus townsendi</i> (I)			Guadalupe fur seal
Phocidae				Seals
		<i>Mirounga leonina</i> (II)		Southern elephant seal
	<i>Monachus</i> spp. (I)			Monk seals

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Procyonidae</i>				<i>Coatis, olingos</i>
			<i>Bassaricyon gabbii</i> (III Costa Rica)	Olingo
			<i>Bassariscus sumichrasti</i> (III Costa Rica)	Cacomistle
			<i>Nasua narica</i> (III Honduras)	White-nosed coati
			<i>Nasua nasua solitaria</i> (III Uruguay)	South Brazilian coati
			<i>Potos flavus</i> (III Honduras)	Kinkajou
<i>Ursidae</i>				<i>Bears</i>
		Ursidae spp. (II) (Except for the species included in Annex A)		Bears
	<i>Ailuropoda melanoleuca</i> (I)			Giant panda
	<i>Helarctos malayanus</i> (I)			Sun bear
	<i>Melursus ursinus</i> (I)			Sloth bear
	<i>Tremarctos ornatus</i> (I)			Spectacled bear
	<i>Ursus arctos</i> (I/II) (Only the populations of Bhutan, China, Mexico and Mongolia and the subspecies <i>Ursus arctos isabellinus</i> are listed in Appendix I; all other populations and subspecies are listed in Appendix II)			Brown bear
	<i>Ursus thibetanus</i> (I)			Asian black bear
<i>Viverridae</i>				<i>Binturong, civets, linsangs, otter-civet, palm civet</i>
			<i>Arctictis binturong</i> (III India)	Binturong
			<i>Civettictis civetta</i> (III Botswana)	African civet
		<i>Cynogale bennettii</i> (II)		Otter civet
		<i>Hemigalus derbyanus</i> (II)		Banded palm civet
			<i>Paguma larvata</i> (III India)	Masked palm civet

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
			<i>Paradoxurus hermaphroditus</i> (III India)	Asian palm civet
			<i>Paradoxurus jerdoni</i> (III India)	Jerdon's palm civet
		<i>Prionodon linsang</i> (II)		Banded linsang
	<i>Prionodon pardicolor</i> (I)			Spotted linsang
			<i>Viverra civettina</i> (III India)	Malabar large-spotted civet
			<i>Viverra zibetha</i> (III India)	Large Indian civet
			<i>Viverricula indica</i> (III India)	Small Indian civet
CETACEA				Cetaceans (dolphins, porpoises, whales)
	CETACEA spp. (I/II) ⁽¹⁾			Cetaceans
CHIROPTERA				
<i>Phyllostomidae</i>				Broad-nosed bats
			<i>Platyrrhinus lineatus</i> (III Uruguay)	White-lined bat
<i>Pteropodidae</i>				Fruit bats, flying foxes
		<i>Acerodon</i> spp. (II) (Except for the species included in Annex A)		Flying foxes
	<i>Acerodon jubatus</i> (I)			Golden-capped fruit bat
		<i>Pteropus</i> spp. (II) (Except for the species included in Annex A)		Flying foxes
	<i>Pteropus insularis</i> (I)			Ruck flying fox
	<i>Pteropus livingstonii</i> (II)			Comoro flying fox
	<i>Pteropus loochoensis</i> (I)			Japanese flying fox
	<i>Pteropus mariannus</i> (I)			Marianas flying fox

⁽¹⁾ All species are listed in Appendix II except *Balaena mysticetus*, *Eubalaena* spp., *Balaenoptera acutorostrata* (except population of West Greenland), *Balaenoptera bonaerensis*, *Balaenoptera borealis*, *Balaenoptera edeni*, *Balaenoptera musculus*, *Balaenoptera omurai*, *Balaenoptera physalus*, *Megaptera novaeangliae*, *Orcaella brevirostris*, *Orcaella heinsohni*, *Sotalia* spp., *Sousa* spp., *Eschrichtius robustus*, *Lipotes vexillifer*, *Caperea marginata*, *Neophocaena phocaenoides*, *Phocoena sinus*, *Physeter macrocephalus*, *Platanista* spp., *Berardius* spp., *Hyperoodon* spp., which are listed in Appendix I. Specimens of the species listed in Appendix II to the Convention, including products and derivatives other than meat products for commercial purposes, taken by the people of Greenland under licence granted by the competent authority concerned, shall be treated as belonging to Annex B. A zero annual export quota is established for live specimens from the Black Sea population of *Tursiops truncatus* removed from the wild and traded for primarily commercial purposes.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Pteropus molossinus</i> (I)			Caroline flying fox
	<i>Pteropus pelewensis</i> (I)			Pelew flying fox
	<i>Pteropus pilosus</i> (I)			Large Pelew flying fox
	<i>Pteropus rodricensis</i> (II)			Rodrigues flying fox
	<i>Pteropus samoensis</i> (I)			Samoan flying fox
	<i>Pteropus tonganus</i> (I)			Pacific flying fox
	<i>Pteropus ualanus</i> (I)			Kosrae flying fox
	<i>Pteropus voeltzkowi</i> (II)			Pemba flying fox
	<i>Pteropus yapensis</i> (I)			Yap flying fox
CINGULATA				
<i>Dasypodidae</i>				<i>Armadillos</i>
			<i>Cabassous centralis</i> (III Costa Rica)	Northern naked-tailed armadillo
			<i>Cabassous tatouay</i> (III Uruguay)	Greater naked-tailed armadillo
		<i>Chaetophractus nationi</i> (II) (A zero annual export quota has been established. All specimens shall be deemed to be specimens of species included in Annex A and the trade in them shall be regulated accordingly)		Andean hairy armadillo
	<i>Priodontes maximus</i> (I)			Giant armadillo
DASYUROMORPHIA				
<i>Dasyuridae</i>				<i>Dunnarts, marsupial mice, planigales</i>
	<i>Sminthopsis longicaudata</i> (I)			Long-tailed dunnart
	<i>Sminthopsis psammophila</i> (I)			Sandhill dunnart
<i>Thylacinidae</i>				<i>Tasmanian wolf, thylacine</i>
	<i>Thylacinus cynocephalus</i> (possibly extinct) (I)			Thylacine

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
DIPROTODONTIA				
<i>Macropodidae</i>				Kangaroos, wallabies
		<i>Dendrolagus inustus</i> (II)		Grizzled tree-kangaroo
		<i>Dendrolagus ursinus</i> (II)		Ursine tree-kangaroo
	<i>Lagorchestes hirsutus</i> (I)			Rufous hare-wallaby
	<i>Lagostrophus fasciatus</i> (I)			Banded hare-wallaby
	<i>Onychogalea fraenata</i> (I)			Bridled nail-tail wallaby
	<i>Onychogalea lunata</i> (I)			Crescent nail-tail wallaby
<i>Phalangeridae</i>				Cuscus
		<i>Phalanger intercastellanus</i> (II)		Eastern common cuscus
		<i>Phalanger mimicus</i> (II)		Southern common cuscus
		<i>Phalanger orientalis</i> (II)		Northern common cuscus
		<i>Spilocuscus kraemeri</i> (II)		Admiralty Island cuscus
		<i>Spilocuscus maculatus</i> (II)		Common spotted cuscus
		<i>Spilocuscus papuensis</i> (II)		Waigeou cuscus
<i>Potoroidae</i>				Rat-kangaroos
	<i>Bettongia</i> spp. (I)			Bettongs
	<i>Caloprymnus campestris</i> (possibly extinct) (I)			Desert rat-kangaroo
<i>Vombatidae</i>				Wombats
	<i>Lasiorhinus krefftii</i> (I)			Northern hairy-nosed wombat
LAGOMORPHA				
<i>Leporidae</i>				Hares, rabbits
	<i>Caprolagus hispidus</i> (I)			Hispid hare
	<i>Romerolagus diazi</i> (I)			Volcano rabbit

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
MONOTREMATA				
<i>Tachyglossidae</i>				<i>Echidnas, spiny anteaters</i>
		<i>Zaglossus</i> spp. (II)		Long-beaked echidnas
PERAMELEMORPHIA				
<i>Chaeropodidae</i>				<i>Bandicoots</i>
	<i>Chaeropus ecaudatus</i> (possibly extinct) (I)			Pig-footed bandicoot
<i>Peramelidae</i>				
	<i>Perameles bougainville</i> (I)			Western barred bandicoot
<i>Thylacomyidae</i>				
	<i>Macrotis lagotis</i> (I)			Greater bilby
	<i>Macrotis leucura</i> (I)			Lesser bilby
PERISSODACTYLA				
<i>Equidae</i>				<i>Horses, wild asses, zebras</i>
	<i>Equus africanus</i> (I) (Excludes the domesticated form referenced as <i>Equus asinus</i> , which is not subject to the provisions of this Regulation)			African ass
	<i>Equus grevyi</i> (I)			Grévy's zebra
	<i>Equus hemionus</i> (I/II) (The species is listed in Appendix II but subspecies <i>Equus hemionus hemionus</i> and <i>Equus hemionus khur</i> are listed in Appendix I)			Asiatic wild ass
	<i>Equus kiang</i> (II)			Kiang
	<i>Equus przewalskii</i> (I)			Przewalski's horse
		<i>Equus zebra hartmannae</i> (II)		Hartmann's mountain zebra
	<i>Equus zebra zebra</i> (I)			Cape mountain zebra

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Rhinocerotidae</i>				<i>Rhinoceroses</i>
	Rhinocerotidae spp. (I) (Except for the subspecies included in Annex B)			Rhinoceroses
		<i>Ceratotherium simum simum</i> (II) (Only the populations of South Africa and Swaziland; all other populations are included in Annex A. For the exclusive purpose of allowing international trade in live animals to appropriate and acceptable destinations and trade in hunting trophies. All other specimens shall be deemed to be specimens of species included in Annex A and trade in them shall be regulated accordingly)		Southern white rhinoceros
<i>Tapiridae</i>				<i>Tapirs</i>
	Tapiridae spp. (I) (Except for the species included in Annex B)			Tapirs
		<i>Tapirus terrestris</i> (II)		South American tapir
PHOLIDOTA				
<i>Manidae</i>				<i>Pangolins</i>
		<i>Manis</i> spp. (II) (A zero annual export quota has been established for <i>Manis crassicaudata</i> , <i>Manis culionensis</i> , <i>Manis javanica</i> and <i>Manis pentadactyla</i> for specimens removed from the wild and traded for primarily commercial purposes)		Pangolins
PILOSA				
<i>Bradypodidae</i>				<i>Three-toed sloths</i>
		<i>Bradypus variegatus</i> (II)		Brown-throated sloth
<i>Megalonychidae</i>				<i>Two-toed sloth</i>
			<i>Choloepus hoffmanni</i> (III) Costa Rica)	Hoffmann's two-toed sloth
<i>Myrmecophagidae</i>				<i>American anteaters</i>
		<i>Myrmecophaga tridactyla</i> (II)		Giant anteater

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
			<i>Tamandua mexicana</i> (III Guatemala)	Northern tamandua
PRIMATES				<i>Primates (apes and monkeys)</i>
		PRIMATES spp. (II) (Except for the species included in Annex A)		Primates
<i>Atelidae</i>				<i>Howlers, spider monkeys</i>
	<i>Alouatta coibensis</i> (I)			Coiba Island howler
	<i>Alouatta palliata</i> (I)			Mantled howler
	<i>Alouatta pigra</i> (I)			Guatemalan black howler
	<i>Ateles geoffroyi frontatus</i> (I)			Black-browed spider monkey
	<i>Ateles geoffroyi panamensis</i> (I)			Red spider monkey
	<i>Brachyteles arachnoides</i> (I)			Southern muriqui
	<i>Brachyteles hypoxanthus</i> (I)			
	<i>Oreonax flavicauda</i> (I)			Yellow-tailed woolly monkey
<i>Cebidae</i>				<i>Marmosets, tamarins, New-world monkeys</i>
	<i>Callimico goeldii</i> (I)			Goeldi's marmoset
	<i>Callithrix aurita</i> (I)			Buffy-tufted marmoset
	<i>Callithrix flaviceps</i> (I)			Buffy-headed marmoset
	<i>Leontopithecus</i> spp. (I)			Lion tamarins
	<i>Saguinus bicolor</i> (I)			Pied tamarin
	<i>Saguinus geoffroyi</i> (I)			Geoffroy's tamarin
	<i>Saguinus leucopus</i> (I)			White-footed tamarin
	<i>Saguinus martinsi</i> (I)			
	<i>Saguinus oedipus</i> (I)			Cottontop tamarin
	<i>Saimiri oerstedii</i> (I)			Central American squirrel monkey
<i>Cercopithecidae</i>				<i>Old-world monkeys</i>
	<i>Cercocebus galeritus</i> (I)			Tana River mangabey

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Cercopithecus diana</i> (I)			Diana monkey
	<i>Cercopithecus roloway</i> (I)			Roloway monkey
	<i>Cercopithecus solatus</i> (II)			Sun-tailed monkey
	<i>Colobus satanas</i> (II)			Black colobus
	<i>Macaca silenus</i> (I)			Lion-tailed macaque
	<i>Mandrillus leucophaeus</i> (I)			Drill
	<i>Mandrillus sphinx</i> (I)			Mandrill
	<i>Nasalis larvatus</i> (I)			Proboscis monkey
	<i>Ptilocolobus foai</i> (II)			Central African red colobus
	<i>Ptilocolobus gordonorum</i> (II)			Uzungwa red colobus
	<i>Ptilocolobus kirkii</i> (I)			Zanzibar red colobus
	<i>Ptilocolobus pennantii</i> (II)			Pennant's red colobus
	<i>Ptilocolobus preussi</i> (II)			Preuss's red colobus
	<i>Ptilocolobus rufomitratu</i> s (I)			Tana River red colobus
	<i>Ptilocolobus tephrosceles</i> (II)			Ugandan red colobus
	<i>Ptilocolobus tholloni</i> (II)			Thollon's red colobus
	<i>Presbytis potenziani</i> (I)			Mentawai langur
	<i>Pygathrix</i> spp. (I)			Douc langurs
	<i>Rhinopithecus</i> spp. (I)			Snub-nosed monkeys
	<i>Semnopithecus ajax</i> (I)			Kashmir grey langur
	<i>Semnopithecus dussumieri</i> (I)			Southern Plains grey langur
	<i>Semnopithecus entellus</i> (I)			Northern Plains grey langur
	<i>Semnopithecus hector</i> (I)			Tarai grey langur
	<i>Semnopithecus hypoleucos</i> (I)			Black-footed grey langur
	<i>Semnopithecus priam</i> (I)			Tufted grey langur
	<i>Semnopithecus schistaceus</i> (I)			Nepal grey langur

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Simias concolor</i> (I)			Simakobou
	<i>Trachypithecus delacouri</i> (II)			Delacour's langur
	<i>Trachypithecus francoisi</i> (II)			François's langur
	<i>Trachypithecus geei</i> (I)			Gee's golden langur
	<i>Trachypithecus hatinhensis</i> (II)			Hatinh langur
	<i>Trachypithecus johnii</i> (II)			Nilgiri langur
	<i>Trachypithecus laotum</i> (II)			Laotian langur
	<i>Trachypithecus pileatus</i> (I)			Capped langur
	<i>Trachypithecus poliocephalus</i> (II)			White-headed langur
	<i>Trachypithecus shortridgei</i> (I)			Shortridge's langur
<i>Cheirogaleidae</i>				<i>Dwarf lemurs and mouse-lemurs</i>
	<i>Cheirogaleidae</i> spp. (I)			Dwarf lemurs and mouse lemurs
<i>Daubentoniidae</i>				<i>Aye-aye</i>
	<i>Daubentonia madagascariensis</i> (I)			Aye-aye
<i>Hominidae</i>				<i>Chimpanzees, gorillas, orang-utan</i>
	<i>Gorilla beringei</i> (I)			Eastern gorilla
	<i>Gorilla gorilla</i> (I)			Western gorilla
	<i>Pan</i> spp. (I)			Chimpanzee and bonobo
	<i>Pongo abelii</i> (I)			Sumatran orangutan
	<i>Pongo pygmaeus</i> (I)			Bornean orangutan
<i>Hylobatidae</i>				<i>Gibbons</i>
	<i>Hylobatidae</i> spp. (I)			Gibbons
<i>Indriidae</i>				<i>Indri, sifakas and woolly lemurs</i>
	<i>Indriidae</i> spp. (I)			Indri, sifakas and woolly lemurs

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Lemuridae</i>				<i>Large lemurs</i>
	<i>Lemuridae</i> spp. (I)			<i>Large lemurs</i>
<i>Lepilemuridae</i>				<i>Sportive lemurs</i>
	<i>Lepilemuridae</i> spp. (I)			<i>Sportive lemurs</i>
<i>Lorisidae</i>				<i>Lorises</i>
	<i>Nycticebus</i> spp. (I)			<i>Slow lorises</i>
<i>Pitheciidae</i>				<i>Uacaris, titis, sakis</i>
	<i>Cacajao</i> spp. (I)			<i>Uacaris</i>
	<i>Callicebus barbarabrownae</i> (II)			<i>Barbara Brown's Titi</i>
	<i>Callicebus melanochir</i> (II)			<i>Coastal Black-handed Titi</i>
	<i>Callicebus nigrifrons</i> (II)			<i>Black-fronted Titi</i>
	<i>Callicebus personatus</i> (II)			<i>Atlantic titi</i>
	<i>Chiropotes albinasus</i> (I)			<i>White-nosed saki</i>
<i>Tarsiidae</i>				<i>Tarsiers</i>
	<i>Tarsius</i> spp. (II)			<i>Tarsiers</i>
PROBOSCIDEA				
<i>Elephantidae</i>				<i>Elephants</i>
	<i>Elephas maximus</i> (I)			<i>Asian elephant</i>

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Loxodonta africana</i> (I) (Except for the populations of Botswana, Namibia, South Africa and Zimbabwe, which are included in Annex B)	<i>Loxodonta africana</i> (II) (Only the populations of Botswana, Namibia, South Africa and Zimbabwe ⁽¹⁾ ; all other populations are included in Annex A)		African elephant
RODENTIA				
<i>Chinchillidae</i>				<i>Chinchillas</i>
	<i>Chinchilla</i> spp. (I) (Specimens of the domesticated form are not subject to the provisions of this Regulation)			Chinchillas
<i>Cuniculidae</i>				Pacas
			<i>Cuniculus paca</i> (III Honduras)	Lowland paca
<i>Dasyproctidae</i>				Agoutis
			<i>Dasyprocta punctata</i> (III Honduras)	Central American agouti
<i>Erethizontidae</i>				New-world porcupines

⁽¹⁾ Populations of Botswana, Namibia, South Africa and Zimbabwe (listed in Annex B): For the exclusive purpose of allowing: (a) trade in hunting trophies for non-commercial purposes; (b) trade in live animals to appropriate and acceptable destinations as defined in Resolution Conf. 11.20 for Botswana and Zimbabwe and for *in situ* conservation programmes for Namibia and South Africa; (c) trade in hides; (d) trade in hair; (e) trade in leather goods for commercial or non-commercial purposes for Botswana, Namibia and South Africa and for non-commercial purposes for Zimbabwe; (f) trade in individually marked and certified Ekipas incorporated in finished jewellery for non-commercial purposes for Namibia and ivory carvings for non-commercial purposes for Zimbabwe; (g) trade in registered raw ivory (for Botswana, Namibia, South Africa and Zimbabwe whole tusks and pieces) subject to the following: (i) only registered government-owned stocks, originating in the State (excluding seized ivory and ivory of unknown origin); (ii) only to trading partners that have been verified by the Secretariat, in consultation with the Standing Committee, to have sufficient national legislation and domestic trade controls to ensure that the imported ivory will not be re-exported and will be managed in accordance with all requirements of Resolution Conf. 10.10 (Rev. CoP14) concerning domestic manufacturing and trade; (iii) not before the Secretariat has verified the prospective importing countries and the registered government-owned stocks; (iv) raw ivory pursuant to the conditional sale of registered government-owned ivory stocks agreed at COP12 which are 20 000 kg (Botswana), 10 000 kg (Namibia), 30 000 kg (South Africa); (v) in addition to the quantities agreed at CoP12, government-owned ivory from Botswana, Zimbabwe, Namibia and South Africa registered by the 31st of January 2007 and verified by the Secretariat may be traded and despatched, with the ivory in (g)(iv) in a single sale per destination under strict supervision of the Secretariat; (vi) the proceeds of the trade are used exclusively for elephant conservation and community conservation and development programmes within or adjacent to the elephant range; and (vii) the additional quantities specified in (g)(v) shall be traded only after the Standing Committee has agreed that the above conditions have been met; (h) no further proposals to allow trade in elephant ivory from populations already on Annex B shall be submitted to the Conference of the Parties for the period from CoP14 and ending nine years from the date of the single sale of ivory that is to take place in accordance with provisions in paragraph (g)(i), (g)(ii), (g)(iii), (g)(vi), and (g)(vii). In addition, such further proposals shall be dealt with in accordance with Decisions 14.77 and 14.78. On a proposal from the Secretariat, the Standing Committee can decide to cause this trade to cease partially or completely in the event of non-compliance by exporting or importing countries, or in the case of proven detrimental impacts of the trade on other elephant populations. All other specimens shall be deemed to be specimens of species included in Annex A and the trade in them shall be regulated accordingly.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
			<i>Sphiggurus mexicanus</i> (III Honduras)	Mexican hairy dwarf porcupine
			<i>Sphiggurus spinosus</i> (III Uruguay)	Paraguayan hairy dwarf porcupine
<i>Hystriidae</i>				Old-world porcupines
	<i>Hystrix cristata</i>			Crested porcupine
<i>Muridae</i>				Mice, rats
	<i>Leporillus conditor</i> (I)			Greater stick-nest rat
	<i>Pseudomys fieldi praeconis</i> (I)			Shark Bay mouse
	<i>Xeromys myoides</i> (I)			False water rat
	<i>Zyomys pedunculatus</i> (I)			Central Australian rock rat
<i>Sciuridae</i>				Ground squirrels, tree squirrels
	<i>Cynomys mexicanus</i> (I)			Mexican prairie dog
			<i>Marmota caudata</i> (III India)	Long-tailed marmot
			<i>Marmota himalayana</i> (III India)	Himalayan marmot
		<i>Ratufa</i> spp. (II)		Giant squirrels
		<i>Callosciurus erythraeus</i>		Pallas's Squirrel
		<i>Sciurus carolinensis</i>		Grey squirrel
			<i>Sciurus deppei</i> (III Costa Rica)	Deppe's squirrel
		<i>Sciurus niger</i>		Eastern Fox Squirrel
SCANDENTIA				
		SCANDENTIA spp. (II)		Treeshrews
SIRENIA				
<i>Dugongidae</i>				Dugong
	<i>Dugong dugon</i> (I)			Dugong

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Trichechidae</i>				<i>Manatees</i>
	Trichechidae spp. (I/II) (<i>Trichechus inunguis</i> and <i>Trichechus manatus</i> are listed in Appendix I. <i>Trichechus senegalensis</i> is listed in Appendix II)			Manatees
AVES				<i>Birds</i>
ANSERIFORMES				
<i>Anatidae</i>				<i>Ducks, geese, swans etc.</i>
	<i>Anas aucklandica</i> (I)			Auckland Islands teal
		<i>Anas bernieri</i> (II)		Madagascar teal
	<i>Anas chlorotis</i> (I)			Brown teal
		<i>Anas formosa</i> (II)		Baikal teal
	<i>Anas laysanensis</i> (I)			Laysan duck
	<i>Anas nesiotis</i> (I)			Campbell Island teal
	<i>Anas querquedula</i>			Garganey
	<i>Asarcornis scutulata</i> (I)			White-winged duck
	<i>Aythya innotata</i>			Madagascar pochard
	<i>Aythya nyroca</i>			Ferruginous duck
	<i>Branta canadensis leucopareia</i> (I)			Aleutian goose
	<i>Branta ruficollis</i> (II)			Red-breasted goose
	<i>Branta sandvicensis</i> (I)			Nene
			<i>Cairina moschata</i> (III Honduras)	Muscovy duck
		<i>Coscoroba coscoroba</i> (II)		Coscoroba swan
		<i>Cygnus melancoryphus</i> (II)		Black-necked swan

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
		<i>Dendrocygna arborea</i> (II)		West Indian whistling-duck
			<i>Dendrocygna autumnalis</i> (III Honduras)	Black-bellied whistling-duck
			<i>Dendrocygna bicolor</i> (III Honduras)	Fulvous whistling-duck
	<i>Mergus octosetaceus</i>			Brazilian merganser
		<i>Oxyura jamaicensis</i>		Ruddy duck
	<i>Oxyura leucocephala</i> (II)			White-headed duck
	<i>Rhodonessa caryophyllacea</i> (possibly extinct) (I)			Pink-headed duck
		<i>Sarkidiornis melanotos</i> (II)		Comb duck
	<i>Tadorna cristata</i>			Crested shelduck
APODIFORMES				
Trochilidae				Hummingbirds
		Trochilidae spp. (II) (Except for the species included in Annex A)		Hummingbirds
	<i>Glaucis dohrnii</i> (I)			Hook-billed hermit
CHARADRIIFORMES				
Burhinidae				Thick-knees
			<i>Burhinus bistriatus</i> (III Guatemala)	Double-striped thick-knee
Laridae				Gulls, terns
	<i>Larus relictus</i> (I)			Relict gull
Scolopacidae				Curlews, greenshanks
	<i>Numenius borealis</i> (I)			Eskimo curlew
	<i>Numenius tenuirostris</i> (I)			Slender-billed curlew
	<i>Tringa guttifer</i> (I)			Nordmann's greenshank
CICONIIFORMES				
Ardeidae				Egrets, herons

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Ardea alba</i>			Great egret
	<i>Bubulcus ibis</i>			Cattle egret
	<i>Egretta garzetta</i>			Little egret
<i>Balaenicipitidae</i>				<i>Shoebill, whale-headed stork</i>
		<i>Balaeniceps rex</i> (II)		Shoebill
<i>Ciconiidae</i>				Storks
	<i>Ciconia boyciana</i> (I)			Oriental stork
	<i>Ciconia nigra</i> (II)			Black stork
	<i>Ciconia stormi</i>			Storm's stork
	<i>Jabiru mycteria</i> (I)			Jabiru
	<i>Leptoptilos dubius</i>			Greater adjutant stork
	<i>Mycteria cinerea</i> (I)			Milky stork
<i>Phoenicopteridae</i>				Flamingos
		Phoenicopteridae spp. (II) (Except for the species included in Annex A)		Flamingos
	<i>Phoenicopiterus ruber</i> (II)			Greater flamingo
<i>Threskiornithidae</i>				Ibises, spoonbills
		<i>Eudocimus ruber</i> (II)		Scarlet ibis
	<i>Geronticus calvus</i> (II)			Bald ibis
	<i>Geronticus eremita</i> (I)			Waldrapp
	<i>Nipponia nippon</i> (I)			Crested ibis
	<i>Platalea leucorodia</i> (II)			Eurasian spoonbill
	<i>Pseudibis gigantea</i>			Giant ibis
COLUMBIFORMES				
<i>Columbidae</i>				Doves, pigeons

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Caloenas nicobarica</i> (I)			Nicobar pigeon
	<i>Claravis godefrida</i>			Purple-winged ground-dove
	<i>Columba livia</i>			Rock pigeon
	<i>Ducula mindorensis</i> (I)			Mindoro zone-tailed pigeon
		<i>Gallicolumba luzonica</i> (II)		Luzon bleeding-heart
		<i>Goura</i> spp. (II)		Crowned-pigeons
	<i>Leptotila wellsi</i>			Grenada dove
			<i>Nesoenas mayeri</i> (III Mauritius)	Pink pigeon
	<i>Streptopelia turtur</i>			European turtle-dove
CORACIFORMES				
Bucerotidae				Hornbills
		<i>Aceros</i> spp. (II) (Except for the species included in Annex A)		Hornbills
	<i>Aceros nipalensis</i> (I)			Rufous-necked hornbill
		<i>Anorrhinus</i> spp. (II)		Hornbills
		<i>Anthracoceros</i> spp. (II)		Hornbills
		<i>Berenicornis</i> spp. (II)		Hornbills
		<i>Buceros</i> spp. (II) (Except for the species included in Annex A)		Hornbills
	<i>Buceros bicornis</i> (I)			Great hornbill
		<i>Penelopides</i> spp. (II)		Hornbills
	<i>Rhinoplax vigil</i> (I)			Helmeted hornbill
		<i>Rhyticeros</i> spp. (II) (Except for the species included in Annex A)		Hornbills
	<i>Rhyticeros subruficollis</i> (I)			Plain-pouched hornbill
CUCULIFORMES				
Musophagidae				Turacos

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
		<i>Tauraco</i> spp. (II) (Except for the species included in Annex A)		Turacos
	<i>Tauraco bannermani</i> (II)			Bannerman's turaco
FALCONIFORMES				<i>Diurnal birds of prey (eagles, falcons, hawks, vultures)</i>
		FALCONIFORMES spp. (II) (Except for the species included in Annex A and for one species of the family Cathartidae included in Annex C; the other species of that family are not included in the Annexes to this Regulation)		Diurnal birds of prey
Accipitridae				<i>Hawks, eagles</i>
	<i>Accipiter brevipes</i> (II)			Levant sparrowhawk
	<i>Accipiter gentilis</i> (II)			Northern goshawk
	<i>Accipiter nisus</i> (II)			Eurasian sparrowhawk
	<i>Aegypius monachus</i> (II)			Cinereous vulture
	<i>Aquila adalberti</i> (I)			Adalbert's eagle
	<i>Aquila chrysaetos</i> (II)			Golden eagle
	<i>Aquila clanga</i> (II)			Greater spotted eagle
	<i>Aquila heliaca</i> (I)			Imperial eagle
	<i>Aquila pomarina</i> (II)			Lesser spotted eagle
	<i>Buteo buteo</i> (II)			Common buzzard
	<i>Buteo lagopus</i> (II)			Rough-legged buzzard
	<i>Buteo rufinus</i> (II)			Long-legged buzzard
	<i>Chondrohierax uncinatus wilsonii</i> (I)			Cuban hook-billed kite
	<i>Circaetus gallicus</i> (II)			Short-toed snake-eagle
	<i>Circus aeruginosus</i> (II)			Western marsh-harrier
	<i>Circus cyaneus</i> (II)			Northern harrier
	<i>Circus macrourus</i> (II)			Pallid harrier

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Circus pygargus</i> (II)			Montagu's harrier
	<i>Elanus caeruleus</i> (II)			Black-winged kite
	<i>Eutriorchis astur</i> (II)			Madagascar serpent-eagle
	<i>Gypaetus barbatus</i> (II)			Lammergeier
	<i>Gyps fulvus</i> (II)			Eurasian griffon
	<i>Haliaeetus</i> spp. (I/II) (<i>Haliaeetus albicilla</i> is listed in Appendix I; the other species are listed in Appendix II)			Sea-eagles
	<i>Harpia harpyja</i> (I)			Harpy eagle
	<i>Hieraaetus fasciatus</i> (II)			Bonelli's eagle
	<i>Hieraaetus pennatus</i> (II)			Booted eagle
	<i>Leucopternis occidentalis</i> (II)			Grey-backed hawk
	<i>Milvus migrans</i> (II) (Except for <i>Milvus migrans lineatus</i> which is included in Annex B)			Black kite
	<i>Milvus milvus</i> (II)			Red kite
	<i>Neophron percnopterus</i> (II)			Egyptian vulture
	<i>Pernis apivorus</i> (II)			European honey-buzzard
	<i>Pithecophaga jefferyi</i> (I)			Great Philippine eagle
<i>Cathartidae</i>				<i>New world vultures</i>
	<i>Gymnogyps californianus</i> (I)			California condor
			<i>Sarcoramphus papa</i> (III Honduras)	King vulture
	<i>Vultur gryphus</i> (I)			Andean condor
<i>Falconidae</i>				<i>Falcons</i>
	<i>Falco araeus</i> (I)			Seychelles kestrel
	<i>Falco biarmicus</i> (II)			Lanner falcon
	<i>Falco cherrug</i> (II)			Saker falcon
	<i>Falco columbarius</i> (II)			Merlin

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Falco eleonora</i> (II)			Eleonora's falcon
	<i>Falco jugger</i> (I)			Laggar falcon
	<i>Falco naumanni</i> (II)			Lesser kestrel
	<i>Falco newtoni</i> (I) (Only the population of the Seychelles)			Newton's kestrel
	<i>Falco pelegrinoides</i> (I)			Barbary falcon
	<i>Falco peregrinus</i> (I)			Peregrine falcon
	<i>Falco punctatus</i> (I)			Mauritius kestrel
	<i>Falco rusticolus</i> (I)			Gyr falcon
	<i>Falco subbuteo</i> (II)			Eurasian hobby
	<i>Falco tinnunculus</i> (II)			Common kestrel
	<i>Falco vespertinus</i> (II)			Red-footed falcon
<i>Pandionidae</i>				Ospreys
	<i>Pandion haliaetus</i> (II)			Osprey
GALLIFORMES				
<i>Cracidae</i>				
	<i>Crax alberti</i> (III Colombia)			Blue-knobbed curassow
	<i>Crax blumenbachii</i> (I)			Red-billed curassow
			<i>Crax daubentoni</i> (III Colombia)	Yellow-knobbed curassow
		<i>Crax fasciolata</i>		Bare-faced Curassow
			<i>Crax globulosa</i> (III Colombia)	Wattled curassow
			<i>Crax rubra</i> (III Colombia, Costa Rica, Guatemala and Honduras)	Great curassow
	<i>Mitu mitu</i> (I)			Alagoas curassow
	<i>Oreophasis derbianus</i> (I)			Horned guan

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
			<i>Ortalis vetula</i> (III Guatemala/Honduras)	Plain chachalaca
			<i>Pauxi pauxi</i> (III Colombia)	Helmeted curassow
	<i>Penelope albipennis</i> (I)			White-winged guan
			<i>Penelope purpurascens</i> (III Honduras)	Crested guan
			<i>Penelopina nigra</i> (III Guatemala)	Highland guan
	<i>Pipile jacutinga</i> (I)			Black-fronted piping guan
	<i>Pipile pipile</i> (I)			Trinidad piping guan
<i>Megapodiidae</i>				<i>Megapodes</i> , scrubfowl
	<i>Macrocephalon maleo</i> (I)			Maleo
<i>Phasianidae</i>				Grouse, guineafowl, partridges, pheasants, tragopans
		<i>Argusianus argus</i> (II)		Great argus
	<i>Catreus wallichii</i> (I)			Cheer pheasant
	<i>Colinus virginianus ridgwayi</i> (I)			Masked bobwhite
	<i>Crossoptilon crossoptilon</i> (I)			White eared-pheasant
	<i>Crossoptilon mantchuricum</i> (I)			Brown eared-pheasant
		<i>Gallus sonneratii</i> (II)		Grey junglefowl
		<i>Ithaginis cruentus</i> (II)		Blood pheasant
	<i>Lophophorus impejanus</i> (I)			Himalayan monal
	<i>Lophophorus lhuysii</i> (I)			Chinese monal
	<i>Lophophorus sclateri</i> (I)			Sclater's monal
	<i>Lophura edwardsi</i> (I)			Edwards' pheasant
		<i>Lophura hatinhensis</i>		Vietnamese fireback
	<i>Lophura imperialis</i> (I)			Imperial pheasant
	<i>Lophura swinhoii</i> (I)			Swinhoe's pheasant

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
			<i>Meleagris ocellata</i> (III Guatemala)	Ocellated turkey
	<i>Odontophorus strophium</i>			Gorgeted wood-quail
	<i>Ophrysia superciliosa</i>			Himalayan quail
		<i>Pavo muticus</i> (II)		Green peafowl
		<i>Polyplectron bicalcaratum</i> (II)		Grey peacock-pheasant
		<i>Polyplectron germaini</i> (II)		Germain's peacock-pheasant
		<i>Polyplectron malacense</i> (II)		Malayan peacock-pheasant
	<i>Polyplectron napoleonis</i> (I)			Palawan peacock-pheasant
		<i>Polyplectron schleiermachersi</i> (II)		Bornean peacock-pheasant
	<i>Rheinardia ocellata</i> (I)			Crested argus
	<i>Syrmaticus ellioti</i> (I)			Elliot's pheasant
	<i>Syrmaticus humiae</i> (I)			Hume's pheasant
	<i>Syrmaticus mikado</i> (I)			Mikado pheasant
	<i>Tetraogallus caspius</i> (I)			Caspian snowcock
	<i>Tetraogallus tibetanus</i> (I)			Tibetan snowcock
	<i>Tragopan blythii</i> (I)			Blyth's tragopan
	<i>Tragopan caboti</i> (I)			Cabot's tragopan
	<i>Tragopan melanocephalus</i> (I)			Western tragopan
			<i>Tragopan satyra</i> (III Nepal)	Satyr tragopan
	<i>Tympanuchus cupido attwateri</i> (I)			Attwater's prairie-chicken
GRUIFORMES				
<i>Gruidae</i>				Cranes
		Gruidae spp. (II) (Except for the species included in Annex A)		Cranes
	<i>Grus americana</i> (I)			Whooping crane

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Grus canadensis</i> (I/II) (The species is listed in Appendix II but subspecies <i>Grus canadensis nesiotis</i> and <i>Grus canadensis pulla</i> are listed in Appendix I)			Sandhill crane
	<i>Grus grus</i> (II)			Common crane
	<i>Grus japonensis</i> (I)			Red-crowned crane
	<i>Grus leucogeranus</i> (I)			Siberian crane
	<i>Grus monacha</i> (I)			Hooded crane
	<i>Grus nigricollis</i> (I)			Black-necked crane
	<i>Grus vipio</i> (I)			White-necked crane
Otididae				Bustards
		Otididae spp. (II) (Except for the species included in Annex A)		Bustards
	<i>Ardeotis nigriceps</i> (I)			Indian bustard
	<i>Chlamydotis macqueenii</i> (I)			Macqueen's bustard
	<i>Chlamydotis undulata</i> (I)			Houbara bustard
	<i>Houbaropsis bengalensis</i> (I)			Bengal florican
	<i>Otis tarda</i> (II)			Great bustard
	<i>Sypheotides indicus</i> (II)			Lesser florican
	<i>Tetrax tetrax</i> (II)			Little bustard
Rallidae				Coots, rails
	<i>Gallirallus sylvestris</i> (I)			Lord Howe rail
Rhynochetidae				Kagu
	<i>Rhynochetos jubatus</i> (I)			Kagu
PASSERIFORMES				
Atrichornithidae				Scrub-birds
	<i>Atrichornis clamosus</i> (I)			Noisy scrub-bird

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
Cotingidae				Cotingas
			<i>Cephalopterus ornatus</i> (III Colombia)	Amazonian umbrella bird
			<i>Cephalopterus penduliger</i> (III Colombia)	Long-wattled umbrella bird
	<i>Cotinga maculata</i> (I)			Banded cotinga
		<i>Rupicola</i> spp. (II)		Cocks-of-the-rock
	<i>Xipholena atropurpurea</i> (I)			White-winged cotinga
Emberizidae				Cardinals, tanagers
		<i>Gubernatrix cristata</i> (II)		Yellow cardinal
		<i>Paroaria capitata</i> (II)		Yellow-billed cardinal
		<i>Paroaria coronata</i> (II)		Red-crested cardinal
		<i>Tangara fastuosa</i> (II)		Seven-coloured tanager
Estrildidae				Mannikins, waxbills
		<i>Amandava formosa</i> (II)		Green avadavat
		<i>Lonchura fuscata</i>		Timor sparrow
		<i>Lonchura oryzivora</i> (II)		Java sparrow
		<i>Poephila cincta cincta</i> (II)		Southern black-throated finch
Fringillidae				Finches
	<i>Carduelis cucullata</i> (I)			Red siskin
		<i>Carduelis yarrellii</i> (II)		Yellow-faced siskin
Hirundinidae				Martins
	<i>Pseudochelidon sirintarae</i> (I)			White-eyed river-martin
Icteridae				New-world blackbirds
	<i>Xanthopsar flavus</i> (I)			Saffron-cowled blackbird

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Meliphagidae</i>				<i>Honey-eaters</i>
	<i>Lichenostomus melanops cassidix</i> (I)			Helmeted honeyeater
<i>Muscicapidae</i>				<i>Old-world flycatchers, babblers, etc.</i>
	<i>Acrocephalus rodericanus</i> (III Mauritius)			Rodrigues brush-warbler
		<i>Cyornis ruckii</i> (II)		Rueck's blue-flycatcher
	<i>Dasyornis broadbenti litoralis</i> (possibly extinct) (I)			Western rufous bristlebird
	<i>Dasyornis longirostris</i> (I)			Western bristlebird
		<i>Garrulax canorus</i> (II)		Chinese Hwamei
		<i>Garrulax taewanus</i> (II)		Taiwan Hwamei
		<i>Leiothrix argentauris</i> (II)		Silver-eared mesia
		<i>Leiothrix lutea</i> (II)		Red-billed leiothrix
		<i>Liocichla omeiensis</i> (II)		Omei Shan liocichla
	<i>Picathartes gymnocephalus</i> (I)			White-necked rockfowl
	<i>Picathartes oreas</i> (I)			Grey-necked rockfowl
			<i>Terpsiphone bourbonensis</i> (III Mauritius)	Mascarene paradise-flycatcher
<i>Paradisaeidae</i>				<i>Birds of paradise</i>
		Paradisaeidae spp. (II)		Birds of paradise
<i>Pittidae</i>				<i>Pittas</i>
		<i>Pitta guajana</i> (II)		Banded pitta
	<i>Pitta gurneyi</i> (I)			Gurney's pitta
	<i>Pitta kochi</i> (I)			Whiskered pitta
		<i>Pitta nympha</i> (II)		Fairy pitta

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
Pycnonotidae				Bulbuls
		<i>Pycnonotus zealandicus</i> (II)		Straw-headed bulbul
Sturnidae				Mynas
		<i>Gracula religiosa</i> (II)		Hill myna
	<i>Leucopsar rothschildi</i> (I)			Bali myna
Zosteropidae				White-eyes
	<i>Zosterops albogularis</i> (I)			White-chested white-eye
PELECANIFORMES				
Fregatidae				Frigatebirds
	<i>Fregata andrewsi</i> (I)			Christmas frigatebird
Pelecanidae				Pelicans
	<i>Pelecanus crispus</i> (I)			Dalmatian pelican
Sulidae				Boobies
	<i>Papasula abbotti</i> (I)			Abbott's booby
PICIFORMES				
Capitonidae				Barbets
			<i>Semnornis ramphastinus</i> (III Colombia)	Toucan barbet
Picidae				Woodpeckers
	<i>Campephilus imperialis</i> (I)			Imperial woodpecker
	<i>Dryocopus javensis richardsi</i> (I)			Tristram's woodpecker
Ramphastidae				Toucans
			<i>Bailloni bailloni</i> (III Argentina)	Saffron toucanet
		<i>Pteroglossus aracari</i> (II)		Black-necked aracari
			<i>Pteroglossus castanotis</i> (III Argentina)	Chestnut-eared aracari
		<i>Pteroglossus viridis</i> (II)		Green aracari

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
			<i>Ramphastos dicolorus</i> (III Argentina)	Red-breasted toucan
		<i>Ramphastos sulfuratus</i> (II)		Keel-billed toucan
		<i>Ramphastos toco</i> (II)		Toco toucan
		<i>Ramphastos tucanus</i> (II)		Red-billed toucan
		<i>Ramphastos vitellinus</i> (II)		Channel-billed toucan
			<i>Selenidera maculirostris</i> (III Argentina)	Spot-billed toucanet
PODICIPEDIFORMES				
<i>Podicipedidae</i>				Grebes
		<i>Podilymbus gigas</i> (I)		Atitlan Grebe
PROCELLARIIFORMES				
<i>Diomedeidae</i>				Albatrosses
		<i>Phoebastria albatrus</i> (I)		Short-tailed albatross
PSITTACIFORMES				Cockatoos, lories, macaws, parakeets, parrots etc.
		PSITTACIFORMES spp. (II) (Except for the species included in Annex A and excluding <i>Agapornis roseicollis</i> , <i>Melopsittacus undulatus</i> , <i>Nymphicus hollandicus</i> and <i>Psittacula krameri</i> , which are not included in the Annexes to this Regulation)		Parrots, etc.
<i>Cacatuidae</i>				Cockatoos
		<i>Cacatua goffiniana</i> (I)		Tanimbar cockatoo
		<i>Cacatua haematuropygia</i> (I)		Philippine cockatoo
		<i>Cacatua moluccensis</i> (I)		Salmon-crested cockatoo
		<i>Cacatua sulphurea</i> (I)		Yellow-crested cockatoo
		<i>Probosciger aterrimus</i> (I)		Palm cockatoo

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Loriidae</i>				<i>Lories, lorikeets</i>
	<i>Eos histrio</i> (I)			Red and blue lory
	<i>Vini</i> spp. (I/II) (<i>Vini ultramarina</i> is listed in Appendix I, the other species are listed in Appendix II)			Blue lorikeets
<i>Psittacidae</i>				<i>Amazons, macaws, parakeets, parrots</i>
	<i>Amazona arausiaca</i> (I)			Red-necked parrot
	<i>Amazona auropalliata</i> (I)			Yellow-naped parrot
	<i>Amazona barbadensis</i> (I)			Yellow-shouldered parrot
	<i>Amazona brasiliensis</i> (I)			Red-tailed parrot
	<i>Amazona finschi</i> (I)			Lilac-crowned parrot
	<i>Amazona guildingii</i> (I)			St Vincent parrot
	<i>Amazona imperialis</i> (I)			Imperial parrot
	<i>Amazona leucocephala</i> (I)			Cuban parrot
	<i>Amazona oratrix</i> (I)			Yellow-headed parrot
	<i>Amazona pretrei</i> (I)			Red-spectacled parrot
	<i>Amazona rhodocorytha</i> (I)			Red-browed parrot
	<i>Amazona tucumana</i> (I)			Tucuman parrot
	<i>Amazona versicolor</i> (I)			Saint Lucia parrot
	<i>Amazona vinacea</i> (I)			Vinaceous parrot
	<i>Amazona viridigenalis</i> (I)			Green-cheeked parrot
	<i>Amazona vittata</i> (I)			Puerto Rican parrot
	<i>Anodorhynchus</i> spp. (I)			Blue macaws
	<i>Ara ambiguus</i> (I)			Great green macaw
	<i>Ara glaucogularis</i> (I)			Blue-throated macaw

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Ara macao</i> (I)			Scarlet macaw
	<i>Ara militaris</i> (I)			Military macaw
	<i>Ara rubrogenys</i> (I)			Red-fronted macaw
	<i>Cyanopsitta spixii</i> (I)			Spix's macaw
	<i>Cyanoramphus cookii</i> (I)			Norfolk Island parakeet
	<i>Cyanoramphus forbesi</i> (I)			Chatham Island yellow-fronted parakeet
	<i>Cyanoramphus novaezelandiae</i> (I)			Red-fronted parakeet
	<i>Cyanoramphus saisseti</i> (I)			Red-crowned parakeet
	<i>Cyclopsitta diophthalma coxeni</i> (I)			Coxen's double-eyed fig parrot
	<i>Eunymphicus cornutus</i> (I)			Horned parakeet
	<i>Guarouba guarouba</i> (I)			Golden parakeet
	<i>Neophema chrysogaster</i> (I)			Orange-bellied parrot
	<i>Ognorhynchus icterotis</i> (I)			Yellow-eared parrot
	<i>Pezoporus occidentalis</i> (possibly extinct) (I)			Night parrot
	<i>Pezoporus wallicus</i> (I)			Ground parrot
	<i>Pionopsitta pileata</i> (I)			Pileated parrot
	<i>Primolius couloni</i> (I)			Blue-headed macaw
	<i>Primolius maracana</i> (I)			Blue-winged macaw
	<i>Psephotus chrysopterygius</i> (I)			Golden-shouldered parrot
	<i>Psephotus dissimilis</i> (I)			Hooded parrot
	<i>Psephotus pulcherrimus</i> (possibly extinct) (I)			Paradise parrot
	<i>Psittacula echo</i> (I)			Mauritius parakeet
	<i>Pyrrhura cruentata</i> (I)			Blue-throated parakeet
	<i>Rhynchopsitta</i> spp. (I)			Thick-billed parrots

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Strigops habroptilus</i> (I)			Kakapo
RHEIFORMES				
<i>Rheidae</i>				<i>Rheas</i>
	<i>Pterocnemia pennata</i> (I) (Except <i>Pterocnemia pennata pennata</i> which is included in Annex B)			Lesser rhea
		<i>Pterocnemia pennata pennata</i> (II)		Lesser rhea
		<i>Rhea americana</i> (II)		Greater rhea
SPHENISCIFORMES				
<i>Spheniscidae</i>				<i>Penguins</i>
		<i>Spheniscus demersus</i> (II)		Jackass penguin
	<i>Spheniscus humboldti</i> (I)			Humboldt penguin
STRIGIFORMES				Owls
		STRIGIFORMES spp. (II) (Except for the species included in Annex A)		Owls
<i>Strigidae</i>				Owls
	<i>Aegolius funereus</i> (II)			Boreal owl
	<i>Asio flammeus</i> (II)			Short-eared owl
	<i>Asio otus</i> (II)			Long-eared owl
	<i>Athene noctua</i> (II)			Little owl
	<i>Bubo bubo</i> (II) (Except for <i>Bubo bubo bengalensis</i> which is included in Annex B)			Eurasian eagle-owl
	<i>Glaucidium passerinum</i> (II)			Eurasian pygmy-owl
	<i>Heteroglaux blewitti</i> (I)			Forest owlet
	<i>Mimizuku gurneyi</i> (I)			Lesser eagle-owl
	<i>Ninox natalis</i> (I)			Christmas hawk-owl
	<i>Ninox novaeseelandiae undulata</i> (I)			Norfolk boobook

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Nyctea scandiaca</i> (II)			Snowy owl
	<i>Otus ireneae</i> (II)			Sokoke scops-owl
	<i>Otus scops</i> (II)			Eurasian scops-owl
	<i>Strix aluco</i> (II)			Tawny owl
	<i>Strix nebulosa</i> (II)			Great grey owl
	<i>Strix uralensis</i> (II) (Except for <i>Strix uralensis davidi</i> which is included in Annex B)			Ural owl
	<i>Surnia ulula</i> (II)			Northern hawk owl
<i>Tytonidae</i>				<i>Barn owls</i>
	<i>Tyto alba</i> (II)			Barn owl
	<i>Tyto soumagnei</i> (I)			Soumagne's owl
STRUTHIONIFORMES				
<i>Struthionidae</i>				<i>Ostrich</i>
	<i>Struthio camelus</i> (I) (Only the populations of Algeria, Burkina Faso, Cameroon, the Central African Republic, Chad, Mali, Mauritania, Morocco, the Niger, Nigeria, Senegal and the Sudan; all other populations are not included in the Annexes to this Regulation)			Ostrich
TINAMIFORMES				
<i>Tinamidae</i>				<i>Tinamous</i>
	<i>Tinamus solitarius</i> (I)			Solitary tinamou
TROGONIFORMES				
<i>Trogonidae</i>				<i>Quetzals</i>
	<i>Pharomachrus mocinno</i> (I)			Resplendent quetzal
REPTILIA				<i>Reptiles</i>
CROCODYLIA				<i>Alligators, caimans, crocodiles</i>
		CROCODYLIA spp. (II) (Except for the species included in Annex A)		Alligators, caimans, crocodiles

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
Alligatoridae				Alligators, caimans
	<i>Alligator sinensis</i> (I)			Chinese alligator
	<i>Caiman crocodilus apaporiensis</i> (I)			Rio Apaporis spectacled caiman
	<i>Caiman latirostris</i> (I) (Except for the population of Argentina, which is included in Annex B)			Broad-nosed caiman
	<i>Melanosuchus niger</i> (I) (Except for the population of Brazil, which is included in Annex B, and population of Ecuador, which is included in Annex B and is subject to a zero annual export quota until an annual export quota has been approved by the CITES Secretariat and the IUCN/SSC Crocodile Specialist Group)			Black caiman
Crocodylidae				Crocodiles
	<i>Crocodylus acutus</i> (I) (Except for the population of Cuba, which is included in Annex B)			American crocodile
	<i>Crocodylus cataphractus</i> (I)			African slender-snouted crocodile
	<i>Crocodylus intermedius</i> (I)			Orinoco crocodile
	<i>Crocodylus mindorensis</i> (I)			Philippine crocodile
	<i>Crocodylus moreletii</i> (I) (Except for the populations of Belize and Mexico, which are included in Annex B, with a zero quota for wild specimens traded for commercial purposes)			Morelet's crocodile
	<i>Crocodylus niloticus</i> (I) (Except for the populations of Botswana, Egypt [subject to a zero quota for wild specimens traded for commercial purposes], Ethiopia, Kenya, Madagascar, Malawi, Mozambique, Namibia, South Africa, Uganda, the United Republic of Tanzania [subject to an annual export quota of no more than 1600 wild specimens including hunting trophies, in addition to ranched specimens], Zambia and Zimbabwe; these populations are included in Annex B)			Nile crocodile

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Crocodylus palustris</i> (I)			Mugger crocodile
	<i>Crocodylus porosus</i> (I) (Except for the populations of Australia, Indonesia and Papua New Guinea, which are included in Annex B)			Estuarine crocodile
	<i>Crocodylus rhombifer</i> (I)			Cuban crocodile
	<i>Crocodylus siamensis</i> (I)			Siamese crocodile
	<i>Osteolaemus tetraspis</i> (I)			West African dwarf crocodile
	<i>Tomistoma schlegelii</i> (I)			False gharial
<i>Gavialidae</i>				<i>Gavial</i> or gharial
	<i>Gavialis gangeticus</i> (I)			Gharial
RHYNCHOCEPHALIA				
<i>Sphenodontidae</i>				Tuataras
	<i>Sphenodon</i> spp. (I)			Tuataras
SAURIA				
<i>Agamidae</i>				Spiny-tailed lizards (<i>Agamas</i> , <i>mastigures</i>)
		<i>Uromastyx</i> spp. (II)		Spiny-tailed lizards
<i>Chamaeleonidae</i>				Chameleons
		<i>Bradypodion</i> spp. (II)		Dwarf chameleons
		<i>Brookesia</i> spp. (II) (Except for the species included in Annex A)		Dwarf chameleons
	<i>Brookesia perarmata</i> (I)			Dwarf spiny chameleon
		<i>Calumma</i> spp. (II)		Madagascar chameleons
		<i>Chamaeleo</i> spp. (II) (Except for the species included in Annex A)		Chameleons
	<i>Chamaeleo chamaeleon</i> (II)			European chameleon
		<i>Furcifer</i> spp. (II)		Madagascar chameleons
		<i>Kinyongia</i> spp. (II)		Dwarf chameleons

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
		<i>Nadzikambia</i> spp. (II)		Dwarf chameleons
<i>Cordylidae</i>				<i>Spiny-tailed lizards</i>
		<i>Cordylus</i> spp. (II)		Girdled lizards
<i>Gekkonidae</i>				Geckos
		<i>Cyrtodactylus serpensinsula</i> (II)		Serpent Island gecko
			<i>Hoplodactylus</i> spp. (III New Zealand)	Sticky-toed geckos
			<i>Naultinus</i> spp. (III New Zealand)	New Zealand tree geckos
		<i>Phelsuma</i> spp. (II) (Except for the species included in Annex A)		Day geckos
		<i>Phelsuma guentheri</i> (II)		Round Island day gecko
		<i>Uroplatus</i> spp. (II)		Flat-tailed geckos
<i>Helodermatidae</i>				<i>Gila monster and beaded lizard</i>
		<i>Heloderma</i> spp. (II) (Except for the subspecies included in Annex A)		Gila monster and beaded lizard
		<i>Heloderma horridum charlesbogerti</i> (I)		Guatemalan beaded lizard
<i>Iguanidae</i>				<i>Iguanas</i>
		<i>Amblyrhynchus cristatus</i> (II)		Galapagos marine iguana
		<i>Brachylophus</i> spp. (I)		Fiji iguanas
		<i>Conolophus</i> spp. (II)		Galapagos land iguanas
		<i>Ctenosaura bakeri</i> (II)		Utila Island spiny-tailed iguana
		<i>Ctenosaura oedirhina</i> (II)		Roatan spiny-tailed iguana
		<i>Ctenosaura melanosterna</i> (II)		Rio Aguan Valley spiny-tailed iguana
		<i>Ctenosaura palearis</i> (II)		Guatemalan Spiny-tailed iguana

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Cyclura</i> spp. (I)			Ground iguanas
		<i>Iguana</i> spp. (II)		Iguanas
		<i>Phrynosoma blainvillii</i> (II)		
		<i>Phrynosoma cerroense</i> (II)		
		<i>Phrynosoma coronatum</i> (II)		Coast horned lizard
		<i>Phrynosoma wigginsi</i> (II)		
	<i>Sauromalus varius</i> (I)			San Esteban Island chuck-walla
<i>Lacertidae</i>				<i>Lizards</i>
	<i>Gallotia simonyi</i> (I)			Hierro giant lizard
	<i>Podarcis lilfordi</i> (II)			Lilford's wall lizard
	<i>Podarcis pityusensis</i> (II)			Ibiza wall lizard
<i>Scincidae</i>				<i>Skinks</i>
		<i>Corucia zebrata</i> (II)		Prehensile-tailed skink
<i>Teiidae</i>				<i>Caiman lizards, tegu lizards</i>
		<i>Crocodilurus amazonicus</i> (II)		Dragon lizard
		<i>Dracaena</i> spp. (II)		Caiman lizards
		<i>Tupinambis</i> spp.(II)		Tegus
<i>Varanidae</i>				<i>Monitor lizards</i>
		<i>Varanus</i> spp. (II) (Except for the species included in Annex A)		Monitor lizards
	<i>Varanus bengalensis</i> (I)			Indian monitor
	<i>Varanus flavescens</i> (I)			Yellow monitor
	<i>Varanus griseus</i> (I)			Desert monitor
	<i>Varanus komodoensis</i> (I)			Komodo dragon
	<i>Varanus nebulosus</i> (I)			Clouded monitor
	<i>Varanus olivaceus</i> (II)			Gray's monitor

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Xenosauridae</i>				<i>Chinese crocodile lizard</i>
		<i>Shinisaurus crocodilurus</i> (II)		Chinese crocodile lizard
SERPENTES				Snakes
<i>Boidae</i>				<i>Boas</i>
		Boidae spp. (II) (Except for the species included in Annex A)		Boas
	<i>Acrantophis</i> spp. (I)			Madagascar ground boas
	<i>Boa constrictor occidentalis</i> (I)			Argentine boa constrictor
	<i>Epicrates inornatus</i> (I)			Puerto Rican boa
	<i>Epicrates monensis</i> (I)			Virgin Island tree boa
	<i>Epicrates subflavus</i> (I)			Jamaican boa
	<i>Eryx jaculus</i> (II)			Spotted sand boa
	<i>Sanzinia madagascariensis</i> (I)			Madagascar tree boa
<i>Bolyeriidae</i>				<i>Round Island boas</i>
		Bolyeriidae spp. (II) (Except for the species included in Annex A)		Round Island boas
	<i>Bolyeria multocarinata</i> (I)			Round Island boa
	<i>Casarea dussumieri</i> (I)			Round Island keel-scaled boa
<i>Colubridae</i>				<i>Typical snakes, water snakes, whip snakes</i>
			<i>Atretium schistosum</i> (III India)	Olive keel-back
			<i>Cerberus rynchops</i> (III India)	Dog-faced water snake
		<i>Clelia clelia</i> (II)		Mussurana
		<i>Cyclagras gigas</i> (II)		False cobra
		<i>Elachistodon westermanni</i> (II)		Indian egg-eating snake
		<i>Ptyas mucosus</i> (II)		Common rat snake

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
			<i>Xenochrophis piscator</i> (III India)	Checkered keel-back
Elapidae				Cobras, coral snakes
		<i>Hoplocephalus bungaroides</i> (II)		Broad-headed snake
			<i>Micrurus diastema</i> (III Honduras)	Atlantic coral snake
			<i>Micrurus nigrocinctus</i> (III Honduras)	Central American coral snake
		<i>Naja atra</i> (II)		Chinese spitting cobra
		<i>Naja kaouthia</i> (II)		Monocellate cobra
		<i>Naja mandalayensis</i> (II)		Burmese spitting cobra
		<i>Naja naja</i> (II)		Indian cobra
		<i>Naja oxiana</i> (II)		Central Asian cobra
		<i>Naja philippinensis</i> (II)		North Philippine spitting cobra
		<i>Naja sagittifera</i> (II)		Andaman cobra
		<i>Naja samarensis</i> (II)		South-east Philippine spitting cobra
		<i>Naja siamensis</i> (II)		Indochinese spitting cobra
		<i>Naja sputatrix</i> (II)		South Indonesian spitting cobra
		<i>Naja sumatrana</i> (II)		Golden spitting cobra
	<i>Ophiophagus hannah</i> (II)		King cobra	
Loxocemidae				Mexican dwarf boa
		Loxocemidae spp. (II)		Mexican dwarf boa
Pythonidae				Pythons
		Pythonidae spp. (II) (Except for the subspecies included in Annex A)		Pythons
		<i>Python molurus molurus</i> (I)		Indian python

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Tropidophiidae</i>				Wood boas
		<i>Tropidophiidae</i> spp. (II)		Wood boas
<i>Viperidae</i>				Vipers
			<i>Crotalus durissus</i> (III Honduras)	Neotropical rattlesnake
		<i>Crotalus durissus unicolor</i>		Aruba rattlesnake
			<i>Daboia russelii</i> (III India)	Russell's viper
	<i>Vipera latifii</i>			Latifi's viper
	<i>Vipera ursinii</i> (I) (Only the population of Europe, except the area which formerly constituted the USSR; these latter populations are not included in the Annexes to this Regulation)			Orsini's viper
		<i>Vipera wagneri</i> (II)		Wagner's viper
TESTUDINES				
<i>Carettochelyidae</i>				Pig-nosed turtles
		<i>Carettochelys insculpta</i> (II)		Pig-nosed turtle
<i>Chelidae</i>				Austro-American sideneck turtles
		<i>Chelodina mccordi</i> (II)		Roti snake-necked turtle
	<i>Pseudemydura umbrina</i> (I)			Western swamp turtle
<i>Cheloniidae</i>				Sea turtles
	<i>Cheloniidae</i> spp. (I)			Sea turtles
<i>Chelydridae</i>				Snapping turtles
			<i>Macrochelys temminckii</i> (III United States of America)	Alligator snapping turtle
<i>Dermatemydidae</i>				Central American river turtle
		<i>Dermatemys mawii</i> (II)		Central American river turtle

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
Dermochelyidae				Leatherback turtle
	<i>Dermochelys coriacea</i> (I)			Leatherback turtle
Emydidae				Box turtles, freshwater turtles
		<i>Chrysemys picta</i>		Painted turtle
		<i>Glyptemys insculpta</i> (II)		Wood turtle
	<i>Glyptemys muhlenbergii</i> (I)			Bog turtle
			<i>Graptemys</i> spp. (III United States of America)	Map turtles
		<i>Terrapene</i> spp. (II) (Except for the species included in Annex A)		Box turtles
	<i>Terrapene coahuila</i> (I)			Aquatic box turtle
		<i>Trachemys scripta elegans</i>		Red-eared terrapin
Geoemydidae				
	<i>Batagur affinis</i> (I)			Southern river terrapin
	<i>Batagur baska</i> (I)			Batagur
		<i>Batagur</i> spp. (Except for the species included in Annex A)		
		<i>Cuora</i> spp. (II)		Asian box turtles
	<i>Geoclemys hamiltonii</i> (I)			Black pond turtle
			<i>Geoemyda spengleri</i> (III China)	Black-breasted leaf turtle
		<i>Heosemys annandalii</i> (II)		Yellow-headed temple turtle
		<i>Heosemys depressa</i> (II)		Arakan forest turtle
		<i>Heosemys grandis</i> (II)		Giant Asian turtle
		<i>Heosemys spinosa</i> (II)		Spiny turtle
		<i>Leucocephalon yuwonoi</i> (II)		Sulawesi forest turtle
		<i>Malayemys macrocephala</i> (II)		Snail-eating turtle
		<i>Malayemys subtrijuga</i> (II)		Ricefield turtle
	<i>Mauremys annamensis</i> (II)		Annam pond turtle	

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
			<i>Mauremys iversoni</i> (III China)	Fujian pond turtle
			<i>Mauremys megalcephala</i> (III China)	Big-headed pond turtle
		<i>Mauremys mutica</i> (II)		Yellow pond turtle
			<i>Mauremys nigricans</i> (III China)	Red-necked turtle
			<i>Mauremys pritchardi</i> (III China)	Pritchard's pond turtle
			<i>Mauremys reevesii</i> (III China)	Reeves's turtle
			<i>Mauremys sinensis</i> (III China)	Chinese stripe-necked turtle
	<i>Melanochelys tricarinata</i> (I)			Three-keeled land tortoise
	<i>Morenia ocellata</i> (I)			Burmese swamp turtle
		<i>Notochelys platynota</i> (II)		Malayan flat-shelled turtle
			<i>Ocadia glyphistoma</i> (III China)	Notch-mouthed stripe-necked turtle
			<i>Ocadia philippeni</i> (III China)	Philippen's stripe-necked turtle
		<i>Orlitia borneensis</i> (II)		Malayan giant turtle
		<i>Pangshura</i> spp. (II) (Except for the species included in Annex A)		Roofed turtles
	<i>Pangshura tecta</i> (I)			Indian roofed turtle
			<i>Sacalia bealei</i> (III China)	Beal's eyed turtle
			<i>Sacalia pseudocellata</i> (III China)	Chinese false-eyed turtle
			<i>Sacalia quadriocellata</i> (III China)	Four-eyed turtle
		<i>Siebenrockiella crassicollis</i> (II)		Black marsh turtle
		<i>Siebenrockiella leytenensis</i> (II)		Philippine pond turtle
<i>Platysternidae</i>				<i>Big-headed turtle</i>
		<i>Platysternon megacephalum</i> (II)		Big-headed turtle

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Podocnemididae</i>				<i>Afro-American sideneck turtles</i>
		<i>Erymnochelys madagascariensis</i> (II)		Madagascar sideneck turtle
		<i>Peltocephalus dumerilianus</i> (II)		Big-headed sideneck turtle
		<i>Podocnemis</i> spp. (II)		Sideneck turtles
<i>Testudinidae</i>				<i>Tortoises</i>
		Testudinidae spp. (II) (Except for the species included in Annex A; a zero annual export quota has been established for <i>Geochelone sulcata</i> for specimens removed from the wild and traded for primarily commercial purposes)		Tortoises
	<i>Astrochelys radiata</i> (I)			Radiated tortoise
	<i>Astrochelys yniphora</i> (I)			Angonoka
	<i>Chelonoidis nigra</i> (I)			Galapagos giant tortoise
	<i>Gopherus flavomarginatus</i> (I)			Bolson tortoise
	<i>Malacochersus tornieri</i> (II)			Pancake tortoise
	<i>Psammobates geometricus</i> (I)			Geometric tortoise
	<i>Pyxis arachnoides</i> (I)			Madagascar spider tortoise
	<i>Pyxis planicauda</i> (I)			Madagascar flat-shelled tortoise
	<i>Testudo graeca</i> (II)			Spur-thighed tortoise
	<i>Testudo hermanni</i> (II)			Hermann's tortoise
	<i>Testudo kleinmanni</i> (I)			Egyptian tortoise
	<i>Testudo marginata</i> (II)			Marginated tortoise
<i>Trionychidae</i>				<i>Softshell turtles, terrapins</i>
		<i>Amyda cartilaginea</i> (II)		Southeast Asian soft-shelled turtle
	<i>Apalone spinifera atra</i> (I)			Cuatro Cienagas soft-shell turtle

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Aspideretes gangeticus</i> (I)			Indian soft-shell turtle
	<i>Aspideretes hurum</i> (I)			Peacock soft-shell turtle
	<i>Aspideretes nigricans</i> (I)			Black soft-shell turtle
		<i>Chitra</i> spp. (II)		Narrow-headed softshell turtles
		<i>Lissemys punctata</i> (II)		Indo-Gangetic flapshell turtle
		<i>Lissemys scutata</i> (II)		Burmese flapshell turtle
			<i>Palea steindachneri</i> (III China)	Wattle-necked softshell turtle
		<i>Pelochelys</i> spp. (II)		Giant softshell turtles
			<i>Pelodiscus axenaria</i> (III China)	Hunan softshell turtle
			<i>Pelodiscus maackii</i> (III China)	Amur softshell turtle
			<i>Pelodiscus parviformis</i> (III China)	Chinese softshell turtle
			<i>Rafetus swinhoi</i> (III China)	Yangtze softshell turtle
AMPHIBIA				Amphibians
ANURA				Frogs and toads
<i>Bufo</i> spp.				Toads
	<i>Altiphrynoides</i> spp. (I)			Malcolm's Ethiopian toad
	<i>Atelopus zeteki</i> (I)			Golden frog
	<i>Bufo periglenes</i> (I)			Golden toad
	<i>Bufo superciliaris</i> (I)			Cameroon toad
	<i>Nectophrynoides</i> spp. (I)			African viviparous toads
	<i>Nimbaphrynoides</i> spp. (I)			Nimba toads
	<i>Spinophrynoides</i> spp. (I)			Osgood's Ethiopian toad

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
<i>Calyptocephalellidae</i>				
			<i>Calyptocephalella gayi</i> (III Chile)	
<i>Dendrobatidae</i>				Poison frogs
		<i>Allobates femoralis</i> (II)		Brilliant-thighed poison frog
		<i>Allobates zaparo</i> (II)		Sanguine poison frog
		<i>Cryptophyllobates azureiventris</i> (II)		Sky-blue poison frog
		<i>Dendrobates</i> spp. (II)		Poison-arrow frogs
		<i>Epipedobates</i> spp. (II)		Poison-arrow frogs
		<i>Phyllobates</i> spp. (II)		Poison-arrow frogs
<i>Hylidae</i>				
		<i>Agalychnis</i> spp. (II)		
<i>Mantellidae</i>				<i>Mantella</i> frogs
		<i>Mantella</i> spp. (II)		Mantella frogs
<i>Microhylidae</i>				Tomato frogs
		<i>Dyscophus antongilii</i> (I)		Tomato frog
		<i>Scaphiophryne gottlebei</i> (II)		Red rain frog
<i>Ranidae</i>				Frogs
		<i>Conraua goliath</i>		Goliath frog
		<i>Euphlyctis hexadactylus</i> (II)		Six-fingered frog
		<i>Hoplobatrachus tigerinus</i> (II)		Tiger frog
		<i>Rana catesbeiana</i>		American bullfrog
<i>Rheobatrachidae</i>				Gastric brooding frogs
		<i>Rheobatrachus</i> spp. (II) (Except for the species included in Annex A)		Gastric brooding frog
		<i>Rheobatrachus silus</i> (II)		Platypus frog

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
CAUDATA				
<i>Ambystomatidae</i>				<i>Axolotls</i>
		<i>Ambystoma dumerilii</i> (II)		Lake Patzcuaro salamander
		<i>Ambystoma mexicanum</i> (II)		Axolotl
<i>Cryptobranchidae</i>				<i>Giant salamanders</i>
	<i>Andrias</i> spp. (I)			Giant salamanders
<i>Salamandridae</i>				<i>Salamanders and newts</i>
	<i>Neurergus kaiseri</i> (I)			Kaiser's spotted newt
ELASMOBRANCHII				<i>Sharks and rays</i>
LAMNIFORMES				
<i>Cetorhinidae</i>				<i>Basking sharks</i>
		<i>Cetorhinus maximus</i> (II)		Basking shark
<i>Lamnidae</i>				<i>Great white shark</i>
		<i>Carcharodon carcharias</i> (II)		Great white shark
			<i>Lamna nasus</i> (III 27 Member States) ⁽¹⁾	Porbeagle
ORECTOLOBIFORMES				
<i>Rhincodontidae</i>				<i>Whale sharks</i>
		<i>Rhincodon typus</i> (II)		Whale shark
RAJIFORMES				
<i>Pristidae</i>				<i>Sawfishes</i>
	<i>Pristidae</i> spp. (I) (Except for the species included in Annex B)			Sawfishes

⁽¹⁾ The inclusion of *Lamna nasus* into Annex C applies as soon as the inclusion of this species in Appendix III to the Convention takes effect, i.e. 90 days after the Convention Secretariat communicates to all Parties that the species is included in Appendix III to the Convention.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
		<i>Pristis microdon</i> (II) (For the exclusive purpose of allowing international trade in live animals to appropriate and acceptable aquaria for primarily conservation purposes. All other specimens shall be deemed to be specimens of species included in Annex A and the trade in them shall be regulated accordingly)		Freshwater sawfish
ACTINOPTERYGII				Fish
ACIPENSERIFORMES				
		ACIPENSERIFORMES spp. (II) (Except for the species included in Annex A)		Sturgeons and paddlefish
<i>Acipenseridae</i>				Sturgeons
	<i>Acipenser brevirostrum</i> (I)			Shortnose sturgeon
	<i>Acipenser sturio</i> (I)			Common sturgeon
ANGUILLIFORMES				
<i>Anguillidae</i>				Freshwater eels
		<i>Anguilla anguilla</i> (II)		European eel
CYPRINIFORMES				
<i>Catostomidae</i>				Cui-ui
	<i>Chasmistes cujus</i> (I)			Cui-ui
<i>Cyprinidae</i>				Blind carps, plaesok
		<i>Caecobarbus geertsii</i> (II)		African blind barb fish
	<i>Probarbus jullieni</i> (I)			Ikan temoleh
OSTEOGLOSSIFORMES				
<i>Osteoglossidae</i>				Arapaimas, bonytongues
		<i>Arapaima gigas</i> (II)		Arapaima
	<i>Scleropages formosus</i> (I)			Asian arowana

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
PERCIFORMES				
<i>Labridae</i>				Wrasses
		<i>Cheilinus undulatus</i> (II)		Humphead wrasse
<i>Sciaenidae</i>				Totoabas
	<i>Totoaba macdonaldi</i> (I)			Totoaba
SILURIFORMES				
<i>Pangasiidae</i>				Pangasid catfish
	<i>Pangasianodon gigas</i> (I)			Giant catfish
SYNGNATHIFORMES				
<i>Syngnathidae</i>				Pipefishes, seahorses
		<i>Hippocampus</i> spp. (II)		Seahorses
SARCOPTERYGII				Lungfishes
CERATODONTIFORMES				
<i>Ceratodontidae</i>				Australian lungfishes
		<i>Neoceratodus forsteri</i> (II)		Australian lungfish
COELACANTHIFORMES				
<i>Latimeriidae</i>				Coelacanths
	<i>Latimeria</i> spp. (I)			Coelacanths
ECHINODERMATA (STARFISH, BRITTLE STARS, SEA URCHINS AND SEA CUCUMBERS)				
HOLOTHUROIDEA				Sea cucumbers
ASPIDOCHIROTIDA				
<i>Stichopodidae</i>				Sea cucumbers
			<i>Isostichopus fuscus</i> (III Ecuador)	Brown sea cucumber

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
ARTHROPODA (ARTHROPODS)				
ARACHNIDA				Spiders and scorpions
ARANEAE				
<i>Theraphosidae</i>				Red-kneed tarantulas, tarantulas
		<i>Aphonopelma albiceps</i> (II)		
		<i>Aphonopelma pallidum</i> (II)		Chihuahua rose-grey tarantula
		<i>Brachypelma</i> spp. (II)		Central American tarantulas
SCORPIONES				
<i>Scorpionidae</i>				Scorpions
		<i>Pandinus dictator</i> (II)		
		<i>Pandinus gambiensis</i> (II)		Giant Senegalese scorpion
		<i>Pandinus imperator</i> (II)		Emperor scorpion
INSECTA				Insects
COLEOPTERA				Beetles
<i>Lucanidae</i>				Stag beetles
			<i>Colophon</i> spp. (III South Africa)	Cape stag beetles
<i>Scarabaeidae</i>				Scarab beetles
		<i>Dynastes satanas</i> (II)		Satanas beetle
LEPIDOPTERA				Butterflies
<i>Nymphalidae</i>				
			<i>Agrias amydon boliviensis</i> (III Bolivia)	
			<i>Morpho godartii lachaumei</i> (III Bolivia)	
			<i>Prepona praeneste buckleyana</i> (III Bolivia)	

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
Papilionidae				<i>Birdwing and swallowtail butterflies</i>
		<i>Atrophaneura jophon</i> (II)		Sri Lankan rose
		<i>Atrophaneura palu</i>		Palu swallowtail butterfly
		<i>Atrophaneura pandiyana</i> (II)		Malabar rose
		<i>Bhutanitis</i> spp. (II)		Swallowtail butterflies
		<i>Graphium sandawanum</i>		Apo swallowtail butterfly
		<i>Graphium stresemanni</i>		Seram swallowtail
		<i>Ornithoptera</i> spp. (II) (except for the species included in Annex A)		Birdwing butterflies
	<i>Ornithoptera alexandrae</i> (I)			Queen Alexandra's birdwing
		<i>Papilio benguetanus</i>		
	<i>Papilio chikae</i> (I)			Luzon peacock swallowtail
		<i>Papilio esperanza</i>		
	<i>Papilio homerus</i> (I)			Homerus swallowtail
	<i>Papilio hospiton</i> (I)			Corsican swallowtail
		<i>Papilio morondavana</i>		Madagascar emperor swallowtail
		<i>Papilio neumoegeni</i>		
		<i>Parides ascanius</i>		Fluminense swallowtail butterfly
		<i>Parides hahneli</i>		Hahnel's amazonian swallowtail butterfly
	<i>Parnassius apollo</i> (II)			Mountain apollo
		<i>Teinopalpus</i> spp. (II)		Kaiser-I-Hind butterflies
	<i>Trogonoptera</i> spp. (II)		Birdwing butterflies	
	<i>Troides</i> spp. (II)		Birdwing butterflies	
ANNELIDA (SEGMENTED WORMS AND LEECHES)				
HIRUDINOIDEA				<i>Leeches</i>

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
ARHYNCHOBDELLIDA				
<i>Hirudinidae</i>				<i>Leeches</i>
		<i>Hirudo medicinalis</i> (II)		Northern medicinal leech
		<i>Hirudo verbana</i> (II)		Southern medicinal leech
MOLLUSCA (MOLLUSCS)				
BIVALVIA				<i>Bivalve molluscs (clams, mussels etc.)</i>
MYTILOIDA				
<i>Mytilidae</i>				<i>Marine mussels</i>
		<i>Lithophaga lithophaga</i> (II)		European date mussel
UNIONOIDA				
<i>Unionidae</i>				<i>Freshwater mussels, pearly mussels</i>
	<i>Conradilla caelata</i> (I)			Birdwing pearly mussel
		<i>Cyprogenia aberti</i> (II)		Western fanshell mussel
	<i>Dromus dromas</i> (I)			Dromedary pearly mussel
	<i>Epioblasma curtisii</i> (I)			Curtis' pearly mussel
	<i>Epioblasma florentina</i> (I)			Yellow-blossom pearly mussel
	<i>Epioblasma sampsonii</i> (I)			Wabash riffleshell
	<i>Epioblasma sulcata perobliqua</i> (I)			White catspaw mussel
	<i>Epioblasma torulosa gubernaculum</i> (I)			Green-blossom pearly mussel
		<i>Epioblasma torulosa rangiana</i> (II)		Northern riffleshell
	<i>Epioblasma torulosa torulosa</i> (I)			Turbercled-blossom pearly mussel
	<i>Epioblasma turgidula</i> (I)			Turgid-blossom pearly mussel
	<i>Epioblasma walkeri</i> (I)			Tan riffleshell
	<i>Fusconaia cuneolus</i> (I)			Fine-rayed pigtoe pearly mussel
	<i>Fusconaia edgariana</i> (I)			Shiny pigtoe pearly mussel

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Lampsilis higginsii</i> (I)			Higgins' eye pearly mussel
	<i>Lampsilis orbiculata orbiculata</i> (I)			Pink mucket pearly mussel
	<i>Lampsilis satur</i> (I)			Sandback pocketbook mussel
	<i>Lampsilis virescens</i> (I)			Alabama lamp pearly mussel
	<i>Plethobasus cicatricosus</i> (I)			White warty-back pearly mussel
	<i>Plethobasus cooperianus</i> (I)			Orange-footed pimpleback mussel
		<i>Pleurobema clava</i> (II)		Clubshell pearly mussel
	<i>Pleurobema plenum</i> (I)			Rough pigtoe pearly mussel
	<i>Potamilus capax</i> (I)			Fat pocketbook pearly mussel
	<i>Quadrula intermedia</i> (I)			Cumberland monkey-face pearly mussel
	<i>Quadrula sparsa</i> (I)			Appalachian monkey-face pearly mussel
	<i>Toxolasma cylindrella</i> (I)			Pale lilliput pearly mussel
	<i>Unio nickliniana</i> (I)			Nicklin's pearly mussel
	<i>Unio tampicoensis tecomatensis</i> (I)			Tampico pearly mussel
	<i>Villosa trabalis</i> (I)			Cumberland bean pearly mussel
VENEROIDA				
<i>Tridacnidae</i>				<i>Giant clams</i>
		<i>Tridacnidae</i> spp. (II)		Giant clams
GASTROPODA				<i>Slugs, snails and conches</i>
MESOGASTROPODA				
<i>Strombidae</i>				<i>Conches</i>
		<i>Strombus gigas</i> (II)		Queen conch
STYLOMMATOPHORA				
<i>Achatinellidae</i>				<i>Agate snails, oahu tree snails</i>
	<i>Achatinella</i> spp. (I)			Little agate shells
<i>Camaenidae</i>				<i>Green tree snail</i>
		<i>Papustyla pulcherrima</i> (II)		Manus green tree snail

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
CNIDARIA (CORALS, FIRE CORALS, SEA ANEMONES)				
ANTHOZOA				Corals, sea anemones
ANTIPATHARIA				
		ANTIPATHARIA spp. (II)		Black corals
GORGONACEAE				
<i>Coralliidae</i>				
			<i>Corallium elatius</i> (III China)	
			<i>Corallium japonicum</i> (III China)	
			<i>Corallium konjoi</i> (III China)	
			<i>Corallium secundum</i> (III China)	
HELIOPORACEA				
<i>Helioporidae</i>				Blue coral
		Helioporidae spp. (II) (Includes only the species <i>Heliopora coerulea</i>) ⁽¹⁾		Blue coral
SCLERACTINIA				
		SCLERACTINIA spp. (II) ⁽¹⁾		Stony corals
STOLONIFERA				
<i>Tubiporidae</i>				Organpipe corals
		Tubiporidae spp. (II) ⁽¹⁾		Organpipe corals
HYDROZOA				Sea ferns, fire corals, stinging medusas
MILLEPORINA				
<i>Milleporidae</i>				Wello fire corals
		Milleporidae spp. (II) ⁽¹⁾		Wello fire corals

⁽¹⁾ The following are not subject to the provisions of this Regulation:

Fossils;

Coral sand, that is to say, material consisting entirely or in part of finely crushed fragments of dead coral no larger than 2 mm in diameter and which may also contain, amongst other things, the remains of Foraminifera, mollusc and crustacean shell, and coralline algae;

Coral fragments (including gravel and rubble), that is to say, unconsolidated fragments of broken finger-like dead coral and other material between 2 and 30 mm measured in any direction.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
STYLASTERINA				
Stylasteridae				Lace corals
		Stylasteridae spp. (II) ⁽¹⁾		Lace corals
FLORA				
AGAVACEAE				Agaves
	<i>Agave parviflora</i> (I)			Santa Cruz striped agave
		<i>Agave victoriae-reginae</i> (II) #4		Queen Victoria agave
		<i>Nolina interrata</i> (II)		Dehesa bear-grass
AMARYLLIDACEAE				Amaryllids
		<i>Galanthus</i> spp. (II) #4		Snowdrops
		<i>Sternbergia</i> spp. (II) #4		Sternbergias
ANACARDIACEAE				
		<i>Operculicarya hyphaenoides</i> (II)		Jabihy
		<i>Operculicarya pachypus</i> (II)		Tabily
APOCYNACEAE				
		<i>Hoodia</i> spp. (II) #9		Hoodia
		<i>Pachypodium</i> spp. (II) (Except for the species included in Annex A) #4		Elephant trunks
		<i>Pachypodium ambongense</i> (I)		
		<i>Pachypodium baronii</i> (I)		
		<i>Pachypodium decaryi</i> (I)		
		<i>Rauwolfia serpentina</i> (II) #2		Snake-root devil-pepper
ARALIACEAE				Aralias
		<i>Panax ginseng</i> (II) (Only the population of the Russian Federation; no other population is included in the Annexes to this Regulation) #3		Asian ginseng

⁽¹⁾ The following are not subject to the provisions of this Regulation:

Fossils;

Coral sand, that is to say, material consisting entirely or in part of finely crushed fragments of dead coral no larger than 2 mm in diameter and which may also contain, amongst other things, the remains of Foraminifera, mollusc and crustacean shell, and coralline algae;

Coral fragments (including gravel and rubble), that is to say, unconsolidated fragments of broken finger-like dead coral and other material between 2 and 30 mm measured in any direction.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
		<i>Panax quinquefolius</i> (II) #3		American ginseng
ARAUCARIACEAE				<i>Araucarias</i>
	<i>Araucaria araucana</i> (I)			Monkey-puzzle tree
BERBERIDACEAE				<i>Barberries</i>
		<i>Podophyllum hexandrum</i> (II) #2		Himalayan may-apple
BROMELIACEAE				<i>Air plants, bromelias</i>
		<i>Tillandsia harrisii</i> (II) #4		Harris' tillandsia
		<i>Tillandsia kammii</i> (II) #4		Kamm's tillandsia
		<i>Tillandsia kautskyi</i> (II) #4		Kautsky's tillandsia
		<i>Tillandsia mauryana</i> (II) #4		Maury's tillandsia
		<i>Tillandsia sprengeliana</i> (II) #4		Sprengel's tillandsia
		<i>Tillandsia sucrei</i> (II) #4		Sucre tillandsia
		<i>Tillandsia xerographica</i> (II) ⁽¹⁾ #4		Xerographic tillandsia
CACTACEAE				<i>Cacti</i>
		CACTACEAE spp. (II) (Except for the species included in Annex A and <i>Pereskia</i> spp., <i>Pereskopsis</i> spp. and <i>Quiabentia</i> spp.) ⁽²⁾ #4		Cacti
	<i>Ariocarpus</i> spp. (I)			Living rock cacti
	<i>Astrophytum asterias</i> (I)			Star cactus
	<i>Aztekium ritteri</i> (I)			Aztec cactus

⁽¹⁾ Trade of specimens with source code A is allowed only if specimens traded possess cataphylls.

⁽²⁾ Artificially propagated specimens of the following hybrids and/or cultivars are not subject to the provisions of this Regulation:

Hatiora x graeseri

Schlumbergera x buckleyi

Schlumbergera russelliana x Schlumbergera truncata

Schlumbergera orssichiana x Schlumbergera truncata

Schlumbergera opuntioides x Schlumbergera truncata

Schlumbergera truncata (cultivars)

Cactaceae spp. colour mutants grafted on the following grafting stocks: *Harrisia Jusbertii*, *Hylocereus trigonus* or *Hylocereus undatus*

Opuntia microdasys (cultivars)

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Coryphantha werdermannii</i> (I)			Jobali pincushion cactus
	<i>Discocactus</i> spp. (I)			Discocacti
	<i>Echinocereus ferreirianus</i> ssp. <i>lindsayi</i> (I)			Lindsay's hedgehog cacti
	<i>Echinocereus schmollii</i> (I)			Lamb's-tail cactus
	<i>Escobaria minima</i> (I)			Nelle's cactus
	<i>Escobaria sneedii</i> (I)			Sneed's pincushion cactus
	<i>Mammillaria pectinifera</i> (I)			Conchilique
	<i>Mammillaria solisioides</i> (I)			Pitayita
	<i>Melocactus conoideus</i> (I)			Conelike Turk's-cap cactus
	<i>Melocactus deinacanthus</i> (I)			Wonderfully-bristled Turk's cap cactus
	<i>Melocactus glaucescens</i> (I)			Woolly waxy-stemmed Turk's-cap cactus
	<i>Melocactus paucispinus</i> (I)			Few-spined Turk's-cap cactus
	<i>Obregonia denegrii</i> (I)			Artichoke cactus
	<i>Pachycereus militaris</i> (I)			Grenadier's cap
	<i>Pediocactus bradyi</i> (I)			Brady's pincushion cactus
	<i>Pediocactus knowltonii</i> (I)			Knowlton's cactus
	<i>Pediocactus paradeinei</i> (I)			Houserock valley cactus
	<i>Pediocactus peeblesianus</i> (I)			Peebles's Navajo cactus
	<i>Pediocactus sileri</i> (I)			Siler's pincushion cactus
	<i>Pelecypora</i> spp. (I)			Pine cane cactus
	<i>Sclerocactus brevihamatus</i> ssp. <i>tobuschii</i> (I)			Tobusch fishhook cactus
	<i>Sclerocactus erectocentrus</i> (I)			Needle-spined pineapple cactus
	<i>Sclerocactus glaucus</i> (I)			Uinta Basin hookless cactus
	<i>Sclerocactus mariposensis</i> (I)			Mariposa cactus
	<i>Sclerocactus mesae-verdae</i> (I)			Mesa Verde cactus
	<i>Sclerocactus nyensis</i> (I)			Tonopah fishhook cactus

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Sclerocactus papyracanthus</i> (I)			Grama-grass cactus
	<i>Sclerocactus pubispinus</i> (I)			Great-Basin fishhook cactus
	<i>Sclerocactus wrightiae</i> (I)			Wright's fishhook cactus
	<i>Strombocactus</i> spp. (I)			Peyote
	<i>Turbincarpus</i> spp. (I)			Turbincarps
	<i>Uebelmannia</i> spp. (I)			Uebelmann cacti
CARYOCARACEAE				Ajos
		<i>Caryocar costaricense</i> (II) #4		Ajillo
COMPOSITAE (ASTERA- CEAE)				Asters, daisies, costus
	<i>Saussurea costus</i> (I) (also known as <i>S. lappa</i> , <i>Aucklandia lappa</i> or <i>A. costus</i>)			Costus
CRASSULACEAE				<i>Dudleyas</i> , <i>crassulas</i>
		<i>Dudleya stolonifera</i> (II)		Laguna beach dudleya
		<i>Dudleya traskiae</i> (II)		Santa Barbara Island dudleya
CUCURBITACEAE				
		<i>Zygosicyos pubescens</i> (II) (also known as <i>Xerosicyos pubescens</i>)		Tobory
		<i>Zygosicyos tripartitus</i> (II)		Betoboky
CUPRESSACEAE				Cypresses
	<i>Fitzroya cupressoides</i> (I)			Alerce
	<i>Pilgerodendron wiferum</i> (I)			Pilgerodendron
CYATHEACEAE				Tree ferns
		<i>Cyathea</i> spp. (II) #4		Tree ferns
CYCADACEAE				Cycads
		CYCADACEAE spp. (II) (Except for the species included in Annex A) #4		Cycads
	<i>Cycas beddomei</i> (I)			Beddome's cycad

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
DICKSONIACEAE				Tree ferns
		<i>Cibotium barometz</i> (II) #4		
		<i>Dicksonia</i> spp. (II) (Only the populations of the Americas; no other populations are included in the Annexes to this Regulation. This includes the synonyms <i>Dicksonia berteriana</i> , <i>D. externa</i> , <i>D. sellowiana</i> and <i>D. stuebelii</i>) #4		Tree ferns
DIDIEREACEAE				<i>Didiereas</i>
		DIDIEREACEAE spp. (II) #4		Alluaudias, didiereas
DIOSCOREACEAE				Yams
		<i>Dioscorea deltoidea</i> (II) #4		Elephant's foot
DROSERACEAE				Sundews
		<i>Dionaea muscipula</i> (II) #4		Venus fly-trap
EUPHORBIACEAE				Spurges
		<p><i>Euphorbia</i> spp. (II) #4</p> <p>(Succulent species only except for:</p> <ol style="list-style-type: none"> 1) <i>Euphorbia misera</i>; 2) artificially propagated specimens of cultivars of <i>Euphorbia trigona</i>; 3) artificially propagated specimens of <i>Euphorbia lactea</i> grafted on artificially propagated root stock of <i>Euphorbia nerifolia</i>, when they are: <ul style="list-style-type: none"> — crested, or — fan-shaped, or — colour mutants; 4) artificially propagated specimens of cultivars of <i>Euphorbia 'Milibii'</i> when they are: <ul style="list-style-type: none"> — readily recognisable as artificially propagated specimens, and — introduced into or (re-) exported from the Union in shipments of 100 or more plants; <p style="margin-left: 40px;">which are not subject to the provisions of this Regulation, and</p> 5) the species included in Annex A) 		Euphorbias

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Euphorbia ambovombensis</i> (I)			
	<i>Euphorbia capsaintemariensis</i> (I)			
	<i>Euphorbia cremersii</i> (I) (Includes the forma <i>viridifolia</i> and the var. <i>rakotozafyi</i>)			
	<i>Euphorbia cylindrifolia</i> (I) (Includes the ssp. <i>tuberifera</i>)			
	<i>Euphorbia decaryi</i> (I) (Includes the vars. <i>ampanihyensis</i> , <i>robinsonii</i> and <i>sprirosticha</i>)			
	<i>Euphorbia francoisii</i> (I)			
	<i>Euphorbia handiensis</i> (II)			
	<i>Euphorbia lambii</i> (II)			
	<i>Euphorbia moratii</i> (I) (Includes the vars. <i>antsingiensis</i> , <i>bemarahensis</i> and <i>multiflora</i>)			
	<i>Euphorbia parvicyathophora</i> (I)			
	<i>Euphorbia quartzitcola</i> (I)			
	<i>Euphorbia stygiana</i> (II)			
	<i>Euphorbia tulearensis</i> (I)			

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
FOUQUIERIACEAE				Ocotillos, boojums
		<i>Fouquieria columnaris</i> (II) #4		Boojum tree
	<i>Fouquieria fasciculata</i> (I)			Arbol del barril
	<i>Fouquieria purpusii</i> (I)			
GNETACEAE				Joint firs
			<i>Gnetum montanum</i> (III Ne-pal) #1	
JUGLANDACEAE				Walnuts, gavilan
		<i>Oreomunnea pterocarpa</i> (II) #4		Gavilàn
LAURACEAE				
		<i>Aniba rosaeodora</i> (II) (also known as <i>A. duckei</i>) #12		Brazilian rosewood
LEGUMINOSAE (FABACEAE)				Legumes
		<i>Caesalpinia echinata</i> (II) #10		Brazil wood
	<i>Dalbergia nigra</i> (I)			Brazilian rosewood
			<i>Dalbergia retusa</i> (III Guatemala) (Only the population of Guatemala; all other populations are included in Annex D) #5	Black rosewood
			<i>Dalbergia stevensonii</i> (III Guatemala) (Only the population of Guatemala; all other populations are included in Annex D) #5	Honduras rosewood
			<i>Dipteryx panamensis</i> (III Costa Rica / Nicaragua)	Almendra
		<i>Pericopsis elata</i> (II) #5		Afrormosia

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
		<i>Platymiscium pleiostachyum</i> (II) #4		Quira macawood
		<i>Pterocarpus santalinus</i> (II) #7		Red sandalwood
LILIACEAE				Lilies
		<i>Aloe</i> spp. (II) (Except for the species included in Annex A and <i>Aloe vera</i> , also known as <i>Aloe barbadensis</i> , which is not included in the Annexes to this Regulation) #4		Aloes
	<i>Aloe albida</i> (I)			
	<i>Aloe albiflora</i> (I)			
	<i>Aloe alfredii</i> (I)			
	<i>Aloe bakeri</i> (I)			
	<i>Aloe bellatula</i> (I)			
	<i>Aloe calcairophila</i> (I)			
	<i>Aloe compressa</i> (I) (Includes the vars. <i>paucituberculata</i> , <i>rugosquamosa</i> and <i>schistophila</i>)			
	<i>Aloe delphinensis</i> (I)			
	<i>Aloe descoingsii</i> (I)			
	<i>Aloe fragilis</i> (I)			
	<i>Aloe haworthioides</i> (I) (Includes the var. <i>aurantiaca</i>)			
	<i>Aloe helenae</i> (I)			
	<i>Aloe laeta</i> (I) (Includes the var. <i>maniaensis</i>)			
	<i>Aloe parallelifolia</i> (I)			
	<i>Aloe parvula</i> (I)			
	<i>Aloe pillansii</i> (I)			
	<i>Aloe polyphylla</i> (I)			
	<i>Aloe rauhii</i> (I)			

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Aloe suzannae</i> (I)			
	<i>Aloe versicolor</i> (I)			
	<i>Aloe vossii</i> (I)			
MAGNOLIACEAE				Magnolias
			<i>Magnolia liliifera</i> var. <i>obovata</i> (III Nepal) #1	Safan
MELIACEAE				Mahoganies, cedars
			<i>Cedrela fissilis</i> (III Bolivia) (Only the population of Bolivia; all other populations are included in Annex D) #5	
			<i>Cedrela lilloi</i> (III Bolivia) (Only the population of Bolivia; all other populations are included in Annex D) #5	
			<i>Cedrela odorata</i> (III Bolivia / Brazil / Colombia / Guatemala / Peru) (Only the populations of the countries that listed the species in Appendix III; all other populations are included in Annex D) #5	Spanish cedar
		<i>Swietenia humilis</i> (II) #4		Honduras mahogany
		<i>Swietenia macrophylla</i> (II) (Population of the Neotropics — includes Central and South America and the Caribbean) #6		Big-leaf mahogany
		<i>Swietenia mahagoni</i> (II) #5		Caribbean mahogany
NEPENTHACEAE				Pitcher plants (old-world)
		<i>Nepenthes</i> spp. (II) (Except for the species included in Annex A) #4		Tropical pitcher plants
	<i>Nepenthes khasiana</i> (I)			Indian pitcher plant
	<i>Nepenthes rajah</i> (I)			Giant tropical pitcher plant

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
ORCHIDACEAE				Orchids
		ORCHIDACEAE spp. (II) (Except for the species included in Annex A) ⁽¹⁾ #4		Orchids
	For all of the following Annex A orchid species, seedling or tissue cultures are not subject to the provisions of this Regulation, when: <ul style="list-style-type: none"> — they are obtained <i>in vitro</i>, in solid or liquid media, and — meet the definition of ‘artificially propagated’ in accordance with Article 56 of Commission Regulation (EC) No 865/2006, and — when introduced into or (re-)exported from the Union are transported in sterile containers 			
	<i>Aerangis ellisii</i> (I)			
	<i>Cephalanthera cucullata</i> (II)			Hooded helleborine
	<i>Cypripedium calceolus</i> (II)			Lady’s slipper orchid
	<i>Dendrobium cruentum</i> (I)			
	<i>Goodyera macrophylla</i> (II)			Madeiran lady’s-tresses
	<i>Laelia jongheana</i> (I)			

⁽¹⁾ Artificially propagated hybrids of *Cymbidium*, *Dendrobium*, *Phalaenopsis* and *Vanda* are not subject to the provisions of this Regulation, when specimens are readily recognizable as artificially propagated and do not show any signs of having been collected in the wild such as mechanical damage or strong dehydration resulting from collection, irregular growth and heterogeneous size and shape within a taxon and shipment, algae or other epiphyllous organisms adhering to leaves, or damage by insects or other pests; and

- (a) when shipped in non flowering state, the specimens must be traded in shipments consisting of individual containers (such as cartons, boxes, crates or individual shelves of CC-containers) each containing 20 or more plants of the same hybrid; the plants within each container must exhibit a high degree of uniformity and healthiness; and the shipment must be accompanied by documentation, such as an invoice, which clearly states the number of plants of each hybrid; or
- (b) when shipped in flowering state, with at least one fully open flower per specimen, no minimum number of specimens per shipment is required but specimens must be professionally processed for commercial retail sale, e.g. labelled with printed labels or packaged with printed packages indicating the name of the hybrid and the country of final processing. This should be clearly visible and allow easy verification.

Plants not clearly qualifying for the exemption must be accompanied by appropriate CITES documents.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Laelia lobata</i> (I)			
	<i>Liparis loeselii</i> (II)			Fen orchid
	<i>Ophrys argolica</i> (II)			Eyed bee orchid
	<i>Ophrys lunulata</i> (II)			Crescent ophrys
	<i>Orchis scopolorum</i> (II)			Madeiran orchid
	<i>Paphiopedilum</i> spp. (I)			Asian slipper orchids
	<i>Peristeria elata</i> (I)			Holy ghost orchid
	<i>Phragmipedium</i> spp. (I)			South American slipper orchids
	<i>Renanthera imschootiana</i> (I)			Red vanda
	<i>Spiranthes aestivalis</i> (II)			Summer lady's-tresses
OROBANCHACEAE				<i>Broomrapes</i>
		<i>Cistanche deserticola</i> (II) #4		Desert cistanche
PALMAE (ARECACEAE)				<i>Palms</i>
		<i>Beccariophoenix madagascariensis</i> (II) #4		Manarano
	<i>Chrysalidocarpus decipiens</i> (I)			Butterfly palm
		<i>Lemurophoenix halleuxii</i> (II)		Hovitra varimena
			<i>Lodoicea maldivica</i> (III Seychelles) #13	Coco de Mer
		<i>Marojejya darianii</i> (II)		Ravimbe
		<i>Neodypsis decaryi</i> (II) #4		Triangle palm
		<i>Ravenea louvelii</i> (II)		Lakamarefo
		<i>Ravenea rivularis</i> (II)		Gora
		<i>Satranala decussilvae</i> (II)		Satranabe
		<i>Voanioala gerardii</i> (II)		Voanioala
PAPAVERACEAE				<i>Poppies</i>
			<i>Meconopsis regia</i> (III Nepal) #1	Himalayan poppy

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
PASSIFLORACEAE				
		<i>Adenia olaboensis</i> (II)		Vahisasety
PINACEAE				Pine family
	<i>Abies guatemalensis</i> (I)			Guatemalan fir
			<i>Pinus koraiensis</i> (III Russian Federation) #5	
PODOCARPACEAE				Podocarps
			<i>Podocarpus neriifolius</i> (III Nepal) #1	Yellow wood
	<i>Podocarpus parlatorei</i> (I)			Parlatore's podocarp
PORTULACACEAE				Portulacas, purslanes
		<i>Anacampseros</i> spp. (II) #4		Purslanes
		<i>Avonia</i> spp. (II) #4		
		<i>Lewisia serrata</i> (II) #4		Saw-toothed lewisia
PRIMULACEAE				Primulas, cyclamens
		<i>Cyclamen</i> spp. (II) ⁽¹⁾ #4		Cyclamens
RANUNCULACEAE				Buttercups
		<i>Adonis vernalis</i> (II) #2		Yellow adonis
		<i>Hydrastis canadensis</i> (II) #8		Golden seal
ROSACEAE				Roses, cherries
		<i>Prunus africana</i> (II) #4		African cherry
RUBIACEAE				Ayugue
	<i>Balmea stormiae</i> (I)			Ayugue
SARRACENIACEAE				Pitcher plants (new world)
		<i>Sarracenia</i> spp. (II) (Except for the species included in Annex A) #4		Pitcher plants

⁽¹⁾ Artificially propagated specimens of cultivars of *Cyclamen persicum* are not subject to the provisions of this Regulation. However, the exemption does not apply to such specimens traded as dormant tubers.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
	<i>Sarracenia oreophila</i> (I)			Green pitcher plant
	<i>Sarracenia rubra</i> ssp. <i>alabamensis</i> (I)			Alabama canebrake pitcher plant
	<i>Sarracenia rubra</i> ssp. <i>jonesii</i> (I)			Mountain sweet pitcher plant
SCROPHULARIACEAE				Figworts
		<i>Picrorhiza kurrooa</i> (II) (excludes <i>Picrorhiza scrophulariiflora</i>) #2		Indian gentian
STANGERIACEAE				<i>Stangerias</i> (cycads)
		<i>Bowenia</i> spp. (II) #4		Cycads
	<i>Stangeria eriopus</i> (I)			Stangeria
TAXACEAE				Yews
		<i>Taxus chinensis</i> and infraspecific taxa of this species (II) #2		Chinese yew
		<i>Taxus cuspidata</i> and infraspecific taxa of this species (II) ⁽¹⁾ #2		Japanese yew
		<i>Taxus fuana</i> and infraspecific taxa of this species (II) #2		Tibetan yew
		<i>Taxus sumatrana</i> and infraspecific taxa of this species (II) #2		Sumatran yew
		<i>Taxus wallichiana</i> (II) #2		Himalayan yew
THYMELAEACEAE (AQUILARIACEAE)				Agarwood, ramin
		<i>Aquilaria</i> spp. (II) #4		Agarwood
		<i>Gonystylus</i> spp. (II) #4		Ramin
		<i>Gyrinops</i> spp. (II) #4		Agarwood
TROCHODENDRACEAE (TETRACENTRACEAE)				<i>Tetracentrons</i>
			<i>Tetracentron sinense</i> (III Nepal) #1	

⁽¹⁾ Artificially propagated hybrids and cultivars of *Taxus cuspidata*, live, in pots or other small containers, each consignment being accompanied by a label or document stating the name of the taxon or taxa and the text 'artificially propagated', are not subject to the provisions of this Regulation.

Wednesday 16 April 2014

	Annex A	Annex B	Annex C	Common name
VALERIANACEAE				Valerians
		<i>Nardostachys grandiflora</i> (II) #2		
VITACEAE				
		<i>Cyphostemma elephantopus</i> (II)		Lazampasika
		<i>Cyphostemma montagnacii</i> (II)		Lazambohitra
WELWITSCHIACEAE				Welwitschias
		<i>Welwitschia mirabilis</i> (II) #4		Welwitschia
ZAMIACEAE				Cycads
		ZAMIACEAE spp. (II) (Except for the species included in Annex A) #4		Cycads
		<i>Ceratozamia</i> spp. (I)		Horncones
		<i>Chigua</i> spp. (I)		
		<i>Encephalartos</i> spp. (I)		Bread palms
		<i>Microcycas calocoma</i> (I)		Palm corcho
ZINGIBERACEAE				Ginger lilies
		<i>Hedychium philippinense</i> (II) #4		Philippine garland-flower
ZYGOPHYLLACEAE				Lignum-vitae
		<i>Bulnesia sarmientoi</i> (II) #11		Holy wood
		<i>Guaiacum</i> spp. (II) #2		Lignum-vitae

	Annex D	Common name
FAUNA		
CHORDATA (CHORDATES)		
MAMMALIA		Mammals

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
CARNIVORA		
<i>Canidae</i>		<i>Dogs, foxes, wolves</i>
	<i>Vulpes vulpes griffithi</i> (III India) § 1	Red fox
	<i>Vulpes vulpes montana</i> (III India) § 1	Red fox
	<i>Vulpes vulpes pusilla</i> (III India) § 1	Red fox
<i>Mustelidae</i>		<i>Badgers, martens, weasels etc.</i>
	<i>Mustela altaica</i> (III India) § 1	Mountain weasel
	<i>Mustela erminea ferghanae</i> (III India) § 1	Stoat
	<i>Mustela kathiah</i> (III India) § 1	Yellow-bellied weasel
	<i>Mustela sibirica</i> (III India) § 1	Siberian weasel
DIPROTODONTIA		
<i>Macropodidae</i>		<i>Kangaroos, wallabies</i>
	<i>Dendrolagus dorianus</i>	Doria's tree-kangaroo
	<i>Dendrolagus goodfellowi</i>	Goodfellow's tree-kangaroo
	<i>Dendrolagus matschiei</i>	Huon tree-kangaroo
	<i>Dendrolagus pulcherrimus</i>	Golden-mantled tree-kangaroo
	<i>Dendrolagus stellarum</i>	Seri's tree-kangaroo
AVES		<i>Birds</i>
ANSERIFORMES		
<i>Anatidae</i>		<i>Ducks, geese, swans</i>
	<i>Anas melleri</i>	Meller's duck

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
COLUMBIFORMES		
<i>Columbidae</i>		<i>Doves, pigeons</i>
	<i>Columba oenops</i>	Peruvian pigeon
	<i>Didunculus strigirostris</i>	Tooth-billed pigeon
	<i>Ducula pickeringii</i>	Grey imperial-pigeon
	<i>Gallicolumba crinigera</i>	Mindanao bleeding-heart
	<i>Ptilinopus marchei</i>	Flame-breasted fruit-dove
	<i>Turacoena modesta</i>	Black cuckoo-dove
GALLIFORMES		
<i>Cracidae</i>		<i>Chachalacas, curassows, guans</i>
	<i>Crax alector</i>	Black curassow
	<i>Pauxi unicornis</i>	Horned curassow
	<i>Penelope pileata</i>	White-crested guan
<i>Megapodiidae</i>		<i>Megapodes, scrubfowl</i>
	<i>Eulipoa wallacei</i>	Moluccan scrubfowl
<i>Phasianidae</i>		<i>Grouse, guineafowl, partridges, pheasants, tragopans</i>
	<i>Arborophila gingica</i>	White-necklaced partridge
	<i>Lophura bulweri</i>	Bulwer's pheasant
	<i>Lophura diardi</i>	Siamese fireback
	<i>Lophura inornata</i>	Salvadori's pheasant
	<i>Lophura leucomelanos</i>	Kalij pheasant
	<i>Syrmaticus reevesii</i> § 2	Reeves's pheasant
PASSERIFORMES		
<i>Bombycillidae</i>		<i>Waxwings</i>
	<i>Bombycilla japonica</i>	Japanese waxwing

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
<i>Corvidae</i>		<i>Crows, magpies, jays</i>
	<i>Cyanocorax caeruleus</i>	Azure jay
	<i>Cyanocorax dickeyi</i>	Tufted jay
<i>Cotingidae</i>		<i>Cotingas</i>
	<i>Procnias nudicollis</i>	Bare-throated bellbird
<i>Emberizidae</i>		<i>Cardinals, seedeaters, tanagers</i>
	<i>Dacnis nigripes</i>	Black-legged dacnis
	<i>Sporophila falcirostris</i>	Temminck's seedeater
	<i>Sporophila frontalis</i>	Buffy-throated seedeater
	<i>Sporophila hypochroma</i>	Grey-and-chestnut seedeater
	<i>Sporophila palustris</i>	Marsh seedeater
<i>Estrildidae</i>		<i>Mannikins, waxbills</i>
	<i>Amandava amandava</i>	Red avadavat
	<i>Cryptospiza reichenovii</i>	Red-faced crimson-wing
	<i>Erythrura coloria</i>	Red-eared parrotfinch
	<i>Erythrura viridifacies</i>	Green-faced parrotfinch
	<i>Estrilda quartinia</i> (Frequently traded as <i>Estrilda melanotis</i>)	Yellow-bellied waxbill
	<i>Hypargos niveoguttatus</i>	Peters's twinspace
	<i>Lonchura griseicapilla</i>	Grey-headed silverbill
	<i>Lonchura punctulata</i>	Scaly-breasted munia
	<i>Lonchura stygia</i>	Black munia

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
<i>Fringillidae</i>		<i>Finches</i>
	<i>Carduelis ambigua</i>	Black-headed greenfinch
	<i>Carduelis atrata</i>	Black siskin
	<i>Kozlowia roborowskii</i>	Tibetan rosefinch
	<i>Pyrrhula erythaca</i>	Grey-headed bullfinch
	<i>Serinus canicollis</i>	Cape canary
	<i>Serinus citrinelloides hypostictus</i> (Frequently traded as <i>Serinus citrinelloides</i>)	East African citril
<i>Icteridae</i>		<i>New-world blackbirds</i>
	<i>Sturnella militaris</i>	Pampas meadowlark
<i>Muscicapidae</i>		<i>Old-world flycatchers, thrushes</i>
	<i>Cochoa azurea</i>	Javan cochoa
	<i>Cochoa purpurea</i>	Purple cochoa
	<i>Garrulax formosus</i>	Red-winged laughingthrush
	<i>Garrulax galbanus</i>	Yellow-throated laughingthrush
	<i>Garrulax milnei</i>	Red-tailed laughing thrush
	<i>Niltava davidi</i>	Fujian niltava
	<i>Stachyris whiteheadi</i>	Chestnut-faced babbler
	<i>Swynnertonia swynnertoni</i> (Also referenced as <i>Pogonicichla swynnertoni</i>)	Swynnerton's robin
	<i>Turdus dissimilis</i>	Black-breasted thrush
<i>Pittidae</i>		<i>Pittas</i>
	<i>Pitta nipalensis</i>	Blue-naped pitta
	<i>Pitta steerii</i>	Azure-breasted pitta
<i>Sittidae</i>		<i>Nuthatches</i>
	<i>Sitta magna</i>	Giant nuthatch
	<i>Sitta yunnanensis</i>	Yunnan nuthatch

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
<i>Sturnidae</i>		<i>Mynas, starlings</i>
	<i>Cosmopsarus regius</i>	Golden-breasted starling
	<i>Mino dumontii</i>	Yellow-faced myna
	<i>Sturnus erythropygius</i>	White-headed starling
REPTILIA		<i>Reptiles</i>
TESTUDINES		
<i>Geoemydidae</i>		<i>Freshwater turtles</i>
	<i>Melanochelys trijuga</i>	Indian black turtle
SAURIA		
<i>Agamidae</i>		
	<i>Physignathus cocincinus</i>	<i>Chinese water dragon</i>
<i>Anguidae</i>		
	<i>Abronia graminea</i>	Arboreal alligator lizard
<i>Gekkonidae</i>		<i>Geckos</i>
	<i>Rhacodactylus auriculatus</i>	New Caledonia bumpy gecko
	<i>Rhacodactylus ciliatus</i>	Guichenot's giant gecko
	<i>Rhacodactylus leachianus</i>	New Caledonia giant gecko
	<i>Teratoscincus microlepis</i>	Small-scaled wonder gecko
	<i>Teratoscincus scincus</i>	Common wonder gecko
<i>Gerrhosauridae</i>		<i>Spiny-tailed lizards</i>
	<i>Zonosaurus karsteni</i>	Karsten's girdled lizard
	<i>Zonosaurus quadrilineatus</i>	Four-lined girdled lizard
<i>Iguanidae</i>		
	<i>Ctenosaura quinquecarinata</i>	Club-tail iguana
<i>Scincidae</i>		<i>Skinks</i>
	<i>Tribolonotus gracilis</i>	Crocodile skink
	<i>Tribolonotus novaeguineae</i>	New Guinea helmet skink

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
SERPENTES		
<i>Colubridae</i>		<i>Typical snakes, water snakes, whip snakes</i>
	<i>Elaphe carinata</i> § 1	Taiwan stink snake
	<i>Elaphe radiata</i> § 1	Radiated rat snake
	<i>Elaphe taeniura</i> § 1	Taiwan beauty snake
	<i>Enhydris bocourti</i> § 1	Bocourt's water snake
	<i>Homalopsis buccata</i> § 1	Masked water snake
	<i>Langaha nasuta</i>	Northern leafnose snake
	<i>Leioheterodon madagascariensis</i>	Madagascar menarana snake
	<i>Ptyas korros</i> § 1	Indochinese rat snake
	<i>Rhabdophis subminiatus</i> § 1	Redneck keelback
<i>Hydrophiidae</i>		<i>Sea snakes</i>
	<i>Lapemis curtus</i> (Includes <i>Lapemis hardwickii</i>) § 1	Shaw's sea snake
<i>Viperidae</i>		<i>Vipers</i>
	<i>Calloselasma rhodostoma</i> § 1	Malayan pit viper
AMPHIBIA		
ANURA		Frogs and toads
<i>Hylidae</i>		<i>Tree frogs</i>
	<i>Phyllomedusa sauvagii</i>	Waxy monkey tree frog
<i>Leptodactylidae</i>		<i>Neotropical frogs</i>
	<i>Leptodactylus laticeps</i>	Red spotted burrow frog
<i>Ranidae</i>		<i>True frogs</i>
	<i>Limnonectes macrodon</i>	Fanged River Frog or Javan Giant Frog
	<i>Rana shqipERICA</i>	Albanian pool frog

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
CAUDATA		
<i>Hynobiidae</i>		<i>Asiatic salamanders</i>
	<i>Ranodon sibiricus</i>	Semirechensk salamander / Central Asian salamander / Siberian salamander
<i>Plethodontidae</i>		<i>Lungless salamanders</i>
	<i>Bolitoglossa dofleini</i>	Giant palm salamander
<i>Salamandridae</i>		<i>Newts and salamanders</i>
	<i>Cynops ensicauda</i>	Sword-tailed newt
	<i>Echinotriton andersoni</i>	Anderson's salamander
	<i>Pachytriton labiatus</i>	Paddletail newt
	<i>Paramesotriton</i> spp.	Warty newt
	<i>Salamandra algira</i>	North African fire salamander
	<i>Tylototriton</i> spp.	Crocodile newts
ACTINOPTERYGII		<i>Fish</i>
PERCIFORMES		
<i>Apogonidae</i>		
	<i>Pterapogon kauderni</i>	Banggai cardinalfish
ARTHROPODA (ARTHROPODS)		
INSECTA		<i>Insects</i>
LEPIDOPTERA		<i>Butterflies</i>
<i>Papilionidae</i>		<i>Birdwing and swallow-tail butterflies</i>
	<i>Baronia brevicornis</i>	Short-horned baronia
	<i>Papilio grosesmithi</i>	
	<i>Papilio maraho</i>	Broad-tailed swallowtail
MOLLUSCA (MOLLUSCS)		
GASTROPODA		
<i>Haliotidae</i>		
	<i>Haliotis midae</i>	Midas ear abalone

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
FLORA		
AGAVACEAE		Agaves
	<i>Calibanus hookeri</i>	
	<i>Dasyilirion longissimum</i>	Beargrass
ARACEAE		Arums
	<i>Arisaema dracontium</i>	Green dragon
	<i>Arisaema erubescens</i>	
	<i>Arisaema galeatum</i>	
	<i>Arisaema nepenthoides</i>	
	<i>Arisaema sikokianum</i>	
	<i>Arisaema thunbergii</i> var. <i>urashima</i>	
	<i>Arisaema tortuosum</i>	
	<i>Biarum davisii</i> ssp. <i>marmarisense</i>	
	<i>Biarum ditschianum</i>	
COMPOSITAE (ASTERACEAE)		Asters, daisies, costus
	<i>Arnica montana</i> § 3	Mountain tobacco
	<i>Othonna cacalioides</i>	
	<i>Othonna clavifolia</i>	
	<i>Othonna hallii</i>	
	<i>Othonna herrei</i>	
	<i>Othonna lepidocaulis</i>	
	<i>Othonna retrorsa</i>	
ERICACEAE		Heathers, rhododendrons
	<i>Arctostaphylos uva-ursi</i> § 3	Bearberry

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
GENTIANACEAE		<i>Gentians</i>
	<i>Gentiana lutea</i> § 3	Great yellow gentian
LEGUMINOSAE (FABACEAE)		<i>Legumes</i>
	<i>Dalbergia granadillo</i> § 4	Black rosewood
	<i>Dalbergia retusa</i> (Except for the population which is included in Annex C) § 4	Black rosewood
	<i>Dalbergia stevensonii</i> (Except for the population which is included in Annex C) § 4	Honduras rosewood
LILIACEAE		<i>Wakerobins</i>
	<i>Trillium pusillum</i>	Dwarf wakerobin
	<i>Trillium rugelii</i>	Ill-scented wakerobin
	<i>Trillium sessile</i>	Sessile-flowered wakerobin wood-lily
LYCOPODIACEAE		<i>Clubmosses</i>
	<i>Lycopodium clavatum</i> § 3	Stagshorn clubmoss
MELIACEAE		<i>Mahoganies, cedars</i>
	<i>Cedrela fissilis</i> (Except for the population which is included in Annex C) § 4	
	<i>Cedrela lilloi</i> (<i>C. angustifolia</i>) (Except for the population which is included in Annex C) § 4	
	<i>Cedrela montana</i> § 4	
	<i>Cedrela oaxacensis</i> § 4	
	<i>Cedrela odorata</i> (Except for the populations which are included in Annex C) § 4	Spanish cedar
	<i>Cedrela salvadorensis</i> § 4	
	<i>Cedrela tonduzii</i> § 4	
MENYANTHACEAE		<i>Bogbeans</i>
	<i>Menyanthes trifoliata</i> § 3	Bogbean

Wednesday 16 April 2014

	<i>Annex D</i>	<i>Common name</i>
PARMELIACEAE		<i>Parmelioid lichens</i>
	<i>Cetraria islandica</i> § 3	Icelandic moss
PASSIFLORACEAE		<i>Desert roses</i>
	<i>Adenia glauca</i>	Desert rose
	<i>Adenia pechuelli</i>	Desert rose
PEDALIACEAE		<i>Sesame, devil's claw</i>
	<i>Harpagophytum</i> spp. § 3	Devil's claw
PORTULACACEAE		<i>Portulas, purslanes</i>
	<i>Ceraria carrissoana</i>	
	<i>Ceraria fruticulosa</i>	
SELAGINELLACEAE		<i>Clubmosses, spikemosses</i>
	<i>Selaginella lepidophylla</i>	Rose of Jericho

Wednesday 16 April 2014

ANNEX II**Repealed Regulation with list of its successive amendments**

Council Regulation (EC) No 338/97

(OJ L 61, 3.3.1997, p. 1)

Commission Regulation (EC) No 938/97

(OJ L 140, 30.5.1997, p. 1)

Commission Regulation (EC) No 2307/97

(OJ L 325, 27.11.1997, p. 1)

Commission Regulation (EC) No 2214/98

(OJ L 279, 16.10.1998, p. 3)

Commission Regulation (EC) No 1476/1999

(OJ L 171, 7.7.1999, p. 5)

Commission Regulation (EC) No 2724/2000

(OJ L 320, 18.12.2000, p. 1)

Commission Regulation (EC) No 1579/2001

(OJ L 209, 2.8.2001, p. 14)

Commission Regulation (EC) No 2476/2001

(OJ L 334, 18.12.2001, p. 3)

Commission Regulation (EC) No 1497/2003

(OJ L 215, 27.8.2003, p. 3)

Regulation (EC) No 1882/2003 of the European Parliament only Article 3 and Annex III, pt. 66 and of the Council

(OJ L 284, 31.10.2003, p. 1)

Commission Regulation (EC) No 834/2004

(OJ L 127, 29.4.2004, p. 40)

Commission Regulation (EC) No 1332/2005

(OJ L 215, 19.8.2005, p. 1)

Commission Regulation (EC) No 318/2008

(OJ L 95, 8.4.2008, p. 3)

Commission Regulation (EC) No 407/2009

(OJ L 123, 19.5.2009, p. 3)

Regulation (EC) No 398/2009 of the European Parliament and of the Council

(OJ L 126, 21.5.2009, p. 5)

Commission Regulation (EU) No 709/2010

(OJ L 212, 12.8.2010, p. 1)

Commission Regulation (EU) No 101/2012

(OJ L 39, 11.2.2012, p. 133)

Wednesday 16 April 2014

ANNEX III

CORRELATION TABLE

Regulation (EC) No 338/97	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5(1) to (5)	Article 5(1) to (5)
Article 5(6), introductory words	Article 5(6), introductory words
Article 5(6)(i)	Article 5(6)(a)
Article 5(6)(ii)	Article 5(6)(b)
Article 5(7)(a)	Article 5(7), first subparagraph
Article 5(7)(b)	Article 5(7), second subparagraph
Article 6(1), (2) and (3)	Article 6(1), (2) and (3)
Article 6(4)(a)	Article 6(4), first subparagraph
Article 6(4)(b)	Article 6(4), second subparagraph
Article 7(1)(a)	Article 7(1), first subparagraph
Article 7(1)(b), introductory words	Article 7(1), second subparagraph
Article 7(1)(b)(i)	Article 7(1), third subparagraph, point (b)(i)
Article 7(1)(b)(ii)	Article 7(1), third subparagraph, point (b)(ii)
Article 7(1)(b)(iii)	Article 7(1), third subparagraph, point (b)(iii)
Article 7(1)(c)	Article 7(1), third subparagraph
Article 7(2)(a)	Article 7(2), first subparagraph
Article 7(2)(b)	Article 7(2), second subparagraph
Article 7(2)(c)	Article 7(2), third subparagraph
—	Article 7(2), fourth subparagraph
Article 7(3)	Article 7(3), first subparagraph
—	Article 7(3), second subparagraph
Article 7(4)	Article 7(4), first subparagraph
—	Article 7(4), second subparagraph
Article 8	Article 8
Article 9	Article 9
Article 10	Article 10
Article 11(1)	Article 11(1)
Article 11(2)(a)	Article 11(2), first subparagraph
Article 11(2)(b)	Article 11(2), second subparagraph

Wednesday 16 April 2014

Regulation (EC) No 338/97	This Regulation
Article 11(3), (4) and (5)	Article 11(3), (4) and (5)
Article 12(1), (2) and (3)	Article 12(1), (2) and (3)
Article 12(4)	Article 12(4), first subparagraph
—	Article 12(4), second subparagraph
Article 12(5)	Article 12(5)
Article 13(1)(a)	Article 13(1), first subparagraph
Article 13(1)(b)	Article 13(1), second subparagraph
Article 13(2)	Article 13(2)
Article 13(3)(a)	Article 13(3), first subparagraph
Article 13(3)(b)	Article 13(3), second subparagraph
Article 13(3)(c)	Article 13(3), third subparagraph
Article 14(1)(a)	Article 14(1), first subparagraph
Article 14(1)(b)	Article 14(1), second subparagraph
Article 14(1)(c)	Article 14(1), third subparagraph
Article 14(2)	Article 14(2)
Article 14(3)(a)	Article 14(3), first subparagraph
Article 14(3)(b)	Article 14(3), second subparagraph
Article 14(3)(c)	Article 14(3), third subparagraph
Article 15(1), (2) and (3)	Article 15(1), (2) and (3)
Article 15(4)(a)	Article 15(4), first subparagraph
Article 15(4)(b)	Article 15(4), second subparagraph
Article 15(4)(c)	Article 15(4), third subparagraph
Article 15(4)(d)	Article 15(4), fourth subparagraph
Article 15(5) and (6)	Article 15(5) and (6)
Article 16	Article 16
Article 17(1)	Article 17(1)
Article 17(2)(a)	Article 17(2)
Article 17(2)(b)	Article 17(3)
Article 18	Article 21
Article 19(1), first subparagraph	—
Article 19(1), second subparagraph	—
Article 19(2)	—
Article 19(3)	Article 18(1)
Article 19(4)	Article 18(2)
Article 19(5)	Article 18(3)
—	Article 20

Wednesday 16 April 2014

Regulation (EC) No 338/97	This Regulation
Article 20	Article 22
Article 21	—
—	Article 23
Article 22	Article 24
Annex	Annex I
—	Annex II
—	Annex III

Wednesday 16 April 2014

P7_TA(2014)0398

Fishing opportunities and financial contribution provided for in the EU-Seychelles Fisheries Partnership Agreement ***

European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion, on behalf of the European Union, of the Protocol setting out the fishing opportunities and the financial contribution provided for by the Fisheries Partnership Agreement between the European Union and the Republic of Seychelles (16651/2013 — C7-0020/2014 — 2013/0375(NLE))

(Consent)

(2017/C 443/74)

The European Parliament,

- having regard to the draft Council decision (16651/2013),
 - having regard to the draft Protocol setting out the fishing opportunities and the financial contribution provided for by the Fisheries Partnership Agreement between the European Union and the Republic of Seychelles (16648/2013),
 - having regard to the request for consent submitted by the Council in accordance with Article 43 and Article 218(6), second subparagraph, point (a), and (7), of the Treaty on the Functioning of the European Union (C7-0020/2014),
 - having regard to the proposal for a Council regulation concerning the allocation of fishing opportunities under the Protocol to the Fisheries Partnership Agreement between the European Community and the Republic of Seychelles (COM(2013)0765),
 - having regard to the proposal for a Council decision on the signing, on behalf of the European Union, and on the provisional application of the Protocol setting out the fishing opportunities and the financial contribution provided for by the Fisheries Partnership Agreement between the European Community and the Republic of Seychelles (COM(2013)0766),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2), and Rule 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Fisheries and the opinion of the Committee on Budgets (A7-0201/2014),
1. Gives its consent to conclusion of the Protocol;
 2. Calls on the Commission to provide Parliament with relevant information on the joint scientific meetings provided for in Article 4 of the Partnership Agreement and on meetings of the joint committee provided for in Article 9 of the Partnership Agreement, in particular the corresponding minutes and conclusions, together with an annual report on the practical implementation of the multiannual sectoral support programme referred to in Article 3 of the Protocol;
 3. Calls for representatives of its Committee on Fisheries, acting as observers, to be able to attend the above meetings of the joint committee provided for in Article 9 of the Partnership Agreement;
 4. Calls on the Commission to submit to Parliament and the Council, during the final year of the Protocol's validity and before the opening of negotiations on its renewal, an ex-post assessment report on its implementation, containing an analysis of the uptake of fishing opportunities and a cost-benefit analysis of the Protocol, along with a report on possible constraints on fishing operations and damage caused to the Union fleet operating in the Seychelles' Exclusive Economic Zone as a result of piracy in this part of the Indian Ocean;
 5. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Republic of Seychelles.
-

Wednesday 16 April 2014

P7_TA(2014)0399

Fishing opportunities and financial contribution provided for in the EU-Comoros Fisheries Partnership Agreement ***

European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion, on behalf of the European Union, of the Protocol between the European Union and the Union of the Comoros setting out the fishing opportunities and financial contribution provided for in the Fisheries Partnership Agreement currently in force between the two parties (16130/2013 — C7-0011/2014 — 2013/0388(NLE))

(Consent)

(2017/C 443/75)

The European Parliament,

- having regard to the draft Council decision (16130/2013),
 - having regard to the draft protocol between the European Union and the Union of the Comoros setting out fishing opportunities and financial contribution provided for in the Fisheries Partnership Agreement between the two parties currently in force (16127/2013),
 - having regard to the request for consent submitted by the Council in accordance with Article 43 and Article 218(6), second subparagraph, point (a), and (7), of the Treaty on the Functioning of the European Union (C7-0011/2014),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2), and Rule 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Fisheries and the opinion of the Committee on Budgets (A7-0177/2014),
1. Gives its consent to conclusion of the protocol;
 2. Calls on the Commission to forward to Parliament the minutes and the conclusions of the meetings of the Joint Committee to monitor the implementation, interpretation and application of the Agreement, as provided for in Article 9 of the Agreement, as well as the evaluation of the progress made in implementing multiannual sectorial programme provided for in Article 3 of the protocol; calls on the Commission to facilitate the participation of representatives of Parliament as observers in the meetings of the Joint Committee; calls on the Commission to submit to Parliament and the Council, within the last year of application of the protocol and before the opening of negotiations for its renewal, a full report on its implementation, without unnecessary restrictions on document access;
 3. Calls on the Council and the Commission, acting within the limits of their respective powers, to keep Parliament immediately and fully informed at all stages of the procedures related to the new protocol and its renewal, pursuant to Article 13(2) of the Treaty on European Union and Article 218(10) of the Treaty on the Functioning of the European Union;
 4. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Union of the Comoros.
-

Wednesday 16 April 2014

P7_TA(2014)0400

Fishing opportunities and financial contribution provided for in the EU-Madagascar Fisheries Partnership Agreement ***

European Parliament legislative resolution of 16 April 2014 on the draft Council Decision on the conclusion of the Protocol agreed between the European Union and the Republic of Madagascar setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement between the two parties currently in force (14164/1/2012 — C7-0408/2012 — 2012/0238(NLE))

(Consent)

(2017/C 443/76)

The European Parliament,

- having regard to the draft Council decision (14164/1/2012),
 - having regard to the draft Protocol agreed between the European Union and the Republic of Madagascar setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement between the two parties currently in force (14159/2012)
 - having regard to the request for consent submitted by the Council in accordance with Article 43(2) and Article 218(6), second subparagraph, point (a), of the Treaty on the Functioning of the European Union (C7-0408/2012),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2), and Rule 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Fisheries and the opinions of the Committee on Development and the Committee on Budgets (A7-0178/2014),
1. Gives its consent to conclusion of the Protocol;
 2. Instructs its President to forward its position to the Council and Commission, and the governments and parliaments of the Member States and the Republic of Madagascar.
-

Wednesday 16 April 2014

P7_TA(2014)0401

EU-Korea Framework Agreement as regards matters related to readmission ***

European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion of the Framework Agreement between the European Union and its Member States, on the one part, and the Republic of Korea, on the other part, as regards matters related to readmission (05290/2014 — C7-0046/2014 — 2013/0267A (NLE))

(Consent)

(2017/C 443/77)

The European Parliament,

- having regard to the draft Council decision (05290/2014),
 - having regard to the draft Framework Agreement between the European Union and its Member States, on the one part, and the Republic of Korea, on the other part (06151/2010),
 - having regard to the request for consent submitted by the Council in accordance with Article 79(3) and Article 218(6), second subparagraph, point (a), of the Treaty on the Functioning of the European Union (C7-0046/2014),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2), and Rule 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Civil Liberties, Justice and Home Affairs (A7-0267/2014),
1. Gives its consent to the conclusion of the Agreement;
 2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Republic of Korea.
-

Wednesday 16 April 2014

P7_TA(2014)0402

EU-Korea Framework Agreement with the exception of matters related to readmission ***

European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion of the Framework Agreement between the European Union and its Member States, on the one part, and the Republic of Korea, on the other part, with the exception of matters related to readmission (05287/2014 — C7-0044/2014 — 2013/0267B(NLE))

(Consent)

(2017/C 443/78)

The European Parliament,

- having regard to the draft Council decision (05287/2014),
 - having regard to the Framework Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part (06151/2010),
 - having regard to the request for consent submitted by the Council in accordance with Articles 91, 100, 191(4), 207, 212 and Article 218(6), second subparagraph, point (a) of the Treaty on the Functioning of the European Union (C7-0044/2014),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2), and Rule 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Foreign Affairs and the opinion of the Committee on International Trade (A7-0265/2014),
1. Gives its consent to conclusion of the agreement;
 2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Republic of Korea.
-

Wednesday 16 April 2014

P7_TA(2014)0403

EC-Montenegro Stabilisation and Association Agreement (Protocol to take account of the accession of Croatia) ***

European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion on behalf of the European Union and its Member States of the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Montenegro, of the other part, to take account of the accession of the Republic of Croatia to the European Union (14187/2013 — C7-0007/2014 — 2013/0262(NLE))

(Consent)

(2017/C 443/79)

The European Parliament,

- having regard to the draft Council decision (14187/2013),
 - having regard to the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Montenegro, of the other part, to take account of the accession of the Republic of Croatia to the European Union (14190/2013),
 - having regard to the request for consent submitted by the Council in accordance with Article 217, in conjunction with Article 218(6), second subparagraph, point (a)(i) and Article 218(8), second subparagraph, of the Treaty on the Functioning of the European Union (C7-0007/2014),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2) and Rule 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Foreign Affairs (A7-0192/2014),
1. Gives its consent to conclusion of the Protocol;
 2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Republic of Montenegro.
-

Wednesday 16 April 2014

P7_TA(2014)0404

EU-Georgia Framework Agreement on the general principles for the participation of Georgia in Union programmes ***

European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the conclusion of a Protocol to the Partnership and Cooperation Agreement between the European Communities and their Member States, of the one part, and Georgia of the other part, on a Framework Agreement between the European Union and Georgia on the general principles for the participation of Georgia in Union programmes (16612/2013 — C7-0486/2013 — 2013/0257(NLE))

(Consent)

(2017/C 443/80)

The European Parliament,

- having regard to the draft Council decision (16612/2013),
 - having regard to the Protocol to the Partnership and Cooperation Agreement between the European Communities and their Member States, of the one part, and Georgia, of the other part, on a Framework Agreement between the European Union and Georgia, on the general principles for the participation of Georgia in Union programmes (16613/2013),
 - having regard to the request for consent submitted by the Council in accordance with Article 212 and Article 218(6), second subparagraph, point (a), of the Treaty on the Functioning of the European Union (C7-0486/2013),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2) and Rule 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Foreign Affairs (A7-0191/2014),
1. Gives its consent to conclusion of the Protocol;
 2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of Georgia.
-

Wednesday 16 April 2014

P7_TA(2014)0405

Authorisation for Portugal to apply a reduced rate of excise duty in the autonomous regions of Madeira and Azores on certain alcoholic beverages *

European Parliament legislative resolution of 16 April 2014 on the proposal for a Council decision authorising Portugal to apply a reduced rate of excise duty in the autonomous region of Madeira on locally produced and consumed rum and liqueurs and in the autonomous region of the Azores on locally produced and consumed liqueurs and eaux-de-vie (COM(2014)0117 — C7-0104/2014 — 2014/0064(CNS))

(Special legislative procedure — consultation)

(2017/C 443/81)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2014)0117),
 - having regard to Article 349 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0104/2014),
 - having regard to Rules 55 and 46(1) of its Rules of Procedure,
 - having regard to the report of the Committee on Regional Development (A7-0262/2014),
1. Approves the Commission proposal;
 2. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 3. Asks the Council to consult Parliament again if it intends to substantially amend the text approved by Parliament;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.
-

Wednesday 16 April 2014

P7_TA(2014)0406

AIEM tax applicable in the Canary Islands***European Parliament legislative resolution of 16 April 2014 on the proposal for a Council decision on the AIEM tax applicable in the Canary Islands (COM(2014)0171 — C7-0106/2014 — 2014/0093(CNS))****(Special legislative procedure — consultation)**

(2017/C 443/82)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2014)0171),
 - having regard to Article 349 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0106/2014),
 - having regard to Rules 55 and 46(1) of its Rules of Procedure,
 - having regard to the report of the Committee on Regional Development (A7-0263/2014),
1. Approves the Commission proposal;
 2. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 3. Asks the Council to consult Parliament again if it intends to substantially amend the text approved by Parliament;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.
-

Wednesday 16 April 2014

P7_TA(2014)0407

Amendment of the period of application of Council Decision 2004/162/EC concerning the dock dues in the French overseas departments *

European Parliament legislative resolution of 16 April 2014 on the proposal for a Council decision amending the period of application of Council Decision 2004/162/EC concerning the dock dues in the French overseas departments (COM(2014)0181 — C7-0129/2014 — 2014/0101(CNS))

(Special legislative procedure — consultation)

(2017/C 443/83)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2014)0181),
 - having regard to Article 349 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C7-0129/2014),
 - having regard to Rules 55 and 46(1) of its Rules of Procedure,
 - having regard to the report of the Committee on Regional Development (A7-0264/2014),
1. Approves the Commission proposal;
 2. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 3. Asks the Council to consult Parliament again if it intends to substantially amend the text approved by Parliament;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.
-

Wednesday 16 April 2014

P7_TA(2014)0411

Draft amending budget No 1/2014: technical adjustments concerning the European Investment Fund, Horizon 2020 and the Shift2Rail Joint Undertaking**European Parliament resolution of 16 April 2014 on the Council position on Draft amending budget No 1/2014 of the European Union for the financial year 2014, Section III — Commission (08219/2014 — C7-0146/2014 — 2014/2018(BUD))**

(2017/C 443/84)

The European Parliament,

- having regard to Article 314 of the Treaty on the Functioning of the European Union and Article 106a of the Euratom Treaty,
 - having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002⁽¹⁾, and in particular Article 41 thereof,
 - having regard to the general budget of the European Union for the financial year 2014, as definitively adopted on 20 November 2013⁽²⁾,
 - having regard to the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management⁽³⁾,
 - having regard to Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for years 2014-2020⁽⁴⁾,
 - having regard to the proposal for a decision of the European Parliament and of the Council on the participation of the European Union in the capital increase of the European Investment Fund (COM(2014)0066),
 - having regard to the proposal for a Council Regulation establishing the Shift2Rail Joint Undertaking (COM(2013)0922),
 - having regard to Draft amending budget No 1/2014, which the Commission adopted on 11 February 2014 (COM(2014)0078),
 - having regard to the position on Draft amending budget No 1/2014 which the Council adopted on 9 April 2014 and forwarded to Parliament on 10 April 2014 (08219/2014 — C7-0146/2014),
 - having regard to Rules 75b and 75e of its Rules of Procedure,
 - having regard to the report of the Committee on Budgets (A7-0276/2014),
- A. whereas Draft amending budget No 1/2014 relates to a number of adjustments necessary for the implementation of budget 2014 in line with the adoption of the latest legislative acts, and in particular adjustments needed to implement the proposed European Investment Fund (EIF) capital increase, changes arising from the legal basis of Horizon 2020 adopted after the formal adoption of budget 2014, and adjustments linked to the creation of the budget structure for the proposal of the Shift2Rail Joint Undertaking;
- B. whereas the increase in the EIF's capital base will contribute to improving the access of small and medium-sized enterprises to financing through the COSME and Horizon 2020 programmes;
- C. whereas the changes to nomenclature of the Horizon 2020 programme are necessary to align it with the provisions of the legal basis adopted in December 2013;

⁽¹⁾ OJ L 298, 26.10.2012, p. 1.

⁽²⁾ OJ L 51, 20.2.2014.

⁽³⁾ OJ C 373, 20.12.2013, p. 1.

⁽⁴⁾ OJ L 347, 20.12.2013, p. 884.

Wednesday 16 April 2014

- D. whereas the creation of the appropriate budgetary structure for the Shift2Rail Joint Undertaking is necessary and has already been done for other joint undertakings during the 2014 budgetary procedure;
- E. whereas the purpose of Draft amending budget No 1/2014 is to formally enter this budgetary adjustments into the 2014 budget;
- F. whereas the proposed changes are presented as budgetary neutral, with no change to the overall level of expenditure for 2014;
1. Reminds that the work programme for the activity covered by budget line 08 02 04 01 'Science for and with society' indicates commitments of some EUR 53 million in 2014 while Draft amending budget No 1/2014 does not suggest any allocations to this line; reminds the Commission of the commitment made during the budgetary trilogue of 2 April 2014 to immediately proceed to an internal transfer to line 08 02 04 01 'Science for and with society' in order to ensure the smooth start of this activity according to the work programme and as foreseen in the legal base;
 2. Takes note of Draft amending budget No 1/2014, as submitted by the Commission, and of the Council's position thereon;
 3. Approves the Council position on Draft amending budget No 1/2014;
 4. Instructs its President to declare that Amending budget No 1/2014 has been definitively adopted and arrange for its publication in the Official Journal of the European Union;
 5. Instructs its President to forward this resolution to the Council, the Commission and the national parliaments.
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Wednesday 16 April 2014

P7_TA(2014)0412

Introduction of noise-related operating restrictions at European Union airports *II**

European Parliament legislative resolution of 16 April 2014 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on the establishment of rules and procedures with regard to the introduction of noise-related operating restrictions at Union airports within a Balanced Approach and repealing Directive 2002/30/EC (05560/2/2014 — C7-0133/2014 — 2011/0398(COD))

(Ordinary legislative procedure: second reading)

(2017/C 443/85)

The European Parliament,

- having regard to the Council position at first reading (05560/2/2014 — C7-0133/2014),
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the French Senate, the German Bundesrat and the Dutch House of Representatives, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 28 March 2012 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 19 July 2012 ⁽²⁾
 - having regard to its position at first reading ⁽³⁾ on the Commission proposal to Parliament and the Council (COM(2011)0828),
 - having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 72 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on Transport and Tourism (A7-0274/2014),
1. Approves the Council position at first reading;
 2. Takes note of the Commission statement annexed to this resolution;
 3. Notes that the act is adopted in accordance with the Council position;
 4. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;
 5. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;
 6. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 181, 21.6.2012, p. 173.

⁽²⁾ OJ C 277, 13.9.2012, p. 110.

⁽³⁾ Texts adopted of 12.12.2012, P7_TA(2012)0496.

Wednesday 16 April 2014

ANNEX TO THE LEGISLATIVE RESOLUTION

Statement by the Commission on the revision of Directive 2002/49/EC

The Commission is discussing with the Member States Annex II to Directive 2002/49/EC (noise calculation methods) with a view to adopting it in the coming months.

Based on work the WHO is currently undertaking regarding the methodology to assess health implications of the noise impact, the Commission intends to revise Annex III to Directive 2002/49/EC (estimation of health impact, dose response curves).

Wednesday 16 April 2014

P7_TA(2014)0413

Union action for the European Capitals of Culture for the years 2020 to 2033 *II****European Parliament legislative resolution of 16 April 2014 on the Council position at first reading in view of the adoption of a Decision of the European Parliament and of the Council establishing a Union action for the European Capitals of Culture for the years 2020 to 2033 and repealing Decision No 1622/2006/EC (05793/1/2014 — C7-0132/2014 — 2012/0199(COD))****(Ordinary legislative procedure: second reading)**

(2017/C 443/86)

The European Parliament,

- having regard to the Council position at first reading (05793/1/2014 — C7-0132/2014),
 - having regard to the opinions of the Committee of the Regions of 15 February 2012⁽¹⁾ and 30 November 2012⁽²⁾,
 - having regard to its position at first reading⁽³⁾ on the Commission proposal to Parliament and the Council (COM(2012)0407),
 - having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 72 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on Culture and Education (A7-0275/2014),
1. Approves the Council position at first reading;
 2. Notes that the act is adopted in accordance with the Council position;
 3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;
 4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;
 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 113, 18.4.2012, p. 17.

⁽²⁾ OJ C 17, 19.1.2013, p. 97.

⁽³⁾ Texts adopted of 12.12.2013, P7_TA(2013)0590.

Wednesday 16 April 2014

P7_TA(2014)0414

Incidental catches of cetaceans *II**

European Parliament legislative resolution of 16 April 2014 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 812/2004 laying down measures concerning incidental catches of cetaceans in fisheries (06103/1/2014 — C7-0100/2014 — 2012/0216(COD))

(Ordinary legislative procedure: second reading)

(2017/C 443/87)

The European Parliament,

- having regard to the Council position at first reading (06103/1/2014 — C7-0100/2014),
 - having regard to the opinion of the European Economic and Social Committee of 14 November 2012 ⁽¹⁾,
 - having regard to its position at first reading ⁽²⁾ on the Commission proposal to Parliament and the Council (COM(2012)0447),
 - having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 72 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on Fisheries (A7-0272/2014),
1. Approves the Council position at first reading;
 2. Notes that the act is adopted in accordance with the Council position;
 3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;
 4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the Official Journal of the European Union;
 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 11, 15.1.2013, p. 85.

⁽²⁾ Texts adopted of 16.4.2013, P7_TA(2013)0104.

Wednesday 16 April 2014

P7_TA(2014)0415

Posting of workers in the framework of the provision of services *I****European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council on the enforcement of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services (COM(2012)0131 — C7-0086/2012 — 2012/0061(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/88)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0131),
 - having regard to Article 294(2) and Articles 53(1) and 62 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0086/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 19 September 2012 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 29 November 2012 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 5 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Employment and Social Affairs and the opinions of the Committee on Internal Market and Consumer Protection and of the Committee on Legal Affairs (A7-0249/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Approves the joint statement by Parliament, the Council and the Commission annexed hereto, which will be published in the L series of the *Official Journal of the European Union* together with the final legislative act;
 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0061**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the enforcement of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services and amending Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation')***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/67/EU.)*⁽¹⁾ OJ C 351, 15.11.2012, p. 61.⁽²⁾ OJ C 17, 19.1.2013, p. 67.

Wednesday 16 April 2014

ANNEX TO THE LEGISLATIVE RESOLUTION

Joint statement by the European Parliament, the Council and the Commission on Article 4(3)(g)

The fact whether or not the post to which the posted worker is temporarily assigned to carry out his or her work in the framework of the provision of services was filled by the same or another (posted) worker during any previous periods constitutes only one of the possible elements to be taken into account while making an overall assessment of the factual situation in case of doubt.

The mere fact that it can be one of the elements should in no way be interpreted as imposing a ban on the possible replacement of a posted worker by another posted worker or hampering the possibility of such a replacement, which may be inherent in particular to services which are provided on a seasonal, cyclical or repetitive basis.

Wednesday 16 April 2014

P7_TA(2014)0416

Return of cultural objects unlawfully removed from the territory of a Member State *I****European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council on the return of cultural objects unlawfully removed from the territory of a Member State (recast) (COM(2013)0311 — C7-0147/2013 — 2013/0162(COD))****(Ordinary legislative procedure — recast)**

(2017/C 443/89)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0311),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0147/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 18 September 2013 ⁽¹⁾,
 - having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts ⁽²⁾,
 - having regard to the letter of 5 November 2013 from the Committee on Legal Affairs to the Committee on Culture and Education in accordance with Rule 87(3) of its Rules of Procedure,
 - having regard to the undertaking given by the Council representative by letter of 27 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 87 and 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Culture and Education (A7-0058/2014),
- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;
1. Adopts its position at first reading hereinafter set out, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 341, 21.11.2013, p. 98.

⁽²⁾ OJ C 77, 28.3.2002, p. 1.

Wednesday 16 April 2014

P7_TC1-COD(2013)0162

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the return of cultural objects unlawfully removed from the territory of a Member State and amending Regulation (EU) No 1024/2012 (Recast)

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/60/EU.)

Wednesday 16 April 2014

P7_TA(2014)0417

Reducing the consumption of lightweight plastic carrier bags *I****European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Directive 94/62/EC on packaging and packaging waste to reduce the consumption of lightweight plastic carrier bags (COM(2013)0761 — C7-0392/2013 — 2013/0371(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/90)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0761),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0392/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 26 February 2014 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 3 April 2014 ⁽²⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0174/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0371**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Directive 94/62/EC on packaging and packaging waste to reduce the consumption of lightweight plastic carrier bags****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

⁽¹⁾ Not yet published in the Official Journal.⁽²⁾ Not yet published in the Official Journal.

Wednesday 16 April 2014

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) Directive 94/62/EC of the European Parliament and of the Council ⁽⁴⁾ was adopted in order to prevent or reduce the impact of packaging and packaging waste on the environment. Although plastic carrier bags constitute packaging within the meaning of that Directive, its provisions do not contain specific measures relating to the consumption of such bags.
- (2) Consumption of plastic carrier bags results in high levels of littering and an inefficient use of resources and is expected to increase if no action is taken. Littering of plastic carrier bags ~~contributes to the problem~~ **results in environmental pollution and aggravates the widespread problem** of marine litter that threatens marine **in water bodies, threatening aquatic** eco-systems worldwide. [Am. 1]
- (2a) **Furthermore, the accumulation of plastic carrier bags in the environment has a clearly negative impact on certain branches of the economy, such as tourism.** [Am. 2]
- (3) **Lightweight** plastic carrier bags with a thickness below 50 microns, which represent the vast majority of the total number of plastic carrier bags consumed in the Union, are less frequently re-used **reusable** than thicker plastic carrier bags ~~and~~, **thus become waste more quickly, are** more prone to littering **and, due to their light weight, more likely to end up scattered through the environment, both on land and in freshwater and marine-ecosystems.** [Am. 3]
- (3a) **Current recycling rates are very low even though plastic carrier bags are recyclable. Furthermore, the recycling of plastic carrier bags is not expected to reach a significant level, as due to their thinness and light weight, plastic carrier bags do not have a high recycling value. In addition, there is no separate collection for plastic carrier bags, their transportation is costly, and washing them for recycling requires large volumes of water. The recycling of plastic carrier bags therefore does not resolve the problems caused by them.** [Am. 4]
- (3b) **According to the waste hierarchy prevention comes first. Therefore, an EU-wide reduction target has been defined. However, plastic carrier bags serve several purposes and they will still be used in the future. In order to ensure that the needed plastic carrier bags will not end up in the environment, the infrastructure for waste management — especially recycling — should be expanded and consumers should be informed about proper waste disposal.** [Am. 46]
- (4) Consumption levels of plastic carrier bags vary considerably across the Union due **not only** to differences in consumption habits, **and** environmental awareness, ~~as well as the~~ **but mainly to the degree of** effectiveness of policy measures taken by Member States. Some Member States have managed to reduce consumption levels of plastic carrier bags significantly, with the average consumption level in the seven best performing Member States amounting to only 20 % of the EU average consumption. **EU-wide reduction targets should be set compared to the average consumption of plastic carrier bags across the Union so as to take account of reductions already achieved by certain Member States.** [Am. 5]

⁽¹⁾ OJ C , , p. .

⁽²⁾ OJ C , , p. .

⁽³⁾ Position of the European Parliament of 16 April 2014.

⁽⁴⁾ Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10).

Wednesday 16 April 2014

- (4a) *The data available concerning the use of plastic carrier bags in the Union clearly show that consumption is low or has been reduced in those Member States where economic operators do not make plastic carrier bags available free of charge, but instead subject to a small payment. [Am. 6]*
- (4b) *Furthermore, consumer information has been shown to play a decisive part in achieving any goals regarding reduced plastic bag consumption. It is therefore necessary for efforts to be made at institutional level to heighten awareness of the environmental impact of plastic bags and do away with the current perception of plastic as a harmless, cheap and intrinsically worthless commodity. [Am. 7]*
- (5) To promote similar reductions of the average consumption level of lightweight plastic carrier bags, Member States should take measures to **significantly** reduce the consumption of plastic carrier bags with a thickness below 50 microns **with very limited reusability** in line with the overall objectives of the Union's waste policy and the Union's waste hierarchy as provided for in Directive 2008/98/EC of the European Parliament and of the Council⁽¹⁾. Such reduction measures should take account of current consumption levels of plastic carrier bags in individual Member States, with higher levels requiring more ambitious efforts. To monitor progress in reducing the use of lightweight plastic carrier bags national authorities will provide data on their use in accordance with Article 17 of Directive 94/62/EC. [Am. 8]
- (5a) *Measures to be taken by Member States should involve the use of economic instruments such as pricing, which has proved particularly effective to reduce the use of plastic carrier bags. Member States should ensure that economic operators selling food do not provide plastic carrier bags other than very lightweight plastic carrier bags or alternatives to such very lightweight plastic carrier bags, free of charge at the point of sale of goods or products. Member States should also encourage economic operators selling solely non-food items not to provide plastic carrier bags free of charge at the point of sale of goods or products. [Am. 9]*
- (6) ~~Measures to be taken by Member States may involve the~~ **should also be able to** use of economic instruments such as taxes and levies, ~~which have proved particularly effective to reduce the use of plastic carrier bags,~~ as well as marketing restrictions such as bans in derogation of Article 18 of Directive 94/62/EC, subject to the requirements laid down in Articles 34 to 36 of the Treaty on the Functioning of the European Union ("TFEU"). [Am. 10]
- (6a) *Plastic carrier bags used to wrap humid, loose foods such as raw meat, fish and dairy, and plastic bags used to hold unpackaged prepared foodstuffs are required for food hygiene and should therefore be exempt from the scope of this Directive. [Ams 47 and 51]*
- (6b) *Very lightweight plastic carrier bags are routinely used to purchase dry, loose unpackaged foods such as fruits, vegetables or confectionery. The use of very lightweight plastic carrier bags for such purposes helps prevent food wastage, since it enables consumers to purchase the exact amount required rather than a fixed pre-packaged quantity, and since it allows the withdrawal of a product that is no longer fit for consumption specifically without needing to discard entire pre-packaged packages. Nevertheless, very lightweight plastic carrier bags made of conventional plastics are a particular problem with regard to littering. [Am. 12]*
- (6c) *Plastic carrier bags made of biodegradable and compostable materials are less harmful to the environment than conventional plastic carrier bags. Where the use of plastic carrier bags provides important benefits, namely where very lightweight plastic carrier bags are used for dry loose, unpackaged foods such as fruits, vegetables and*

⁽¹⁾ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

Wednesday 16 April 2014

confectionery, those conventional very lightweight plastic carrier bags should be gradually replaced by carrier bags made of recycled paper, or by very lightweight plastic carrier bags that are biodegradable and compostable. Where the use of plastic carrier bags should be reduced, namely the use of lightweight plastic carrier bags, the use of such bags made of biodegradable and compostable materials should also fall under the general reduction target. However, Member States with separate collection of bio-waste should be allowed to reduce the price of biodegradable and compostable lightweight plastic carrier bags. [Am. 13]

- (6d) Education programmes aimed at consumers in general, as well as at children in particular, should play a particular role in the reduction of the use of plastic bags. Those education programmes should be implemented both by Member States as well as by producers and retailers at the point of sale of goods and products. [Am. 14]*
- (6e) The essential requirements with regard to packaging that is recoverable in the form of composting should be amended so as to ensure that a European standard for garden composting is developed. The essential requirements with regard to biodegradable packaging should be amended so as to ensure that only materials that are fully biodegraded are considered to be biodegradable. [Am. 15]*
- (6f) European standard EN 13432 on ‘Requirements for packaging recoverable through composting and biodegradation — Test scheme and evaluation criteria for the final acceptance of packaging’ lays down the characteristics that a material must possess in order to be considered ‘compostable’, namely that it can be recycled through a process of organic recovery comprised of composting and anaerobic digestion. The Commission should ask the European Committee for Standardization to develop a separate standard for garden composting. [Am. 16]*
- (6 g) Some plastic materials are referred to as ‘oxo-biodegradable’ by their manufacturers. In such plastic materials, ‘oxo-biodegradable’ additives, typically metal salts, are incorporated into conventional plastics. As a result of the oxidation of those additives, the plastic materials fragment into small particles, which remain in the environment. It is thus misleading to refer to such plastic materials as ‘biodegradable’. Fragmentation transforms visible littering of items such as plastic carrier bags into invisible littering by secondary microplastics. This is not a solution to the waste problem, but rather increases pollution of the environment by those plastic materials. Such plastic materials should therefore not be used for plastic packaging. [Am. 17]*
- (6h) The use of substances that are carcinogenic, mutagenic or toxic to reproduction and of substances that are endocrine disrupters should be phased out from packaging material so as to avoid unnecessary exposure of humans to such substances and to avoid that such substances enter the environment during the waste phase. [Am. 18]*
- (6i) Harmful substances, particularly hormone-disrupting chemicals, in plastic bags, should be entirely banned to ensure a good level of protection for the environment and human health. [Am. 19]*
- (7) Measures to reduce the consumption of plastic carrier bags should **lead to a sustained reduction in the consumption of lightweight plastic carrier bags and should** not lead to an overall increase in the generation of packaging. [Am. 20]*
- (7a) In order to ensure Union-wide recognition of indications (mark, feature or colour code) for biodegradable and compostable bags, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of defining such indications. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. [Am. 21]*

Wednesday 16 April 2014

- (8) The measures provided for by this Directive are consistent with the Communication from the Commission on the Roadmap to a Resource Efficient Europe ⁽¹⁾ and should contribute to actions against littering undertaken in accordance with Directive 2008/56/EC of the European Parliament and of the Council ⁽²⁾.
- (8a) ***In order not to impede the functioning of the internal market, the same conditions should apply throughout the Union in respect of the materials used. Differences in the way certain materials are dealt with in certain Member States are detrimental to recycling and trade.*** [Am. 22]
- (9) Directive 94/62/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 94/62/EC is hereby amended as follows:

(1) In Article 3, the following points are inserted:

-2a. “plastic carrier bags” shall mean bags, with or without handle, made of plastic materials as defined in point (1) of Article 3 of Commission Regulation (EU) No 10/2011 (*), which are supplied to consumers at the point of sale of goods or products for the purpose of carrying goods. Plastic carrier bags that are necessary for food hygiene to wrap humid, loose foods such as raw meat, fish and dairy and plastic bags to hold unpackaged prepared foodstuffs shall not be considered as plastic carrier bags for the purposes of this Directive; [Ams 48 and 53]

2a. “lightweight plastic carrier bags” shall mean bags made of plastic materials as defined in point (1) of Article 3 of Regulation (EU) No 10/2011 with a wall thickness below 50 microns and which are supplied to consumers at the point of sale of goods or products, ***except very lightweight plastic carrier bag; [Am. 24]***

2b. “very lightweight plastic carrier bags” shall mean bags made of plastic materials as defined in point (1) of Article 3 of Regulation (EU) No 10/2011 with a wall thickness below 10 microns; [Am. 25]

2c. “oxo-fragmentable plastic materials” shall mean plastic materials that include additives that catalyse the fragmentation of the plastic material into micro-fragments of plastic material; [Am. 26]

2d. “bio-waste” shall mean biodegradable garden and park waste, food and kitchen waste from households, restaurants, caterers and retail premises, and comparable waste from food processing plants. It does not include forestry or agricultural residues, manure, sewage sludge, or other biodegradable waste such as natural textiles, paper or processed wood. It also excludes those by-products of food production that never become waste; [Am. 27]

2e. “substances that are carcinogenic, mutagenic or toxic to reproduction” shall mean substances that are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (**); [Am. 28]

⁽¹⁾ Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the Roadmap to a Resource Efficient Europe (COM(2011)0571 final).

⁽²⁾ Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

Wednesday 16 April 2014

2f. “endocrine disrupters” shall mean substances having endocrine disrupting properties for which there is scientific evidence of possible serious effects to human health or which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (***) or which are identified according to Commission Recommendation [.../.../EU] (****);

(*) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

(**) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(***) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(****) Commission Recommendation [.../.../EU] of ... on criteria for the identification of endocrine disrupters (OJ C ...).’ [Am. 29]

(2) In Article 4, the following paragraphs are inserted:

‘-1a. Member State shall ensure that packaging is manufactured in such a way that it does not contain substances in concentrations above 0,01 % that are carcinogenic, mutagenic or toxic to reproduction or that are endocrine disrupters. Member States shall ensure that packaging is manufactured in such a way that it does not contain “oxo-fragmentable” plastic materials. Those measures shall be achieved by ... (*) . [Am. 30]

1a. Member States shall take measures to achieve a **sustained** reduction in the consumption of lightweight plastic carrier bags on their territory ~~within two years of entry into force of this Directive.~~ **of at least:**

— 50 % by ... (**), and

— 80 % by ... (***) ,

as compared to the average consumption in the Union in 2010, respectively. [Am. 31]

Member States shall take measures to ensure that economic operators selling food do not provide plastic carrier bags free of charge, except for very lightweight plastic carrier bags, or alternatives to such very lightweight plastic carrier bags as referred to in the sixth subparagraph.

Member States shall ensure that economic operators selling food charge a price for lightweight plastic carrier bags that is effective and proportionate so as to achieve the reduction targets referred to in the first subparagraph. Member States shall ensure that economic operators selling food charge at least the same price for thicker plastic carrier bags, and that economic operators do not replace lightweight plastic carrier bags by very lightweight plastic carrier bags at the point of sale. Member States shall take such measures by ... (****).

Member States that have set up separate collection for bio-waste may require economic operators selling food to reduce the price by up to 50 % for lightweight plastic carrier bags that are biodegradable and compostable.

Member States shall encourage economic operators selling non-food items to charge for plastic carrier bags to an extent that is effective and proportionate so as to achieve the reduction targets referred to in the first subparagraph. [Am. 32]

Wednesday 16 April 2014

Member States shall take measures to ensure that very lightweight plastic carrier bags used to wrap dry loose, unpackaged foods such as fruits, vegetables and confectionery are replaced progressively by carrier bags that are made of recycled paper, or by very lightweight plastic carrier bags that are biodegradable and compostable. Member States shall achieve a replacement rate of 50 % by ... (***) and of 100 % by ... (*****). [Am. 33]**

~~These measures~~ **Member States may include the use of national reduction targets, other economic instruments as well as maintain or introduce marketing restrictions in derogation from Article 18. Such measures shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. [Am. 34]**

Member States shall report on the effects of these measures on the overall formation of packaging waste when reporting to the Commission in accordance with Article 17.

1b . Consumers shall be allowed by retailers to refuse and to leave at the point of sale any packaging they consider superfluous, in particular as regard to carrier bags. Retailers shall ensure that such packaging is either reused or recycled. [Am. 35]

1c. The Commission and the Member States shall, at least during the first year after the entry into force of this Directive, promote public information and awareness campaigns concerning the adverse environmental impact of excessive use of conventional plastic bags. [Am. 36]

1d. Member States shall ensure that the measures to reduce the consumption of lightweight plastic carrier bags do not lead to an overall increase in the generation of packaging.’ [Am. 38]

(*) Two years after the entry into force of this Directive.

(**) Three years after the entry into force of this Directive.

(***) Five years after the entry into force of this Directive.

(****) Two years after the entry into force of this Directive.

(*****) Three years after the entry into force of this Directive.

(*****) Five years after entry into force of this Directive.

(3) The following Article is inserted:

‘Article 6a

Information to be indicated on plastic bags

If bags are biodegradable and compostable, this shall be clearly indicated on the bag with a mark, feature or colour code. The Commission shall be empowered to adopt delegated acts to define such indications in order to ensure Union-wide recognition. Member States may adopt measures to indicate other characteristics, such as reusability, recyclability and degradability.’ [Am. 39]

(4) The following Article is inserted:

‘Article 20a

Exercise of delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 6a shall be conferred on the Commission for an indeterminate period of time from ... (*).

3. The delegation of power referred to in Article 6a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Wednesday 16 April 2014

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 6a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.' [Am. 40]

(*) Date of entry into force of the amending directive.

(5) In Annex II, points (c) and (d) of paragraph 3 are amended as follows:

'(c) Packaging recoverable in the form of composting

Packaging waste processed for the purpose of composting shall be of such a biodegradable nature that it should be fully compatible with the separate collection and the industrial and/or garden composting process or activity into which it is introduced.

(d) Biodegradable packaging

Biodegradable packaging waste shall be of such a nature that it is capable of undergoing physical, chemical, thermal or biological decomposition such that all of the material ultimately decomposes into carbon dioxide, biomass and water.' [Am. 41]

Article 2

1. Member States shall **amend their national legislation if necessary and shall** bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by twelve months after the entry into force of this Directive. They shall forthwith communicate to the Commission the text of those provisions. [Am. 42]

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 2a

By ... (*) the Commission shall review the effectiveness of this Directive and assess whether further measures need to be taken, to be accompanied, if appropriate, by a legislative proposal. [Am. 43]

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at ...,

For the European Parliament

The President

For the Council

The President

(*) Six years after the entry into force of this Directive.

Wednesday 16 April 2014

P7_TA(2014)0418

Surveillance of external sea borders *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council establishing rules for the surveillance of the external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (COM(2013)0197 — C7-0098/2013 — 2013/0106(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/91)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0197),
 - having regard to Article 294(2) and Article 77(2)(d) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0098/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to its resolution of 23 October 2013 on organised crime, corruption, and money laundering: recommendations on action and initiatives to be taken ⁽¹⁾, with particular reference to the fight against trafficking in human beings and traffickers in death,
 - having regard to the undertaking given by the Council representative by letter of 13 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs and the opinions of the Committee on Foreign Affairs and the Committee on Transport and Tourism (A7-0461/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0106

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council establishing rules for the surveillance of the external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 656/2014.)

⁽¹⁾ Texts adopted, P7_TA(2013)0444.

Wednesday 16 April 2014

P7_TA(2014)0419

Financial responsibility linked to investor-state dispute settlement tribunals established by international agreements to which the EU is party *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council establishing a framework for managing financial responsibility linked to investor-state dispute settlement tribunals established by international agreements to which the European Union is party (COM(2012)0335 — C7-0155/2012 — 2012/0163(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/92)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0335),
 - having regard to Article 294(2) and Article 207(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0155/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the undertaking given by the Council representative by letter of 4 April 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on International Trade (A7-0124/2013),
1. Adopts its position at first reading hereinafter set out ⁽¹⁾;
 2. Approves the joint declaration by the European Parliament, the Council and the Commission annexed to this resolution;
 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0163

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council establishing a framework for managing financial responsibility linked to investor-to-state dispute settlement tribunals established by international agreements to which the European Union is party

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 912/2014.)

⁽¹⁾ This position replaces the amendments adopted on 23 May 2013 (Texts adopted P7_TA(2013)0219).

Wednesday 16 April 2014

ANNEX TO THE LEGISLATIVE RESOLUTION

Joint declaration by the European Parliament, the Council and the Commission

The adoption and application of this Regulation is without prejudice to the division of competence established by the Treaties and shall not be interpreted as an exercise of shared competence by the Union in areas where the Union's competence has not been exercised.

Wednesday 16 April 2014

P7_TA(2014)0420

**Protection against dumped and subsidised imports from countries not members of the EU
***I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1225/2009 on protection against dumped imports from countries not members of the European Community and Council Regulation (EC) No 597/2009 on protection against subsidised imports from countries not members of the European Community (COM(2013)0192 — C7-0097/2013 — 2013/0103(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/93)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0192),
 - having regard to Article 294(2) and Article 207(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0097/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on International Trade (A7-0053/2014),
1. Adopts as its position at first reading hereinafter set out ⁽¹⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0103

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 1225/2009 on protection against dumped imports from countries not members of the European Community and Council Regulation (EC) No 597/2009 on protection against subsidised imports from countries not members of the European Community

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(2) thereof,

Having regard to the proposal from the European Commission,

⁽¹⁾ On the basis of the amendments adopted on 5 February 2014 (Texts adopted, P7_TA(2014)0082).

Wednesday 16 April 2014

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

- (1) The common rules for protection against dumped and subsidised imports from countries which are not members of the European Union are contained in Council Regulation (EC) No 1225/2009 ⁽²⁾ and Council Regulation (EC) No 597/2009 ⁽³⁾ respectively (hereinafter jointly referred to as the 'Regulations'). The Regulations were initially adopted in 1995 following the conclusion of the Uruguay Round. Given that a number of amendments were made to the Regulations since then, the Council decided in 2009 to codify the Regulations in the interest of clarity and rationality.
- (2) While the Regulations have been amended, there has not been a fundamental review of their functioning since 1995. As a result, the Commission launched a review of the Regulations in 2011 in order to, inter alia, better reflect the needs of business at the beginning of the 21st century.
- (3) Following the review, certain provisions of the Regulations should be amended in order to improve transparency and predictability, provide for effective measures to fight against retaliation **by third countries**, improve effectiveness and enforcement and optimise review practice. ~~In addition, certain practices that in recent years have been applied in the context of anti-dumping and anti-subsidy investigations should be included in the Regulations.~~ [Am. 1]
- (4) ~~In order to improve transparency and predictability of anti-dumping and anti-subsidy investigations, the parties affected by the imposition of provisional anti-dumping and countervailing measures, in particular importers, should be made aware of the impending imposition of such measures. The time given should correspond to the period between the submission of the draft implementing act to the anti-dumping committee established pursuant to Article 15 of Regulation (EC) No 1225/2009 and the anti-subsidy committee established pursuant to Article 25 of Regulation (EC) No 597/2009 and the adoption of that act by the Commission. This period is fixed in Article 3(3) of Regulation (EU) No 182/2011. Also, in investigations where it is not appropriate to impose provisional measures, it is desirable that parties are aware sufficiently in advance of such non-imposition.~~ [Am. 2]
- (5) ~~A short period of time in advance of the imposition of provisional measures should be allowed for exporters or producers to check the calculation of their individual dumping or subsidy margin. Calculation errors could then be corrected in advance of the imposition of measures.~~ [Am. 95]
- (6) In order to ensure effective measures to fight against retaliation, Union producers should be able to rely on the Regulations without fear of retaliation by third parties. Existing provisions, under special circumstances, **in particular where diverse and fragmented sectors largely composed of small and medium-sized enterprises (SMEs) are concerned**, provide for the initiation of an investigation without having received a complaint, where sufficient evidence of the existence of dumping, countervailable subsidies, injury and causal link exists. Such special circumstances should include threat of retaliation **from third countries**. [Am. 3]
- (7) When an investigation is not initiated by a complaint, ~~an obligation~~ **a request for cooperation** should be ~~imposed on~~ **made to** Union producers to provide the necessary information in order for the investigation to proceed, in order to ensure that sufficient information is available for carrying out the investigation in case of such threats of retaliation. **Small-sized enterprises and microenterprises should be exempt from that obligation in order to spare them from unreasonable administrative burden and costs.** [Am. 4]

⁽¹⁾ Position of the European Parliament of 16 April 2014.

⁽²⁾ Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community (OJ L 343, 22.12.2009, p. 51).

⁽³⁾ Council Regulation (EC) No 597/2009 of 11 June 2009 on protection against subsidised imports from countries not members of the European Community (OJ L 188, 18.7.2009, p. 93).

Wednesday 16 April 2014

- (8) Third countries increasingly interfere in trade of raw materials with a view to keeping raw materials in those countries for the benefit of domestic downstream users, for instance by imposing export taxes or operating dual pricing schemes. As a result, the costs of raw materials do not result from the operation of normal market forces reflecting supply and demand for a given raw material. Such interference creates additional distortions of trade. As a consequence, Union producers are not only harmed by dumping, but suffer, compared to downstream producers from third countries engaged in such practices, additional distortions of trade. In order to protect trade adequately, the lesser duty rule shall not apply in such cases of structural raw material distortions.
- (9) Within the Union, countervailable subsidies are in principle prohibited pursuant to Article 107(1) TFEU. Therefore, countervailable subsidies granted by third countries are particularly distortive of trade. The amount of State aid authorised by the Commission has steadily been reduced over time. For the anti-subsidy instrument, the lesser duty rule should hence no longer be applied to imports from a country/countries engaged in subsidisation.
- ~~(10) In order to optimise the review practice, duties collected during the investigation should be reimbursed to importers, where measures are not prolonged after the conclusion of an expiry review investigation. This is appropriate given that the conditions required for the continuation of the measures have not been found to exist during the investigation period. [Am. 5]~~
- (11) Certain practices which in recent years have been applied in the context of anti-dumping and anti-subsidy investigations should be included in the Regulations.
- (11a) Any document aimed at clarifying the established practices of the Commission with regard to the application of this Regulation (including the four draft guidelines on the selection of analogue country, on expiry reviews and the duration of measures, on the injury margin and on the Union interest) should be adopted by the Commission only after the entry into force of this Regulation and proper consultation of the European Parliament and of the Council and should then fully reflect the content of this Regulation. [Am. 6]**
- (11b) The Union is not party to ILO Conventions, but its Member States are. For the time being, only 'core' ILO Conventions have been ratified by all Union Member States. In order to keep the definition of sufficient level of social standards based on ILO Conventions listed in Annex Ia to Regulation (EU) No 1225/2009 up to date, the Commission will, by means of delegated acts, update that Annex, as soon as Union Member States have ratified other ILO 'priority' Conventions. [Am. 7]**
- (12) The Union industry should no longer be defined by reference to the initiation thresholds set out in the Regulations.
- (12a) Diverse and fragmented sectors largely composed of SMEs have difficulties in acceding to trade defence proceedings due to the complexity of the procedures and the high costs related thereto. SMEs' access to the instrument should be facilitated by strengthening the role of the SME Help Desk, which should support SMEs in filing complaints and in reaching the necessary thresholds for investigations to be launched. Administrative procedures relating to trade defence proceedings should also be better adapted to SMEs' constraints. [Am. 8]**
- (12b) In anti-dumping cases, the duration of investigations should be limited to nine months and those investigations should be concluded within 12 months of initiation of the proceedings. In anti-subsidy cases, the duration of investigations should be limited to nine months and those investigations should be concluded within 10 months of initiation of the proceedings. In any event, the provisional duties should be imposed only during a period commencing 60 days after the initiation of the proceedings until six months after the initiation of the proceedings. [Am. 9]**
- (12c) Non-confidential elements of undertakings submitted to the Commission should be better disclosed to the interested parties, the European Parliament and the Council. The Commission should be obliged to consult Union industry before accepting any offer of undertaking. [Am. 10]**

Wednesday 16 April 2014

- (13) In initial investigations where dumping or subsidy margins have been found to be less than the de minimis thresholds, the investigation should be immediately terminated in relation to exporters that will not be subject to subsequent review investigations.
- (14) In the framework of anti-dumping and anti-subsidy review investigations, it seems appropriate to be able to change methodology as compared to the investigation that led to the imposition of the measure in order to ensure that, inter alia, coherent methodologies are used across different investigations at a given point in time. This will allow, in particular, scope to change methodologies which are revised over time as situations change.
- (15) When the conditions are met for initiating an anti-circumvention investigation, imports should in all cases be made subject to registration.
- (16) In anti-circumvention investigations, it seems advisable to remove the condition that, in order to be granted an exemption from registration or extended duties, producers of the product concerned should not be related to any producer subject to the original measures. This is because experience shows that sometimes producers of the product concerned are found not to be engaged in circumvention practices but are found to be related to a producer subject to the original measures. In such cases the producer should not be denied an exemption merely on the grounds that the company is related to a producer subject to the original measures. Also, when the circumvention practice takes place in the Union, the fact that importers are related to producers subject to the measures should not be decisive in determining whether the importer may be granted an exemption.
- (17) Where the number of producers in the Union is so large that resort must be made to sampling, a sample of producers should be chosen from among all producers in the Union and not just from among producers lodging the complaint.
- ~~(18) In making the Union interest assessment, the opportunity to provide comments should be given to all producers in the Union and not just those producers lodging the complaint. [Am. 93]~~
- (18a) *The annual report by the Commission to the European Parliament and the Council on its implementation of Regulation (EC) No 1225/2009 and Regulation (EC) No 597/2009 allows a regular and timely monitoring of the trade defence instruments as part of the establishment of a structured interinstitutional dialogue on that issue. The public release of that report, six months after presentation to the European Parliament and the Council, ensures the transparency of the trade defence instruments for stakeholders and the public. [Am. 11]***
- (18b) *The Commission should ensure greater transparency with regard to proceedings, internal procedures and outcomes of investigations, and all non-confidential files should be made accessible to interested parties through a web-based platform. [Am. 12]***
- (18c) *The Commission should inform the European Parliament and the Council of the initiation of any investigations and of developments relating to those investigations on a regular basis. [Am. 13]***
- (18d) *Where the number of producers in the Union is so large that resort must be made to sampling, the Commission should, when choosing a sample of producers, fully take into account the proportion of SMEs in the sample, in particular in the case of diverse and fragmented industry sectors largely composed of SMEs. [Am. 14]***
- (18e) *In order to improve the effectiveness of trade defence instruments, trade unions should be allowed to submit written complaints jointly with the Union industry. [Am. 92]***
- (19) Regulation (EC) No 1225/2009 and Regulation (EC) No 597/2009 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Wednesday 16 April 2014

Article 1

Regulation (EC) No 1225/2009 is amended as follows:

-1. The title is replaced by the following:

'Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Union'; [Am. 15]

-1a. The following recital is inserted:

'(11a) Third countries increasingly interfere in trade with a view to benefitting domestic producers, for instance by imposing export taxes or operating dual pricing schemes. Such interference creates additional distortions of trade. As a consequence, Union producers are not only harmed by dumping, but suffer, compared to producers from third countries engaged in such practices, additional distortions of trade. Differences in the level of labour and environmental standards can also result in additional distortions of trade. Therefore, the lesser duty rule should not apply in such cases, when the exporting country has an insufficient level of social and environmental standards. A sufficient level is defined by the ratification of core International Labour Organisation (ILO) Conventions and of Multilateral Environmental Agreements (MEAs) to which the Union is party. Small and medium-sized enterprises (SMEs) particularly suffer from unfair competition because their small size prevents them from adapting to it. Therefore, the lesser duty rule should not apply when the complaint has been presented on behalf of a sector largely composed of SMEs. The lesser duty rule should always apply, however, when structural raw material distortions are the result of a deliberate choice made by a least developed country to protect the public interest.'; [Am. 16]

-1b. In Article 1(1), the following subparagraph is added:

'The use of any dumped product in connection with the exploration of the Continental Shelf or the Exclusive Economic Zone of a Member State, or the exploitation of its resources, shall be treated as an import under this Regulation and shall be charged to duty accordingly, when causing injury to the Union industry.'; [Am. 17]

-1c. In Article 1, the following paragraph is added:

'4a. For the purpose of this Regulation, it shall be understood that a raw material is the input of a given product which has a significant impact on its cost of production.'; [Am. 18]

-1d. In Article 1, the following paragraph is added:

'4b. A raw material shall be considered to be subject to structural distortion when its price is not solely the result of a normal operation of market forces reflecting supply and demand. Such distortions are the outcome of interference from third countries, which includes, inter alia, export taxes, export restrictions and dual pricing schemes.'; [Am. 19]

-1e. In Article 2(7)(a), the second subparagraph is replaced by the following:

'An appropriate market economy third country shall be selected in a not unreasonable manner, due account being taken of any reliable information made available at the time of selection. The selected country shall also have a sufficient level of social and environmental standards, where sufficient levels are determined on the basis of ratification and effective implementation by the third country of the MEAs, and protocols thereunder, the Union is party to at any point in time and of ILO Conventions listed in Annex Ia. Account shall also be taken of time-limits; where appropriate, a market economy third country which is subject to the same investigation shall be used.'; [Ams. 70 and 86]

Wednesday 16 April 2014

1. In Article 4(1), the introductory wording is replaced by the following:

'1. For the purposes of this Regulation, the term "Union industry" shall be interpreted as referring to the Union producers as a whole of the like products or to those of them whose collective output of the products constitutes a major proportion of the total Union production of those products, except that:'

- 1a. In Article 5(1), the first subparagraph is replaced by the following:

'Except as provided for in paragraph 6, an investigation to determine the existence, degree and effect of any alleged dumping shall be initiated upon a written complaint by any natural or legal person, or any association not having legal personality, acting on behalf of the Union industry. Complaints may also be submitted jointly by the Union industry, or by any natural or legal person or any association not having legal personality acting on behalf thereof, and trade unions.'; [Ams. 87 and 90]

- 1b. In Article 5, the following paragraph is inserted:

'1a. The Commission shall facilitate access to the instrument for diverse and fragmented industry sectors, largely composed of SMEs, in the context of anti-dumping cases, through an SME Help Desk.

The SME Help Desk shall raise awareness of the instrument, provide information and explanations on cases, how to file a complaint and how to better present evidence of dumping and injury.

The SME Help Desk shall make available standard forms for statistics to be submitted for standing purposes and questionnaires.

After the initiation of an investigation, the SME Help Desk shall inform SMEs and their relevant associations likely to be affected by the initiation of proceedings and the relevant deadlines for registering as an interested party.

The SME Help Desk shall assist in addressing questions regarding the completion of questionnaires, where special attention shall be given to queries of SMEs as regards investigations initiated under Article 5(6). To the extent possible, it shall assist in reducing the burden caused by language barriers.

In the event that SMEs provide prima facie evidence of dumping, the SME Help Desk shall provide SMEs with information on the evolution of the volume and value of imports of the product concerned in accordance with Article 14(6).

The SME Help Desk shall also provide guidance on additional methods of contact and liaison with the Hearing Officer and national customs authorities. The SME Help Desk shall also inform SMEs on the possibilities and conditions under which they can request a review of the measures and refund of the anti-dumping duties paid.'; [Am. 20]

- 1c. In Article 5(4), the following subparagraph is added:

'In the case of diverse and fragmented industrial sectors, largely composed of SMEs, the Commission shall assist in reaching those thresholds through the support of the SME Help Desk.'; [Am. 21]

- 1d. In Article 5, paragraph 6 is replaced by the following:

'6. If in special circumstances, in particular where diverse and fragmented sectors largely composed of SMEs are concerned, the Commission decides to initiate an investigation without having received a written complaint by or on behalf of the Union industry for the initiation of such investigation, this shall be done on the basis of sufficient evidence of dumping, injury and a causal link, as described in paragraph 2, to justify such initiation.'; [Am. 22]

Wednesday 16 April 2014

1e. In Article 6, paragraph 9 is replaced by the following:

'9. For proceedings initiated pursuant to Article 5(9), an investigation shall be concluded within nine months. In any event, such an investigation shall in all cases be concluded within one year of initiation, in accordance with the findings made pursuant to Article 8 for undertakings or the findings made pursuant to Article 9 for definitive action. Investigation periods shall, whenever possible, especially in the case of diverse and fragmented sectors largely composed of SMEs, coincide with the financial year.'; [Am. 23]

2. In Article 6, the following paragraphs are added:

'10. Union producers of the like product with the exception of small-sized and micro-sized Union producers are obliged requested to cooperate in proceedings that have been initiated pursuant to Article 5(6). [Am. 24]

10a. The Commission shall ensure the best possible access to information to all interested parties by allowing for an information system whereby interested parties are notified when new non-confidential information is added to the investigation files. Non-confidential information shall also be made accessible through a web-based platform. [Am. 25]

10b. The Commission shall safeguard the effective exercise of the procedural rights of the interested parties and shall ensure that proceedings are handled impartially, objectively and within a reasonable time period, through a Hearing Officer, where appropriate. [Am. 26]

10c. The Commission shall issue questionnaires used in investigations, in all official languages of the Union, upon request of interested parties.'; [Am. 27]

3. Article 7 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Provisional duties may be imposed if proceedings have been initiated in accordance with Article 5, if a notice has been given to that effect and interested parties have been given adequate opportunities to submit information and make comments in accordance with Article 5(10), if a provisional affirmative determination has been made of dumping and consequent injury to the Union industry, and if the Union interest calls for intervention to prevent such injury. The provisional duties shall be imposed no earlier than 60 days from the initiation of the proceedings but no later than six months from the initiation of the proceedings.'; [Am. 28]

(a) in paragraph 1, the following sentence is added:

~~'Provisional duties shall not be applied within a period of two weeks after the information is sent to interested parties under Article 19a. The provision of such information shall not prejudice any subsequent decision that may be taken by the Commission.'~~ [Am. 29]

(b) paragraph 2 is replaced by the following:

'2. The amount of the provisional anti-dumping duty shall not exceed the margin of dumping as provisionally established. Unless structural raw material distortions were found to exist with regard to the product concerned in the exporting country, but it should be less than the margin of dumping if such lesser duty would be adequate to remove the injury to the Union industry.

Such a lesser duty shall not apply in any of the following circumstances:

(a) structural distortions or significant State interference regarding, inter alia, prices, costs and inputs, including for instance raw materials and energy, research and labour, outputs, sales and investments, currency exchange rate and fair trade finance conditions, are found to exist with regard to the product concerned in the exporting country;

Wednesday 16 April 2014

- (b) *the exporting country does not have a sufficient level of social and environmental standards, where sufficient levels are determined on the basis of the ratification and effective implementation by the third country of MEAs, and protocols thereunder, to which the Union is party any point in time, and of ILO Conventions listed in Annex Ia;*
- (c) *the complainant represents a diverse and fragmented industry, largely composed of SMEs;*
- (d) *the investigation or a separate anti-subsidy investigation has established at least provisionally that the exporting country provides one or more subsidies to exporting producers of the product concerned.*

However, such a lesser duty shall always be granted when structural raw materials distortions are found to exist with regard to the product concerned in the exporting country and such country is a least-developed country listed in Annex IV to Regulation (EU) No 978/2012 of the European Parliament and of the Council ().*

(*) *Regulation (EU) No 978/2012 of the European Parliament and of the Council of 25 October 2012 applying a scheme of generalised tariff preferences and repealing Council Regulation (EC) No 732/2008.; [Am. 30]*

3a. *In Article 8, paragraph 1 is replaced by the following:*

'1. Upon condition that a provisional affirmative determination of dumping and injury has been made, the Commission may accept voluntary undertaking offers submitted by any exporter to revise its prices or to cease exports at dumped prices, after specific consultation of the Advisory Committee, provided that such offers effectively eliminate the injurious effect of the dumping. In such a case and as long as such undertakings are in force, provisional duties imposed by the Commission in accordance with Article 7(1) or definitive duties imposed by the Council in accordance with Article 9(4) as the case may be shall not apply to the relevant imports of the product concerned manufactured by the companies referred to in the Commission decision accepting undertakings, as subsequently amended. Price increases under such undertakings shall not be higher than necessary to eliminate the margin of dumping and they shall be less than the margin of dumping if such increases would be adequate to remove the injury to the Union industry, unless the Commission, in the imposition of provisional or definitive duties, has decided that that lesser duty is not to be applied.'; [Am. 31]

3b. *In Article 8, paragraph 4 is replaced by the following:*

'4. Parties which offer an undertaking shall be required to provide a meaningful non-confidential version of such undertaking, so that it may be made available to interested parties to the investigation, the European Parliament and the Council. The parties shall be requested to disclose as much information as possible regarding the content and nature of the undertaking with due regard to the protection of confidential information within the meaning of Article 19. Furthermore, before accepting any such offer the Commission shall consult the Union industry with regard to the main features of the undertaking.'; [Am. 32]

4. Article 9 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. For a proceeding initiated pursuant to Article 5(9), injury shall normally be regarded as negligible where the imports concerned represent less than the volumes set out in Article 5(7). For the same proceeding, there shall be immediate termination where it is determined that the margin of dumping is less than 2 %, expressed as a percentage of the export price.';

Wednesday 16 April 2014

(b) in paragraph 4, the last sentence is replaced by the following:

~~'The amount of the anti-dumping duty shall not exceed the margin of dumping established. Unless structural raw material distortions were found to exist with regard to the product concerned in the exporting country, but it shall be less than the margin of dumping if such lesser duty would be adequate to remove the injury to the Union industry.'~~

Such a lesser duty shall not apply in any of the following circumstances:

- (a) *structural distortions or significant State interferences regarding, inter alia, prices, costs and inputs, including for instance raw materials and energy, research and labour, outputs, sales and investments, currency exchange rate and fair trade finance conditions, is found to exist with regard to the product concerned in the exporting country;*
- (b) *the exporting country does not have a sufficient level of social and environmental standards, where sufficient levels are determined on the basis of the ratification and effective implementation by the third country of MEAs, and protocols thereunder, to which the Union is party any point in time, and of ILO Conventions listed in Annex Ia;*
- (c) *the complainant represents a diverse and fragmented industry, largely composed of SMEs;*
- (d) *the investigation or a separate anti-subsidy investigation has established that the exporting country provides one or more subsidies to exporting producers of the product concerned.*

However, such a lesser duty shall always be granted when structural raw materials distortions are found to exist with regard to the product concerned in the exporting country and that country is a least-developed country listed in Annex IV to Regulation (EU) No 978/2012.; [Am. 33]

5. Article 11 is amended as follows:

(-a) in paragraph 2, the second subparagraph is replaced by the following:

'An expiry review shall be initiated where the request contains sufficient evidence that the expiry of the measures would be likely to result in a continuation or recurrence of dumping and injury. Such likelihood may, for example, be indicated by evidence of continued dumping and injury or evidence that the removal of injury is partly or solely due to the existence of measures or evidence that the circumstances of the exporters, or market conditions, are such that they would indicate the likelihood of further injurious dumping. Such likelihood may also be indicated by continuing interference by the exporting country.'; [Am. 77/rev]

~~(a) in paragraph 5, the following subparagraph is added:~~

~~'If following an investigation pursuant to paragraph 2, the measure expires, any duties collected from the date of the initiation of such investigation shall be repaid provided that this is requested from national customs authorities and granted by those authorities in accordance with the applicable Union customs legislation concerning repayment and remission of duty. Such repayment does not give rise to the payment of interest by the national customs authorities concerned.'~~ [Am. 35]

(b) paragraph 9 is deleted.

6. Article 13 is amended as follows:

(a) in paragraph 3, the second sentence is replaced by the following:

'Initiations shall be made, after consultation of the Advisory Committee, by Commission Regulation which shall also instruct the customs authorities to make imports subject to registration in accordance with Article 14(5) or to request guarantees.'

Wednesday 16 April 2014

(b) in paragraph 4, the first subparagraph is replaced by the following:

'Imports shall not be subject to registration pursuant to Article 14(5) or measures where they are traded by companies which benefit from exemptions. Requests for exemptions duly supported by evidence shall be submitted within the time-limits established in the Commission regulation initiating the investigation. Where the circumventing practice, process or work takes place outside the Union, exemptions may be granted to producers of the product concerned that are found not to be engaged in circumvention practices as defined in paragraphs 1 and 2 of this Article. Where the circumventing practice, process or work takes place inside the Union, exemptions may be granted to importers that can show that they are not engaged in circumvention practices as defined in paragraphs 1 and 2 of this Article.'

6a. In Article 14, paragraph 3 is replaced by the following:

'3. Special provisions, in particular with regard to the common definition of the concept of origin, as contained in Regulation (EEC) No 2913/92 or in accordance with Article 2 thereof, may be adopted pursuant to this Regulation.' [Am. 36]

6b. In Article 14, paragraph 5 is replaced by the following:

'5. The Commission may, after having informed the Member States in due time, direct the customs authorities to take the appropriate steps to register imports, so that measures may subsequently be applied against those imports from the date of such registration. Imports shall be made subject to registration following a request from the Union industry which contains sufficient evidence to justify such action. Imports may also be made subject to registration on the Commission's own initiative.'

Imports shall be made subject to registration from the date of initiation of the investigation where the complaint of the Union industry contains a request for registration and sufficient evidence to justify such action.

Registration shall be introduced by regulation which shall specify the purpose of the action and, if appropriate, the estimated amount of possible future liability. Imports shall not be made subject to registration for a period longer than nine months.' [Am. 79]

6c. In Article 14, paragraph 6 is replaced by the following:

'6. Member States shall report to the Commission every month, on the import trade in products subject to investigation and to measures, and on the amount of duties collected pursuant to this Regulation. The Commission may, upon receiving a specific reasoned request from an interested party, and after receiving the opinion of the Committee referred to in Article 15(2) on it, decide to provide them with information concerning the volume and import values of those products.' [Am. 75]

6d. In Article 14, the following paragraph is added:

'7a. Whenever the Commission intends to adopt or publish any document aimed at clarifying the established practice of the Commission with regard to the application of this Regulation in any of its elements, the Commission, prior to the adoption or publication, shall consult the European Parliament and the Council, aiming at a consensus with a view to the approval of the given document. Any subsequent modification of such documents shall be subject to such procedural requirements. In any event, any of those documents shall be in full conformity with the provisions of this Regulation. No such document shall broaden the discretion of the Commission, as interpreted by the Court of Justice of the European Union, in adopting measures.' [Am. 39]

Wednesday 16 April 2014

7. In Article 17, paragraph 1 is replaced by the following:

‘1. In cases where the number of Union producers, exporters or importers **that cooperate in the investigation with their consent**, types of product or transactions is large, the investigation may be limited to a reasonable number of parties, products or transactions by using samples which are statistically valid on the basis of information available at the time of the selection, or to the largest representative volume of production, sales or exports which can reasonably be investigated within the time available. **In the case of diverse and fragmented industry sectors, largely composed of SMEs, the final selection of parties should, where possible, take into account their proportion of the sector concerned.**’; [Am. 40]

8. The following article is inserted:

‘Article 19a

Information about provisional measures

~~1. The Union producers, importers and exporters and their representative associations, and representatives of the exporting country, may request information on the planned imposition of provisional duties. Requests for such information shall be made in writing within the time limit prescribed in the notice of initiation. Such information shall be provided to those parties, at least two weeks before the expiry of the deadline mentioned in Article 7(1) for the imposition of provisional duties. Such information shall include:~~

~~(a) a summary of the proposed duties for information purposes only, and~~

~~(b) details of the calculation of the dumping margin and the margin adequate to remove the injury to the Union industry, due account being taken of the need to respect the confidentiality obligations contained in Article 19. Parties shall have a period of three working days to provide comments on the accuracy of the calculations. [Am. 41]~~

~~2. In cases where it is intended not to impose provisional duties but to continue the investigation, interested parties shall be informed of the non-imposition of duties two weeks before the expiry of the deadline mentioned in Article 7 (1) for the imposition of provisional duties.’;~~

~~9. Article 21(2) is replaced by the following:~~

~~‘2. In order to provide a sound basis on which the authorities can take account of all views and information in the decision as to whether or not the imposition of measures is in the Union interest, the Union producers, importers and their representative associations, representative users and representative consumer organisations may, within the time-limits specified in the notice of initiation of the anti-dumping investigation, make themselves known and provide information to the Commission. Such information, or appropriate summaries thereof, shall be made available to the other parties specified in this Article, and they shall be entitled to respond to such information.’ [Am. 42]~~

9a. In Article 22, the following paragraph is added:

‘1a. As soon as all Member States have ratified new ILO Conventions, the Commission shall update Annex Ia accordingly, in conformity with the procedure set out in Article 290 TFEU.’; [Am. 43]

9b. The following article is inserted:

‘Article 22a

Report

1. In order to facilitate the monitoring of the implementation of the Regulation by the European Parliament and the Council, the Commission shall, with due regard to the protection of confidential information within the meaning of Article 19, present an annual report on the application and implementation of this Regulation to the European Parliament and to the Council, as a part of a trade defence instrument dialogue between the Commission,

Wednesday 16 April 2014

the European Parliament and the Council. The report shall include information about the application of provisional and definitive measures, the termination of investigations without measures, undertakings, reinvestigations, reviews and verification visits, and the activities of the various bodies responsible for monitoring the implementation of this Regulation and fulfilment of the obligations arising therefrom. The report shall also cover the use of trade defence instruments by third countries targeting the Union, information on the recovery of the Union industry concerned by the measures imposed and appeals against the measures imposed. It shall include the activities of the Hearing Officer of the Commission's Directorate General for Trade and those of the SME Help Desk in relation to the application of this Regulation.

2. The European Parliament may, within one month of the Commission's presentation of the report, invite the Commission to an ad hoc meeting of its responsible committee to present and explain any issues related to the implementation of this Regulation. The report may also be subject to a resolution.

3. No later than six months after presenting the report to the European Parliament and to the Council, the Commission shall make the report public.'; [Am. 44]

9c. The following annex is added:

'Annex Ia

ILO Conventions referred to in Articles 7, 8 and 9

1. Convention concerning Forced or Compulsory Labour, No 29 (1930)
2. Convention concerning Freedom of Association and Protection of the Right to Organise, No 87 (1948)
3. Convention concerning the Application of the Principles of the Right to Organise and to Bargain Collectively, No 98 (1949)
4. Convention concerning Equal Remuneration of Men and Women Workers for Work of Equal Value, No 100 (1951)
5. Convention concerning the Abolition of Forced Labour, No 105 (1957)
6. Convention concerning Discrimination in Respect of Employment and Occupation, No 111 (1958)
7. Convention concerning Minimum Age for Admission to Employment, No 138 (1973)
8. Convention concerning the Prohibition and Immediate Action for the Elimination of the Worst Forms of Child Labour, No 182 (1999)'; [Am. 45]

Article 2

Regulation (EC) No 597/2009 is amended as follows:

-1. The title is replaced by the following:

'Council Regulation (EC) No 597/2009 of 11 June 2009 on protection against subsidised imports from countries not members of the European Union'; [Am. 46]

-1a. The following recital is inserted:

'(9a) Within the Union, countervailable subsidies are as a general rule prohibited pursuant to Article 107(1) TFEU. Therefore, countervailable subsidies granted by third countries are particularly distortive of trade. The amount of State aid authorised by the Commission has steadily been reduced over time. For the anti-subsidy instrument, the lesser duty rule should hence no longer be applied to imports from a country or countries engaged in subsidisation.'; [Am. 47]

Wednesday 16 April 2014

-1b. In Article 1(1), the following subparagraph shall be added:

'The use of any subsidised products in connection with the exploration of the Continental Shelf or the Exclusive Economic Zone of a Member State, or the exploitation of its resources, shall be treated as an import under this Regulation and shall be charged to duty accordingly, when it causes injury to the Union industry.'; [Am. 48]

1. In Article 9(1), the introductory wording is replaced by the following:

'1. For the purposes of this Regulation, the term "Union industry" shall be interpreted as referring to the Union producers as a whole of the like products or to those of them whose collective output of the products constitutes a major proportion of the total Union production of those products, except that:';

1a. In Article 10(1), the first subparagraph is replaced by the following:

'1. Except as provided for in paragraph 8, an investigation to determine the existence, degree and effect of any alleged dumping shall be initiated upon a written complaint by any natural or legal person, or any association not having legal personality, acting on behalf of the Union industry. Complaints may also be submitted jointly by the Union industry, or by any natural or legal person or any association not having legal personality acting on behalf thereof, and trade unions.'; [Am. 91]

1b. In Article 10(6), the following subparagraph is added:

'In the case of diverse and fragmented industrial sectors, largely composed of small-and-medium-sized enterprises (SMEs), the Commission shall assist in reaching these thresholds through the support of the SME Help Desk.'; [Am. 94]

1c. In Article 10, paragraph 8 shall be replaced by the following:

'8. If in special circumstances, in particular where diverse and fragmented sectors largely composed of SMEs are concerned, the Commission decides to initiate an investigation without having received a written complaint by or on behalf of the Union industry for the initiation of such investigation, this shall be done on the basis of sufficient evidence of the existence of countervailable subsidies, injury and a causal link, as described in paragraph 2, to justify such initiation.'; [Am. 49]

1d. In Article 11, paragraph 9 shall be replaced by the following:

'9. For proceedings initiated pursuant to Article 10(11), an investigation shall, whenever possible, be concluded within nine months. In any event, such investigations shall in all cases be concluded within 10 months of their initiation, in accordance with the findings made pursuant to Article 13 for undertakings or the findings made pursuant to Article 15 for definitive action. Investigation periods shall, whenever possible, especially in the case of diverse and fragmented sectors largely composed of SMEs, coincide with the financial year.'; [Am. 51]

2. In Article 11, the following paragraphs are added:

*'11. Union producers of the like product **with the exception of small-sized and micro-sized Union producers** are ~~obliged~~ **requested** to cooperate in proceedings that have been initiated pursuant to Article 10(8). [Am. 50]*

11a. The Commission shall facilitate the access to the instrument for diverse and fragmented sectors, largely composed of SMEs, in the context of anti-subsidy cases, through the SME Help Desk.

The SME Help Desk shall raise awareness of the instrument, provide information and explanations on cases, how to file a complaint and how to better present evidence of countervailable subsidies and injury. The SME Help Desk shall make available standard forms for statistics to be submitted for standing purposes and questionnaires.

Wednesday 16 April 2014

After the initiation of an investigation, the SME Help Desk shall inform SMEs and their relevant associations likely to be affected by the initiation of proceedings and the relevant deadlines for registering as an interested party.

The SME Help Desk shall assist addressing questions regarding the completion of questionnaires, where special attention shall be given to queries of SMEs as regards investigations initiated under Article 10(8). To the extent possible, it shall assist reducing the burden caused by language barriers.

In case SMEs provide prima facie evidence of countervailable subsidies, the SME Help Desk shall provide SMEs with information on the evolution of the volume and value of imports of the product concerned in accordance with Article 24(6).

The SME Help Desk shall also provide guidance on additional methods of contact and liaison with the Hearing Officer and national customs authorities. The SME Help Desk shall also inform SMEs on the possibilities and conditions under which they could request a review of the measures and refund of the countervailable duties paid. [Am. 52]

11b. The Commission shall ensure the best possible access to information to all interested parties by allowing for an information system whereby interested parties are notified when new non-confidential information is added to the investigation files. Non-confidential information shall also be made accessible through a web-based platform. [Am. 53]

11c. The Commission shall safeguard the effective exercise of the procedural rights of the interested parties and shall ensure that proceedings are handled impartially, objectively and within a reasonable time period, through a Hearing Officer, where appropriate. [Am. 54]

11d. The Commission shall issue questionnaires used in investigations, in all official languages of the Union upon request of interested parties.’; [Am. 55]

3. Article 12(1) is amended as follows:

(-a) the second subparagraph shall be replaced by the following:

‘The provisional duties shall be imposed no earlier than 60 days from the initiation of the proceedings but no later than six months from the initiation of the proceedings.’; [Am. 56]

(a) the third subparagraph is replaced by the following:

‘The amount of the provisional countervailing duty shall not exceed the total amount of countervailable subsidies as provisionally established.’;

~~(b) the following subparagraph is added at the end:~~

~~‘Provisional duties shall not be applied within a period of two weeks after the information is sent to interested parties under Article 29b. The provision of such information shall not prejudice any subsequent decision that may be taken by the Commission.’ [Am. 57]~~

3a. In Article 13, paragraph 1 is replaced by the following:

‘1. Upon condition that a provisional affirmative determination of subsidisation and injury has been made, the Commission may accept voluntary undertakings offers under which:

(a) the country of origin and/or export agrees to eliminate or limit the subsidy or take other measures concerning its effects; or

(b) any exporter undertakes to revise its prices or to cease exports to the area in question as long as such exports benefit from countervailable subsidies, provided that the Commission, after specific consultation of the Advisory Committee, has determined that the injurious effect of the subsidies is thereby effectively eliminated.

Wednesday 16 April 2014

In such a case and as long as such undertakings are in force, the provisional duties imposed by the Commission in accordance with Article 12(3) and the definitive duties imposed by the Council in accordance with Article 15(1) shall not apply to the relevant imports of the product concerned manufactured by the companies referred to in the Commission decision accepting undertakings and in any subsequent amendment of such decision.

The lesser duty rule shall not apply to prices agreed under such undertakings in the framework of anti-subsidy proceedings.; [Am. 58]

3b. In Article 13, paragraph 4 is replaced by the following:

'4. Parties which offer an undertaking shall be required to provide a meaningful non-confidential version of such undertaking, so that it may be made available to interested parties to the investigation, the European Parliament and the Council. The parties shall be requested to disclose as much information as possible regarding the content and nature of the undertaking with due regard to the protection of confidential information within the meaning of Article 29. Furthermore, before accepting any such offer the Commission shall consult the Union industry with regard to the main features of such undertaking.; [Am. 59]

4. In Article 14, paragraph 5 is replaced by the following:

'5. The amount of the countervailable subsidies shall be considered to be de minimis if such amount is less than 1 % ad valorem, except where, as regards investigations concerning imports from developing countries, the de minimis threshold shall be 2 % ad valorem.;

5. In Article 15(1), the last subparagraph is replaced by the following:

'The amount of the countervailing duty shall not exceed the amount of countervailable subsidies established.;

6. Article 22 is amended as follows:

~~(a) in paragraph 1 the following subparagraph is added:~~

~~*'If following an investigation pursuant to Article 18, the measure expires, any duties collected after the date of the initiation of such investigation shall be reimbursed. The reimbursement should be requested from national customs authorities in accordance with the applicable Union customs legislation.'* [Am. 60]~~

~~(b) paragraph 6 is deleted.~~

7. Article 23 is amended as follows:

(a) in the second sentence of paragraph 4, the word 'may' is replaced by 'shall'.

(b) in paragraph 6, the second subparagraph is replaced by the following:

'Where the circumventing practice, process or work takes place outside the Union, exemptions may be granted to producers of the product concerned that are found not to be engaged in circumvention practices as defined in paragraph 3.;

(c) in paragraph 6, the third subparagraph is replaced by the following:

'Where the circumventing practice, process or work takes place inside the Union, exemptions may be granted to importers that can show that they are not engaged in circumvention practices as defined in paragraph 3.;

Wednesday 16 April 2014

7a. In Article 24, paragraph 3 is replaced by the following:

'3. Special provisions, in particular with regard to the common definition of the concept of origin, as contained in Regulation (EEC) No 2913/92 or in accordance with Article 2 thereof, may be adopted pursuant to this Regulation.'; [Am. 61]

7b. In Article 24, paragraph 5 is replaced by the following:

'5. The Commission may, after having informed the Member States in due time direct the customs authorities to take the appropriate steps to register imports, so that measures may subsequently be applied against those imports from the date of such registration.

Imports shall be made subject to registration following a request from the Union industry which contains sufficient evidence to justify such action. Imports may also be made subject to registration on the Commission's own initiative.

Imports shall be made subject to registration from the date of initiation of the investigation where the complaint of the Union industry contains a request for registration and sufficient evidence to justify such action.

Registration shall be introduced by regulation which shall specify the purpose of the action and, if appropriate, the estimated amount of possible future liability. Imports shall not be made subject to registration for a period longer than nine months.'; [Am. 78]

7c. In Article 24, paragraph 6 is replaced by the following:

'6. Member States shall report to the Commission every month, on the import trade in products subject to investigation and to measures, and on the amount of duties collected pursuant to this Regulation. The Commission may, upon receiving a specific reasoned request from an interested party, and after receiving the opinion of the Committee referred to in Article 25(2) on it, decide to provide them with information concerning the volume and import values of those products.'; [Am. 76]

7d. In Article 24, the following paragraph is added:

'7a. Whenever the Commission intends to adopt or publish any document aimed at clarifying the established practice of the Commission with regard to the application of this Regulation in any of its elements, the Commission, prior to the adoption or publication, shall consult the European Parliament and the Council, aiming at a consensus with a view to the approval of the given document. Any subsequent modification of such documents shall be subject to such procedural requirements. In any event, any of these documents shall be in full conformity with the provisions of this Regulation. No such document can broaden the discretion of the Commission, as interpreted by the Court of Justice of the European Union, in adopting measures.'; [Am. 64]

8. In Article 27(1), the first subparagraph **paragraph 1** is replaced by the following:

*'1. In cases where the number of Union producers, exporters or importers, **that cooperate in the investigation**, or types of product or transactions is large, the investigation may be limited to:*

(a) a reasonable number of parties, products or transactions by using samples which are statistically valid on the basis of information available at the time of the selection; or

(b) the largest representative volume of the production, sales or exports which can reasonably be investigated within the time available.

In the case of diverse and fragmented industry sectors, largely composed of SMEs, the final selection of parties shall, where possible, take into account their proportion of the sector concerned.'; [Am. 65]

Wednesday 16 April 2014

9. After Article 29, the following Article is inserted:

~~Article 29b~~

~~Information about provisional measures~~

~~1. The Union producers, importers and exporters and their representative associations, and the country of origin and/or export, may request information on the planned imposition of provisional duties. Requests for such information shall be made in writing within the time limit prescribed in the notice of initiation. Such information shall be provided to those parties, at least two weeks before the expiry of the deadline mentioned in Article 12(1) for the imposition of provisional duties.~~

~~Such information shall include:~~

- ~~(a) a summary of the proposed duties for information purposes only, and~~
- ~~(b) details of the calculation of the subsidy margin and the margin adequate to remove the injury to the Union industry, due account being taken of the need to respect the confidentiality obligations contained in Article 29. Parties shall have a period of three working days to provide comments on the accuracy of the calculations.~~

~~2. In cases where it is intended not to impose provisional duties but to continue the investigation, interested parties shall be informed of the non-imposition of duties two weeks before the expiry of the deadline mentioned in Article 12(1) for the imposition of provisional duties.' [Am. 66]~~

10. Article 31(2) is replaced by the following:

~~2. In order to provide a sound basis on which the authorities can take account of all views and information in the decision as to whether or not the imposition of measures is in the Union interest, the Union producers, importers and their representative associations, representative users and representative consumer organisations may, within the time limits specified in the notice of initiation of the countervailing investigation, make themselves known and provide information to the Commission. Such information, or appropriate summaries thereof, shall be made available to the other parties specified in this paragraph, and they shall be entitled to respond to such information.' [Am. 67]~~

- 10a. *The following article is inserted:*

'Article 33a

Report

1. In order to facilitate the monitoring of the implementation of the Regulation by the European Parliament and the Council, the Commission shall, with due regard to the protection of confidential information within the meaning of Article 19, present an annual report on the application and implementation of this Regulation to the European Parliament and to the Council, as a part of a trade defence instrument dialogue between the Commission, the European Parliament and the Council. The report shall include information about the application of provisional and definitive measures, the termination of investigations without measures, undertakings, reinvestigations, reviews and verification visits, and the activities of the various bodies responsible for monitoring the implementation of this Regulation and fulfilment of the obligations arising therefrom. The report shall also cover the use of trade defence instruments by third countries targeting the Union, information on the recovery of the Union industry concerned by the measures imposed and appeals against the measures imposed. It shall include the activities of the Hearing Officer of the Commission's Directorate General for Trade and those of the SME Help Desk in relation to the application of this Regulation.

2. The European Parliament may, within one month of the Commission's presentation of the report, invite the Commission to an ad hoc meeting of its responsible committee to present and explain any issues related to the implementation of this Regulation. The report may also be subject to a resolution.

3. No later than six months after presenting the report to the European Parliament and to the Council, the Commission shall make the report public.' [Am. 68]

Wednesday 16 April 2014

Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall be consolidated with Regulation (EC) No 1225/2009 and Regulation (EC) No 597/2009 by ... (*). [Am. 69]

Article 4

This Regulation shall apply to all investigations for which the notice of initiation pursuant to Article 10(11) of Regulation (EC) No 597/2009 or Article 5(9) of Regulation (EC) No 1225/2009 has been published in the *Official Journal of the European Union* after the date of entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...

For the European Parliament
The President

For the Council
The President

(*) **Three months after the date of entry into force of this Regulation.**

Wednesday 16 April 2014

P7_TA(2014)0421

Statute and funding of European political parties and European political foundations *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on the statute and funding of European political parties and European political foundations (COM(2012)0499 — C7-0288/2012 — 2012/0237(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/94)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0499),
 - having regard to Article 294(2) and Article 224 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0288/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the Court of Auditors of 7 February 2013 ⁽¹⁾,
 - having regard to the opinion of the Economic and Social Committee of 13 February 2013 ⁽²⁾,
 - having regard to the opinion of the Committee of the Regions of 31 January 2013 ⁽³⁾,
 - having regard to its resolution of 6 April 2011 on the application of Regulation (EC) No 2004/2003 on the regulations governing political parties at European level and the rules regarding their funding ⁽⁴⁾,
 - having regard to the undertaking given by the Council representative by letter of 5 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Constitutional Affairs and the opinions of the Committee on Budgets and the Committee on Legal Affairs (A7-0140/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0237

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the statute and funding of European political parties and European political foundations

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU, Euratom) No 1141/2014.)

⁽¹⁾ OJ C 67, 7.3.2013, p. 1.

⁽²⁾ OJ C 133, 9.5.2013, p. 90.

⁽³⁾ OJ C 62, 2.3.2013, p. 77.

⁽⁴⁾ OJ C 296 E, 2.10.2012, p. 46.

Wednesday 16 April 2014

P7_TA(2014)0422

Financing of European political parties *I****European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU, Euratom) No 966/2012 as regards the financing of European political parties (COM(2012)0712 — C7-0393/2012 — 2012/0336(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/95)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0712),
 - having regard to Article 294(2) and Article 322 of the Treaty on the Functioning of the European Union and Article 106a of the Treaty establishing the European Atomic Energy Community, pursuant to which the Commission submitted the proposal to Parliament (C7-0393/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the Court of Auditors of 7 February 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 31 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Budgets and the opinion of the Committee on Constitutional Affairs (A7-0200/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission, the European Court of Auditors and the national parliaments.

P7_TC1-COD(2012)0336**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EU, Euratom) No 966/2012 as regards the financing of European political parties***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU, Euratom) No 1142/2014.)*

⁽¹⁾ OJ C 67, 7.3.2013, p. 1.

Wednesday 16 April 2014

P7_TA(2014)0423

Financial rules applicable to the general budget of the Union *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (COM(2013)0639 — C7-0303/2013 — 2013/0313(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/96)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0639),
 - having regard to Article 294(2) and Article 322 of the Treaty on the Functioning of the European Union and Article 106a of the Treaty establishing the European Atomic Energy Community, pursuant to which the Commission submitted the proposal to Parliament (C7-0303/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the Court of Auditors of 3 December 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 28 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Budgets (A7-0108/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Approves the joint statement by Parliament, the Council and the Commission annexed to this resolution;
 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 4. Instructs its President to forward its position to the Council, the Commission, the European Court of Auditors and the national parliaments.

P7_TC1-COD(2013)0313

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU, Euratom) No 547/2014.)

⁽¹⁾ OJ C 4, 8.1.2014, p. 1.

Wednesday 16 April 2014

ANNEX TO THE LEGISLATIVE RESOLUTION

Joint statement on the separate discharge for Joint Undertakings under Article 209 of the Financial Regulation

1. The European Parliament, the Council and the Commission agree that in order for the Joint Undertakings to benefit from simplified financial rules better adapted to their public-private nature, they should be set up under Article 209 of the Financial Regulation.

However, they also agree that:

- In view of the specific nature and the current status of the Joint Undertakings, and in order to ensure continuity with the 7th Framework Programme, the Joint Undertakings should continue to be subject to a separate discharge to be given by the European Parliament upon recommendation of the Council. For this reason, specific derogations from Article 209 of the Financial Regulation shall be introduced in the constituent acts of the Joint Undertakings to be set up under Horizon 2020 Programme. Those derogations will refer to the separate discharge and will include any additional necessary adaptations.
 - In order to allow the Joint Undertakings to benefit immediately from the simplifications introduced in the new financial framework, it is necessary that the Commission delegated regulation of 30 September 2013 on the model financial regulation for PPP bodies under Article 209 of the Financial Regulation enters into force.
2. The European Parliament and the Council take note that the Commission:
- will ensure that the financial rules of the Joint Undertakings include derogations from the Model Financial Regulation for PPP bodies to reflect the introduction of the separate discharge in their constituent acts;
 - intends to propose relevant modifications to Articles 209 and 60(7) of the Financial Regulation in the framework of the future revision of the Financial Regulation.
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Wednesday 16 April 2014

P7_TA(2014)0424

Carbon dioxide emissions from maritime transport *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport and amending Regulation (EU) No 525/2013 (COM(2013)0480 — C7-0201/2013 — 2013/0224(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/97)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0480),
 - having regard to Article 294(2) and Article 192(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0201/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 16 October 2013 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on Transport and Tourism (A7-0080/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0224

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the monitoring, reporting and verification of carbon dioxide greenhouse gas emissions from maritime transport and amending Regulation (EU) No 525/2013 [Am. 1]

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

⁽¹⁾ OJ C 67, 6.3.2014, p. 170.

Wednesday 16 April 2014

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) The Climate and Energy Package ⁽⁴⁾ calling for contributions of all sectors of the economy to achieving these emission reductions, including international maritime shipping, provides a clear mandate: ‘... in the event that no international agreement which includes international maritime emissions in its reduction targets through the International Maritime Organisation (IMO) has been approved by Member States or no such agreement through the UNFCCC has been approved by the Community by 31 December 2011, the Commission should make a proposal to include international maritime emissions in the Community reduction commitment, with the aim of the proposed act entering into force by 2013. Such a proposal should minimise any negative impact on the Community’s competitiveness while taking into account the potential environmental benefits.’
- (1a) *Maritime transport has an impact on the global climate and on air quality, as a result of carbon dioxide (CO₂) emissions and other emissions, including nitrogen oxides (NO_x), sulphur oxides (SO_x), methane (CH₄), particulate matter (PM) and black carbon (BC).* [Am. 2]
- (1b) *International maritime shipping remains the only means of transportation not included in the Union’s commitment to reduce greenhouse gas emissions. According to the impact assessment accompanying the proposal for this Regulation, Union-related CO₂ emissions from international shipping increased by 48 % between 1990 and 2007.* [Am. 3]
- (1c) *In the light of the rapidly developing scientific understanding of the non-CO₂ impact of maritime transport on the global climate, an updated assessment of that impact should be carried out regularly in the context of this Regulation. Based on its assessments, and taking into account the European Parliament’s resolution of 14 September 2011 on a comprehensive approach to non-CO₂ climate-relevant anthropogenic emissions, the Commission should analyse the implications for policies and measures in order to reduce those emissions.* [Am. 4]
- (1d) *The Commission should also take action to address other activities that lead to emissions of greenhouse gases and air pollutants that are not covered by this Regulation, i.e. the use of refrigerants by fishing boats, and evaporative emissions from the loading-offloading of fuels and bulk goods (e.g. volatile organic compounds (VOCs), PM).* [Am. 5]
- (1e) *The Commission White Paper ‘Roadmap to a Single European Transport Area — Towards a competitive and resource efficient transport system’ of 28 March 2011 calls for a reduction of emissions from maritime transport by 40 % (50 % if feasible) compared to 2005 levels by 2050, namely through the application of the ‘user pays’ and ‘polluter pays’ principles.* [Am. 6]

⁽¹⁾ OJ C 67, 6.3.2014, p. 170.

⁽²⁾ OJ C , , p. .

⁽³⁾ Position of the European Parliament of 16 April 2014.

⁽⁴⁾ Decision No 406/2009/EC of the European Parliament and of the Council of 23 April 2009 on the effort of Member States to reduce their greenhouse gas emissions to meet the Community’s greenhouse gas emission reduction commitments up to 2020 (OJ L 140, 5.6.2009, p. 136) and Directive 2009/29/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 2003/87/EC so as to improve and extend the greenhouse gas emission allowance trading scheme of the Community (OJ L 140, 5.6.2009, p. 63).

Wednesday 16 April 2014

- (1f) *The European Parliament's resolution of 15 December 2011 on the Roadmap to a Single European Transport Area — Towards a competitive and resource efficient transport system calls for a Union-wide uniform 30 % reduction in emissions of CO₂ and pollutants in shipping, to which the IMO agreements on the Energy Efficiency Design Index (EEDI) and the Ship Energy Efficiency Management Plan (SEEMP) are to make a contribution. [Am. 7]*
- (2) In July 2011, the IMO adopted technical and operational measures, in particular the EEDI for new ships and the SEEMP, which will bring improvement in terms of reducing the expected increase in greenhouse gas emissions, but alone cannot lead to the necessary absolute emission reductions of greenhouse gases from international shipping to keep efforts in line with the global objective of limiting increases in global temperatures to 2 °C.
- (3) According to data provided by the IMO, the specific energy consumption and CO₂ emissions of ships could be reduced by ~~up to 75 %~~ **25 to 75 %** by applying operational measures and implementing existing technologies; a significant part of those measures can be regarded as cost-effective **and being such that they could offer net benefits to the sector**, as the reduced fuel costs ensure the pay-back of any operational or investment costs. [Am. 8]
- (4) In order to reduce carbon dioxide emissions from shipping at Union level the best possible option remains **implementing a market based measure, namely, pricing of the emissions or a levy, that requires** setting up a system for monitoring, reporting and verification (MRV) of ~~CO₂~~ **greenhouse gas** emissions based on the fuel consumption of ships ~~as~~. **Collecting data on such emissions is** a first step of a staged approach, **justified by the necessity of reducing such emissions**, for the inclusion of maritime transport emissions in the Union's greenhouse gas reduction commitment. **Public access to the emissions data will contribute to removing market barriers that prevent the uptake of many cost-negative measures which would reduce emissions from the sector.** [Am. 9]
- (5) The adoption of measures to reduce greenhouse gas emissions and fuel consumption is hampered by the existence of market barriers such as lack of reliable information on fuel efficiency of ships or of technologies available for retrofitting ships, lack of access to finance for investments into ship efficiency and split incentives as ship owners would not benefit from their investments into ship efficiency when fuel bills are paid by operators.
- (6) The results of the stakeholder consultation and discussions with international partners indicate that a staged approach for the inclusion of maritime transport emissions in the Union's greenhouse gas reduction commitment should be applied with the implementation of a robust MRV system for ~~CO₂~~ **greenhouse gas** emissions from maritime transport as a first step and ~~the pricing of these emissions~~ **the introduction of new policy instruments, namely, pricing of the emissions or a levy**, at a later stage. This approach facilitates making significant progress at international level on the agreement of greenhouse gas emission reduction targets and further measures to achieve these reductions at minimum cost. [Am. 10]
- (7) The introduction of a Union MRV system is expected to lead to emission reductions ~~of up to 2 % compared to business-as-usual and aggregated net costs reductions of up to 1,2 billion EUR by 2030~~ as it could contribute to the removal of market barriers, in particular those related to the lack of information about ship efficiency. This reduction of transport costs should facilitate international trade. Furthermore, a robust MRV system is a prerequisite for any market-based measure or ~~efficiency standard~~, **other measures aiming at providing a better basis for the 'polluter pays' principle**, whether applied at Union level or globally. **In view of the international nature of shipping, a globally agreed procedure would be the preferred and most effective method of reducing emissions in international maritime transport.** It also provides reliable data to set precise emission reduction targets and to assess the progress of maritime transport's contribution towards achieving a low carbon economy. [Am. 11]

Wednesday 16 April 2014

- (8) All intra-Union voyages, all incoming voyages from the last non-Union port to the first Union port of call and all outgoing voyages from a Union port to the next non-Union port of call should be considered relevant for purposes of monitoring. ~~CO₂~~ **Greenhouse gas** emissions in Union ports including when ships are at berth or move within a port, should be covered as well, in particular as specific measures **and alternative technologies, such as facilities which make it possible for ships to connect to mains electricity while at berth**, for their reduction or avoidance are available. These rules should be applied in a non-discriminatory manner to all ships regardless of their flag. [Am. 12]
- (8a) ***In view of the geographical scope and the concomitant need for the monitoring of greenhouse gas emissions outside the jurisdiction of the Member States, and given the inclusion of shipping companies registered all over the world, the Commission should inform third countries in good time and in an appropriate manner in order to secure maximum international acceptance.*** [Am. 13]
- (9) The proposed MRV system should take the form of a Regulation on account of the complex and highly technical nature of provisions introduced, the need for uniform rules applicable throughout the Union to reflect the international nature of maritime transport with numerous ships being expected to call at ports in different Member States, and to facilitate implementation throughout the Union.
- (10) A robust ship-specific Union MRV system should be based on the calculation of emissions from fuel consumed on, **or on the accurate reporting of real emissions** from, voyages from and to Union ports as fuel sales data could not provide appropriately accurate estimates for the fuel consumption within this specific scope due to the large tank capacities of ships. [Am. 14]
- (11) The Union MRV system should also cover other ~~climate~~ relevant information ~~allowing for the determination of ships' efficiency or~~ **in order to** further analyse the drivers for the development of emissions. ~~This scope also aligns, to~~ **align** the Union MRV system with international initiatives to introduce efficiency standards for existing ships, also covering operational measures, and ~~contributes to~~ **contribute** to the removal of market barriers related to the lack of information. [Am. 15]
- (12) In order to minimise the administrative burden for ship owners and operators, in particular for small and medium sized enterprises, and to optimise the benefits-costs-ratio of the MRV system without jeopardising the objective to cover a widely predominant share of greenhouse gas emissions from maritime transport, the rules for MRV should only apply to large emitters. A threshold of 5 000 gross tonnage (GT) has been selected after detailed objective analysis of sizes and emissions of ships going to and coming from Union ports. Ships above 5 000 GT account for around 55 % of the number of ships calling into Union ports and represent around 90 % of the related emissions. This non-discriminatory threshold would ensure that the most relevant emitters are covered. A lower threshold would result in higher administrative burden while a higher threshold would limit the coverage of emissions and thus the environmental effectiveness of the system.
- (13) ~~To further reduce the administrative effort for ship owners and operators, the monitoring rules should focus on CO₂ as the by far most relevant greenhouse gas emitted by maritime transport which contributes to up to 98 % of the total greenhouse gas emissions of this sector.~~ [Am. 17]
- (14) The rules should take into account existing requirements and data already available on board of ships; therefore, ship owners should be given the opportunity to select one out of the following four monitoring methods: the use of Bunker Fuel Delivery Notes, bunker fuel tank monitoring, flow meters for applicable combustion processes or direct emission measurements. A ship specific monitoring plan should document the choice made and provide further details on the application of the selected method.

Wednesday 16 April 2014

- (15) Any company with responsibility for an entire reporting period over a ship performing shipping activities should be considered responsible for all monitoring and reporting requirements arising in relation to this reporting period, including the submission of a satisfactorily verified emissions report. In case of change of ownership, the new owner will only be responsible for the monitoring and reporting obligations related to the reporting period where the change of ownership has taken place. To facilitate the fulfilment of these obligations the new owner should receive a copy of the latest monitoring plan, and document of compliance if applicable. Change of ownership should also lead to the modification of the monitoring plan in order to allow new ship owner to make their own choices in relation to the monitoring methodology.
- (16) ~~Other greenhouse gases, climate forcers or air pollutants should not be covered by the Union MRV system at this stage to avoid requirements to install not sufficiently reliable and commercially available measurement equipment, which could impede the implementation of the Union MRV system~~ **is an opportunity to ensure coherent regulation of the shipping sector with regard to other sectors.** [Am. 18]
- (16a) **The MARPOL Convention includes the mandatory application of the EEDI to new ships and the use of SEEMPs throughout the entire world fleet.** [Am. 19]
- (17) To minimise the administrative burden for ship owners and operators, reporting and publication of reported information should be organised on an annual basis. By restricting the publication of emissions, fuel consumption and efficiency-related information to annual averages and aggregated figures, confidentiality issues should be addressed. The data reported to the Commission should be integrated with statistics to the extent that these data are relevant for the development, production and dissemination of European statistics in accordance with Commission Decision 2012/504/EU⁽¹⁾.
- (18) Verification by accredited verifiers should ensure that monitoring plans and emission reports are correct and in compliance with the requirements defined by this Regulation. **Therefore, competence requirements are essential for a verifier to be able to perform the verification activities under this Regulation.** As an important element to simplify verification, verifiers should check data credibility by comparing reported data with estimated data based on ship tracking data and characteristics. Such estimates could be provided by the Commission. Verifiers should be independent and competent persons or legal entities and should be accredited by national accreditation bodies established pursuant to Regulation (EC) No 765/2008 of the European Parliament and of the Council⁽²⁾. [Am. 20]
- (19) A document of compliance issued by a verifier should be kept on board of ships to demonstrate compliance with the obligations for monitoring, reporting and verification. Verifiers should inform the Commission on the issuance of such documents.
- (20) Based on experience from similar tasks related to maritime safety, the European Maritime Safety Agency (EMSA) should support the Commission by carrying out certain tasks.

⁽¹⁾ Commission Decision 2012/504/EU of 17 September 2012 on Eurostat (OJ L 251, 18.9.2012, p. 49).

⁽²⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

Wednesday 16 April 2014

- (21) Non compliance with the provisions of this Regulation should result in the application of sanctions. Enforcement of the obligations related to the MRV system should be based on existing instruments, namely those instituted in application of Directive 2009/21/EC⁽¹⁾ and Directive 2009/16/EC⁽²⁾ of the European Parliament and of the Council, and on information on the issuance of documents of compliance. The document confirming compliance of the ship with the monitoring and reporting obligations should be added by the Commission to the list of certificates and documents referred to in Article 13(1) of Directive 2009/16/EC.
- (22) Directive 2009/16/EC provides for the detention of ships in the absence of certificates which have to be carried on board. In the case of ships having failed to comply with monitoring and reporting obligations for more than one reporting period, it is nonetheless appropriate to provide for the possibility of expelling. This should be applied in such a way as to allow the situation to be rectified within a reasonable period of time.
- (23) Regulation (EU) No 525/2013 of the European Parliament and of the Council⁽³⁾ should be amended to establish requirements for the monitoring and reporting of CO₂ emissions from maritime transport by Member States pursuant to this Regulation.
- (24) The Union MRV system should serve as a model for the implementation of a global MRV system. A global MRV system is preferable as it could be regarded as more effective due to the broader scope. In this context, the Commission should share relevant information on the implementation of this Regulation with the IMO and other relevant international bodies on a regular basis and relevant submissions should be made to the IMO. Where an agreement on a global MRV system is reached, the Commission should review the Union MRV system in view of aligning it to the global system.
- (25) In order to make use of the best available practices and scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of reviewing certain technical aspects of monitoring and reporting of ~~CO₂~~ **greenhouse gas** emissions from ships and of further specifying rules for the verification of emission reports and the accreditation of verifiers. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council. [**Am. 21**]
- (26) In order to ensure uniform conditions for the use of automated systems and standard electronic templates for coherent reporting of emissions and other ~~climate-relevant~~ **relevant** information to the Commission and involved States implementing powers should be conferred on the Commission. Those necessary implementing powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽⁴⁾. [**Am. 22**]

⁽¹⁾ Directive 2009/21/EC of the European Parliament and of the Council of 23 April 2009 on compliance with flag State requirements (OJ L 131, 28.5.2009, p. 132).

⁽²⁾ Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on port State control (OJ L 131, 28.5.2009, p. 57).

⁽³⁾ Regulation (EU) No 525/2013 of the European Parliament and of the Council of 21 May 2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at national and Union level relevant to climate change and repealing Decision No 280/2004/EC (OJ L 165, 18.6.2013, p. 13).

⁽⁴⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Wednesday 16 April 2014

- (27) The objective of the proposed action, namely to monitor, report and verify CO_2 **greenhouse gas** emissions from ships as first step of a staged approach to reduce these emissions **and achieve the targets set out in the Commission White Paper 'Roadmap to a Single European Transport Area'**, cannot be sufficiently achieved by the Member States acting individually, due to the international nature of maritime transport and can therefore, by reason of scale and effects of the action, be better achieved at Union level. The Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives. **[Am. 23]**
- (28) The rules establishing the MRV system should comply with the provisions of Directive 95/46/EC ⁽¹⁾ and Regulation (EC) No 45/2001 ⁽²⁾ of the European Parliament and of the Council.
- (29) This Regulation should enter into force on 1 July 2015 to ensure that the Member States and relevant stakeholders have sufficient time to take the necessary measures for the effective application of this Regulation before the first reporting period starts on 1 January 2018,

HAVE ADOPTED THIS REGULATION:

CHAPTER I GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down rules for the accurate monitoring, reporting and verification of ~~carbon dioxide (CO_2)~~ **greenhouse gas** emissions and other ~~climate~~ relevant information from ships arriving at, within or departing from ports under the jurisdiction of a Member State in order to promote the reduction of CO_2 **greenhouse gas** emissions from maritime transport in a cost effective manner. **[Am. 24]**

Article 2

Scope

1. This Regulation applies to ships above 5 000 gross tons in respect of emissions released during their voyages from the last port of call to a port under the jurisdiction of a Member State and from a port under the jurisdiction of a Member State to their next port of call, as well as within ports under the jurisdiction of a Member State.
2. This Regulation does not apply to warships, naval auxiliaries, ~~fish catching or processing ships~~, wooden ships of a primitive build, ships not propelled by mechanical means and government ships used for non-commercial purposes. **[Am. 26]**

Article 3

Definitions

For the purposes of this Regulation the following definitions apply:

- (a) 'emissions' means the release of CO_2 into the atmosphere by ships as provided for in Article 2;
- (b) 'port of call' means the port where a ship stops to load or unload cargo or to embark or disembark passengers, excluding stops for the sole purpose of refuelling, obtaining fresh supplies and/or relieving the crew;

⁽¹⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽²⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and of the free movement of such data (OJ L 8, 12.1.2001, p. 1).

Wednesday 16 April 2014

- (c) 'company' means the owner of a ship as provided for in Article 2 or any other person, such as the manager or the bareboat charterer, who has assumed the responsibility from the ship-owner for its operations;
- (d) 'gross tonnage' (GT) means the metric gross tonnage calculated in accordance with the tonnage measurement regulations contained in Annex 1 to the International Convention on Tonnage Measurement of Ships, 1969;
- (e) 'verifier' means a legal entity carrying out verification activities that is accredited by a national accreditation body pursuant to Regulation (EC) No 765/2008 and this Regulation, **or an agency in charge of a modelling system for the monitoring of ship emissions**; [Am. 28]
- (f) 'verification' means the activities carried out by a verifier to assess the conformity of the documents transmitted by the company with the requirements under this Regulation;
- (g) 'other ~~climate-relevant~~ **relevant** information' means information related to **the greenhouse gas emissions from** the consumption of fuels, ~~transport work~~ **distance sailed, the scope for connecting to mains electricity while at berth** and energy efficiency of ships which allow for analysing emission trends and ~~assessing ships'~~ **indicating shipping performances**; [Am. 29]
- (h) 'emission factor' means the average emission rate of a greenhouse gas relative to the activity data of a source stream assuming complete oxidation for combustion and complete conversion for all other chemical reactions;
- (i) 'uncertainty' means a parameter, associated with the result of the determination of a quantity, that characterises the dispersion of the values that could reasonably be attributed to the particular quantity, including the effects of systematic as well as of random factors, expressed in per cent, and describes a confidence interval around the mean value comprising 95 % of inferred values taking into account any asymmetry of the distribution of values;
- (j) 'conservative' means that a set of assumptions is defined in order to ensure that no under-estimation of annual emissions or over-estimation of distances ~~or amounts of cargo carried~~ occurs; [Am. 30]
- (k) '~~tonnes of CO₂~~' means ~~metric tonnes of CO₂~~; [Am. 31]
- (l) 'reporting period' means one calendar year during which emissions have to be monitored and reported;
- (la) '**ship at berth**' means **a ship which is securely moored or anchored in a Union port while it is loading, unloading or hotelling, including the time spent when not engaged in cargo operations**; [Am. 32]
- (lb) '**ice class**' means **the notation assigned to a ship by the administration or by an organization recognized by the administration showing that the ship has been designed for navigation in sea-ice conditions**. [Am. 33]

CHAPTER II

MONITORING AND REPORTING

SECTION 1

Principles and methods for monitoring and Reporting

Article 4

Common principles for monitoring and reporting

1. Companies shall monitor and report for every ship the amount and type of fuel consumed during a ~~calendar year~~ **reporting period** within ~~each port~~ **all ports** under the jurisdiction of a Member State and for ~~each voyage~~ **all voyages** arriving to and departing from a port located under the jurisdiction of a Member State in accordance with paragraphs 2 to 6. [Am. 34]
2. Monitoring and reporting shall be complete and cover ~~all~~ **CO₂** emissions from the combustion of fuels, **while the ship is at sea as well as at berth**. Companies shall apply appropriate measures to prevent any data gaps within the reporting period. [Am. 35]

Wednesday 16 April 2014

3. Monitoring and reporting shall be consistent and comparable over time. Companies shall use the same monitoring methodologies and data sets subject to changes and derogations approved by the verifier.
4. Companies shall obtain, record, compile, analyse and document monitoring data, including assumptions, references, emission factors and activity data, in a transparent manner that enables the reproduction of the determination of emissions by the verifier.
5. Companies shall ensure that emission determination is neither systematically nor knowingly inaccurate. They shall identify and reduce any source of inaccuracies.
6. Companies shall enable reasonable assurance of the integrity of emission data to be monitored and reported.

6a. Companies shall take account of the recommendations included in the verification reports issued pursuant to Article 13 in their consequent monitoring and reporting. [Am. 36]

Article 5

Methods for monitoring and reporting emissions on maritime transport

1. For the purposes of Article 4(1), (2) and (3), companies shall determine their emissions and other climate relevant information for each of their ships above 5 000 GT in accordance with any of the methods set out in Annex I.

1a. Where an international agreement to monitor greenhouse gas emissions from maritime transport is reached, the Commission shall review the methods set out in Annex I and shall be empowered to adopt delegated acts in accordance with Article 24, concerning, if appropriate, amendments to that Annex in order to specify the use of flow meters for applicable combustion processes and direct emission measurements. [Am. 38]

SECTION 2

MONITORING PLAN

Article 6

Content and submission of the monitoring plan

1. By 31 August 2017, companies shall submit to the verifiers a monitoring plan indicating the method chosen to monitor and report emissions and other ~~climate-relevant~~ **relevant** information for each of their ships above 5 000 GT. **[Am. 39 — adapted for consistency with Article 2(1) on scope.]**
2. By way of derogation from paragraph 1, for ships falling under the scope of this Regulation for the first time after 1 January 2018, the company shall submit a monitoring plan to the verifier without undue delay and no later than two months after their first call in a port under the jurisdiction of a Member State.
3. The monitoring plan referred to in paragraph 1 shall consist of a complete and transparent documentation of the monitoring methodology of a specific ship and shall contain at least the following elements:
 - (a) the identification and type of the ship including the name of the ship, its International Maritime Organisation (IMO) registration number, its port of registry or home port, **the ice class of the ship**, and the name of the ship owner; **[Am. 40]**
 - (b) the name of the company and the address, telephone, fax and e-mail details for a contact person;
 - (c) a description of the **following** emission sources ~~on board of the ship such as main engines, auxiliary engines, boilers and inert gas generators and the fuel types used;~~ **and their associated fuel types on board of the ship as follows:**
 - (i) **main engine(s);**
 - (ii) **auxiliary engine(s);**

Wednesday 16 April 2014

(iii) boiler(s);**(iv) inert gas generator(s); [Am. 41]**

- (d) a description of procedures, systems and responsibilities used to update the completeness of the list of emission sources over the monitoring ~~year~~ **period** for the purpose of ensuring the completeness of monitoring and reporting of the emissions of the ship; **[Am. 42]**
- (e) a description of the procedures used to monitor the completeness of the list of voyages;
- (f) a description of the procedures for monitoring fuel consumption of the ship, including:
- (i) the chosen method as set out in Annex I for calculating the fuel consumption of each emission source including a description of the measurement equipment used, as applicable;
 - (ii) procedures for the measurement of fuel uplifts and fuel in tanks, a description of the measuring instruments involved and the procedures for recording, retrieving, transmitting and storing information regarding measurements, as applicable;
 - (iii) the chosen method for the determination of density, where applicable;
 - (iv) a procedure to ensure that the total uncertainty of fuel measurements is consistent with the requirements of this regulation, where possible referring to national laws, clauses in customer contracts or fuel supplier accuracy standards;
- (g) single emission factors used for each fuel type, or in the case of alternative fuels, the methodologies for determining the emission factors, including the methodology for sampling, methods of analysis, a description of the laboratories used (and confirmed ISO 17025 accreditation where relevant);
- (h) a description of the procedures used for determining activity data per voyage, including:
- (i) the procedures, responsibilities and data sources for determining and recording the distance per voyage made;
 - ~~(ii) the procedures, responsibilities, formulae and data sources for determining and recording the cargo carried and the number of passengers as applicable; [Am. 43]~~
 - (iii) the procedures, responsibilities, formulae and data sources for determining and recording the time spent at sea between the port of departure and the port of arrival;
- (ha) the procedures, responsibilities, formulae and data sources for determining and recording the distance travelled and the time spent when navigating through ice; [Am. 44]**
- (i) a description of the method to be used to determine surrogate data for closing data gaps;
- ~~(j) the date of the latest modification to the monitoring plan. [Am. 45]~~
- (ja) a revision record sheet to record all details of the revision history. [Am. 46]**

4. Companies shall use standardised monitoring plans based on templates. **The Commission shall be empowered to adopt delegated acts in accordance with Article 24 in order to determine** technical rules establishing the templates for the monitoring plans referred to in paragraph 1 ~~shall be determined by means of implementing acts. Those implementing acts~~ **templates** shall be adopted by the Commission in accordance with the procedure referred to in Article 25(2) of this Regulation **as simple as possible and shall not entail needless bureaucracy. [Am. 47]**

Article 7

Modifications of the monitoring plan

Companies shall regularly check if the ship's monitoring plan reflects the nature and functioning of the ship and whether the monitoring methodology can be improved.

Wednesday 16 April 2014

A company shall modify the monitoring plan in any of the following situations set out in points (a) to (e). **The monitoring plan shall be modified only in respect of the specific changes that have occurred as a result of those situations:** [Am. 48]

- (a) where a change of ownership of ships, **or change of DOC holder or of flag** occurs; [Am. 49]
- (b) where new emissions occur due to new emission sources or due to the use of new fuels not yet contained in the monitoring plan;
- (c) where the change in availability of data, due to the use of new measuring instrument types, sampling methods or analysis methods, or for other reasons, leads to higher accuracy in the determination of emissions;
- (d) where data resulting from the previously applied monitoring methodology has been found incorrect;
- (e) where the monitoring plan is not in conformity with the requirements of this Regulation and the verifiers requests the company to modify it.

Companies shall notify any proposals for modification of the monitoring plan to the verifiers without undue delay.

Any significant modification of the monitoring plan shall be subject to assessment by the verifier.

SECTION 3

MONITORING OF EMISSIONS AND OTHER RELEVANT INFORMATION

Article 8

Monitoring of activities within a reporting period

1. From 1 January 2018, companies shall, based on the monitoring plan approved in accordance with Article 13(1), monitor emissions for each ship on a per-voyage and an annual basis by applying the appropriate method among those set out in part B of Annex I and by calculating emissions in accordance with part A of Annex I.

1a. Monitoring may be suspended during periods during which a ship is engaged in emergency situations including life-saving activities. [Am. 50]

Article 9

Monitoring on a per-voyage basis

Based on the monitoring plan approved in accordance to Article 13(1), for each ship and for each voyage arriving to and departing from a port under a Member State's jurisdiction, companies shall monitor in accordance with part A of Annex I and Annex II, the following information:

- (a) port of departure and port of arrival including the date and hour of departure and arrival;
- (b) amount and emission factor for each type of fuel consumed in total ~~and differentiated between fuel used inside and outside emission control areas;~~ [Am. 51]
- (c) CO₂ emitted;
- (d) distance travelled;
- (e) time spent at sea;
- ~~(f) cargo carried;~~ [Am. 53]
- (fa) energy efficiency as determined in Annex II;** [Am. 54]
- ~~(g) transport work.~~ [Am. 55]

Wednesday 16 April 2014

(ga) date and time of the start and finish of periods during which monitoring was suspended due to emergency situations such as life-saving activities, along with a description of same. [Am. 56]

For deep sea shipping calling at a series of Union ports, the European leg should be considered as one voyage. [Am. 57]

By way of derogation from the first paragraph, vessels exclusively operating within the scope of this Regulation and performing multiple voyages per day are exempted from monitoring emissions on a per-voyage basis. [Am. 58]

Article 10

Monitoring on a yearly basis

Based on the monitoring plan approved in accordance to Article 13(1), for each ship and for each calendar year, the company shall monitor in accordance with part A of Annex I and Annex II the following parameters:

- (a) amount and emission factor for each type of fuel consumed in total ~~and differentiated between fuel used inside and outside emission control areas;~~
- (b) total CO₂ emitted;
- (c) aggregated CO₂ emissions from all voyages between ports under a Member State's jurisdiction;
- (d) aggregated CO₂ emissions from all voyages which departed from ports under a Member State's jurisdiction;
- (e) aggregated CO₂ emissions from all voyages to ports under a Member State's jurisdiction;
- (f) CO₂ emissions which occurred within ports under a Member State's jurisdiction at berth;
- (g) total distance travelled;
- (h) total time spent at sea **and at berth**;
- ~~(i) total transport work;~~
- (j) average energy efficiency. [Am. 59]

SECTION 4

REPORTING

Article 11

Content of the emission report

1. From 2019, by 30 April of each year, companies shall submit to the Commission and to the authorities of the flag States concerned, an emission report concerning the emissions and other climate-relevant information during the entire reporting period for each ship under their responsibility, which has been verified as satisfactory by a verifier in accordance with the requirements referred to in Article 14.

2. Where there is a change in ownership of ships, the new company shall ensure that each ship under its responsibility complies with the requirements of this Regulation in relation to the entire reporting period where it takes responsibility for the ship concerned.

3. Companies shall include in the emission report referred to in paragraph 1 the following information:

- (a) data identifying the ship and the company, including:
 - (i) name of the ship,

Wednesday 16 April 2014

- (ii) IMO registration number,
- (iii) port of registry or home port,
- (iiia) the ice class of the ship, [Am. 60]**
- (iv) **certified** technical efficiency of the ship (**expressed by** the Energy Efficiency Design Index (EEDI) ~~or the Estimated Index Value (EIV) in accordance with IMO Resolution MEPC.215 (63), where applicable~~ **to the relevant ship type, [Am. 61]**)
- (v) name of the ship owner,
- (vi) address of the ship owner and his principal place of business,
- (vii) name of the company (if not the ship owner),
- (viii) address of the company (if not the ship owner) and his principal place of business,
- (ix) address, telephone, ~~fax~~ and e-mail details for a contact person; **[Am. 62]**
- (b) information on the monitoring method used and the related level of uncertainty;
- (c) the results from annual monitoring of the parameters in accordance with Article 10;
- (ca) details of suspended monitoring periods due to emergency situations and life-saving activities. [Am. 63]**

Article 12

Format of the emission report

1. The emission report referred to in Article 11 shall be submitted using automated systems and complete data exchange formats, including electronic templates.
2. Technical rules establishing the data exchange format including electronic templates referred to in paragraph 1 shall be determined by means of implementing acts. Those implementing acts shall be adopted by the Commission in accordance with the procedure referred to in Article 25(2) of this Regulation.

CHAPTER III

VERIFICATION AND ACCREDITATION

Article 13

Scope of verification activities and verification report

1. The verifier shall assess the conformity of the monitoring plan referred to in Article 6 with the requirements laid down in Articles 6 and 7. Where the assessment contains recommendations necessary to be incorporated within a monitoring plan, the respective company shall revise its monitoring plan before the reporting period starts.
2. The verifier shall assess the conformity of the emission report with the requirements laid down in Articles 8 to 11 and Annex I and II.
3. In particular the verifier shall ensure that the emissions and other ~~climate-relevant~~ **relevant** information included in the emission report have been determined in accordance with Articles 8, 9 and 10 and the monitoring plan referred to in Article 6. The verifier shall also ensure that the emissions and other ~~climate-relevant~~ **relevant** information declared in the reports are consistent with data calculated from other sources in accordance with Annexes I and II. **[Am. 64]**
4. Where the assessment concludes that, to the best knowledge of the verifier, the emission report is free from material misstatements and errors, the verifier shall issue a verification report. The verification report shall specify all issues relevant to the work carried out by the verifier.

Wednesday 16 April 2014

5. Where the assessments concludes that the emission report includes material misstatements, errors, inconsistencies or does not meet the requirements of Articles 11 and 14 and Annex I, the verifier shall inform the company thereof on a timely basis and ask it to resubmit a reviewed emission report. The company shall correct any communicated non-conformities or inconsistencies so as to allow the verification process to be finished in a timely manner. The verifier shall report in its verification report whether the non-conformities have been resolved by the company during verification.

5a. Where the verifier has identified areas for improvement in the company's performance related to the monitoring and reporting of emissions, including in relation to achieving higher accuracy and enhancing efficiency in the monitoring and reporting, it shall include in the verification report recommendations for improvement. [Am. 65]

Article 14

General obligations and principles for the verifiers

1. The verifier shall be independent from a company or operator of the ship concerned and carry out the activities required under this regulation in the public interest. For that purpose, the verifier and any part of the same legal entity shall not be a company or ship operator, the owner of a company or owned by them nor shall the verifier have relations with the company that could affect its independence and impartiality.

2. When considering the verification of the emission report referred to in Article 11 and of the monitoring procedures applied by the company, the verifier shall assess the reliability, credibility and accuracy of the monitoring systems and of the reported data and information relating to emissions, in particular:

- (a) the assigning of fuel consumption to voyages within the scope of this Regulation;
- (b) the reported fuel consumption data and related measurements and calculations;
- (c) the choice and the employment of emission factors;
- (d) the calculations leading to the determination of the overall emissions;
- (e) the calculations leading to the determination of the energy efficiency.

3. The verifier shall only consider reports submitted in accordance with Article 11 if reliable and credible data and information allow the emissions to be determined with a high degree of certainty and provided that the following are ensured:

- (a) the reported data is coherent in view of estimated data based on ship tracking data and characteristics such as the installed engine power;
- (b) the reported data is free of inconsistencies, in particular when comparing the total volume of fuel purchased annually by each ship and the aggregate fuel consumption during voyages which fall within the scope of this Regulation;
- (c) the collection of the data has been carried out in accordance with the applicable rules;
- (d) the relevant records of the ship are complete and consistent.

Article 15

Verification procedures

~~1. The verifier shall identify potential risks related to the monitoring and reporting process by comparing reported emissions with estimated data based on ship tracking data and characteristics such as the installed engine power. Where significant deviations are found, the verifier shall carry out further analyses. [Am. 66]~~

2. The verifier shall identify potential risks related to the different calculation steps by reviewing all data sources and methodologies used.

Wednesday 16 April 2014

3. The verifier shall take into consideration any effective risk control methods applied by the company to reduce levels of uncertainty, considering the accuracy of the monitoring methods used.
4. The company shall provide the verifier with any additional information that enables it to carry out the verification procedures. The verifier may conduct spot-checks during the verification process to determine the reliability of reported data and information.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 24 in order to further specify the rules for the verification activities referred to in this Regulation and the methods of accreditation of verifiers. These delegated acts shall be based on the principles for verification provided for in Article 14 and on relevant internationally accepted standards.

Article 16

Accreditation of verifiers

1. A verifier assessing monitoring plans and emission reports and issuing verification and compliance documents referred to in Articles 13 and 17 shall be accredited for activities under the scope of the present Regulation by a national accreditation body pursuant to Regulation (EC) No 765/2008.
2. Where no specific provisions concerning the accreditation of verifiers are laid in this Regulation, the relevant provisions of Regulation (EC) No 765/2008 shall apply.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 24, in order to further specify the methods of accreditation of verifiers.

CHAPTER IV

COMPLIANCE AND PUBLICATION OF INFORMATION

Article 17

Issuance of a document of compliance

1. Where the emission report referred to in Article 11 fulfils the requirements of Articles 11, to 15 and those laid down in Annexes I and II, on the basis of a verification report, the verifier shall deliver a document of compliance for the ship concerned.
2. The document of compliance referred to in paragraph 1 shall include the following information:
 - (a) the identity of the ship (name, IMO registration number and port of registry or home port);
 - (b) name and address and principal place of business of the owner of the ship;
 - (c) the identity of the verifier;
 - (d) the date of issue of the document of compliance (the reporting period it refers to and its period of validity).
3. Documents of compliance shall be considered valid documents for a period of 18 months after the end of the reporting period.
4. Without delay, the verifier shall inform the Commission and the authority of the flag State on the issuance of any document of compliance and transmit the information referred to in paragraph 2 using automated systems and complete data exchange formats, including electronic templates established by the Commission in accordance with the procedure established in the present Regulation.
5. Technical rules establishing the data exchange format including electronic templates referred to in paragraph 4 shall be determined by means of implementing acts. Those implementing acts shall be adopted by the Commission in accordance with the procedure referred to in Article 25(2) of this Regulation.

Wednesday 16 April 2014

Article 18

Obligation to carry a valid document of compliance on board

From 30 June 2019 ships arriving at, within or departing from a port under the jurisdiction of a Member State shall carry on board a valid document certifying the ship's compliance with the reporting and monitoring obligations for the concerned reporting period, issued in accordance with Article 17.

Article 19

Compliance with monitoring and reporting obligations and inspections

1. Based on the information published in accordance with Article 21(1), each Member State shall ensure the compliance with the monitoring and reporting requirements set out in Articles 8 to 12 by ships flying its flag.
2. Each Member State shall ensure that any inspection of a ship in a port under its jurisdiction includes verification that the document of compliance referred to in Article 18 is carried on board.
3. Without prejudice to paragraph 2 of this Article and based on the information published in accordance with Article 21, for each ship in failure to comply with Article 21(2) (j) and (k) which entered a port under jurisdiction of a Member State, the Member State shall verify that the document of compliance referred to in Article 18 is carried on board.

3a. During the course of visits and inspections undertaken by EMSA to monitor the implementation of Directive 2009/16/EC, EMSA will also monitor the application of paragraphs 1, 2, and 3 by the competent authorities of Member States and report to the Commission. [Am. 67]

Article 20

Penalties, information exchange and expulsion order

1. Member States shall lay down a system of penalties for failure to comply with the monitoring and reporting requirements set out in Articles 8 to 12 and shall take all the measures necessary to ensure that those penalties are applied. The penalties provided for shall be ~~no less stringent than those foreseen under national legislation on greenhouse gas emissions in case of non-compliance with reporting obligations by operators and~~ be effective, proportionate and dissuasive. Member States shall notify these provisions to the Commission by 1 July 2017, and shall notify any subsequent amendments affecting these provisions to the Commission without delay. **[Am. 68]**
2. Member States shall establish an effective exchange of information and effective cooperation between their national authorities ensuring compliance with the monitoring and reporting requirements or, where applicable, their authority entrusted with the sanctioning procedures. National sanctioning procedures launched by any Member State shall be notified to the Commission, EMSA, to the other Member States and to the flag State concerned.
3. For ships having failed to comply with the monitoring and reporting requirements for more than one reporting period, the national State port authority may issue an expulsion order which shall be notified to the Commission, EMSA, the other Member States and the flag State concerned. As a result of the issuing of such an expulsion order, every Member State shall refuse entry of this ship into any of its ports until the company fulfils its monitoring and reporting requirements in accordance with Articles 8 to 12, confirmed by the notification of a valid document of compliance to the national port State authority which issued the expulsion order.

Wednesday 16 April 2014

Article 21

Publication of information

1. By 30 June each year, the Commission shall make publicly available the **yearly** emissions reported in accordance with Article 11 ~~and, respecting the confidentiality of commercial information on the company's compliance with the monitoring and reporting requirements set out in Articles 11 and 17 to protect a legitimate economic interest pursuant to Articles 3 and 4 of Directive 2003/4/EC of the European Parliament and of the Council~~ ⁽¹⁾. [Am. 69]
2. The publication referred to in paragraph 1 shall include the following information:
 - (a) the identity of the ship (name, IMO registration number ~~and~~, port of registry or home port **and the ice class of the ship**); [Am. 70]
 - (b) the identity of the ship owner (name and address of owner and his principal place of business);
 - (c) technical efficiency of the ship (EEDI ~~or EIV~~ where applicable **to the relevant ship type**); [Am. 71]
 - (d) annual CO₂ emissions;
 - (e) annual total fuel consumption for voyages falling within the scope of this Regulation;
 - (f) annual average fuel consumption and greenhouse gas emissions per distance travelled of voyages falling within the scope of this Regulation;
 - ~~(g) annual average fuel consumption and greenhouse gas emissions per distance travelled and cargo carried on voyages falling within the scope of this Regulation; [Am. 73]~~
 - ~~(h) annual total time spent at sea in voyages falling within the scope of this Regulation; [Am. 74]~~
 - (i) methodology for monitoring applied;
 - (j) the date of issue and the expiry date of the document of compliance;
 - (k) the identity of the verifier having approved the emission report.
3. The Commission shall publish an annual report on emissions and other ~~climate-relevant~~ **relevant** information from maritime transport. [Am. 75]
4. EMSA shall assist the Commission in its work to comply with Articles 11, 12, 17 and 21 of this Regulation, in accordance with Regulation (EC) No 1406/2002 of the European Parliament and of the Council ⁽²⁾.

CHAPTER V

INTERNATIONAL COOPERATION

Article 22

International cooperation

1. The Commission shall inform the IMO and other relevant international bodies on a regular basis of the implementation of this Regulation with a view to facilitate the development of international rules within the IMO for the monitoring, reporting and verification of greenhouse gas emissions from maritime transport.

⁽¹⁾ *Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).*

⁽²⁾ Regulation (EC) No 1406/2002 of the European Parliament and of the Council of 27 June 2002 establishing a European Maritime Safety Agency (OJ L 208, 5.8.2002, p. 1).

Wednesday 16 April 2014

2. The Commission shall maintain technical exchange with third countries on the implementation of this Regulation, in particular the further development of monitoring methods, the organisation of reporting and the verification of emission reports.
3. Where an international agreement on global measures to reduce greenhouse gas emissions from maritime transport is reached, the Commission shall review this Regulation and ~~may, if appropriate, propose amendments to this Regulation~~ **ensure alignment with the relevant international regulations set by the IMO.** [Am. 76]

CHAPTER VI

DELEGATED AND IMPLEMENTING POWERS AND FINAL PROVISIONS

Article 23

Delegation of powers

The power to adopt delegated acts in order to supplement and amend the provisions of Annexes I and II **shall be conferred on the Commission in order** to take into account up-to-date scientific evidence available, as well as **to align the Annexes with** the relevant ~~data available on board of ships and the relevant~~ **international regulations as agreed by the IMO, with the aim of ensuring conformity with** international rules and internationally accepted standards, ~~to identify~~ **regulations, identifying** the most accurate and efficient methods for monitoring of emissions, and ~~to improve~~ **improving** the accuracy of the information requested related to the monitoring and reporting of emissions. **This power** is conferred on the Commission subject to the conditions laid down under Article 24 **only** to the extent it concerns non-essential elements of this Regulation. [Am. 77]

Article 24

Exercise of delegation

1. The power to adopt delegated acts referred to in **Articles 5(1a) and 6(4) and** Articles 15, 16 and 23 shall be conferred on the Commission for a period of five years from ~~1 July 2015 ...~~ (*). **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.** [Am. 78]
2. The delegation of power referred to in ~~Article~~ **Articles 5(1a) and 6(4) and Articles 15, 16 and** 23 may be revoked at any time by the European Parliament or by the Council. A decision of ~~revocation~~ **to revoke** shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force. [Am. 79]
3. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
4. A delegated act adopted pursuant to ~~Article~~ **Articles 5(1a) and 6(4) and** Articles **15, 16 and** 23 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council. [Am. 80]

Article 25

Implementing acts

1. The Commission shall be assisted by the Committee established by Article 8 of Council Decision 93/389/EEC ⁽¹⁾. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

(*) **Date of entry into force of this Regulation.**

⁽¹⁾ Council Decision 93/389/EEC of 24 June 1993 for a monitoring mechanism of Community CO₂ and other greenhouse gas emissions (OJ L 167, 9.7.1993, p. 31).

Wednesday 16 April 2014

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 26

Amendments to Regulation (EU) No 525/2013

Regulation (EU) No 525/2013 is amended as follows:

1. In Article 1, the following point shall be added:

‘(h) monitoring and reporting of greenhouse gas emissions from marine ships pursuant to Articles 9 and 10 of Regulation (EU) No .../... of the European Parliament and of the Council (*).

(*) OJ L ... (+).’

2. The following Article shall be inserted:

‘Article 21a

Reporting emissions from maritime transport

1. Member States shall report to the Commission by 15 January each year (“year X”) for the year X-2, the CO₂ emissions from maritime transport pursuant to Articles 9 and 10 of Regulation (EU) No .../... (*).
 2. The Commission shall be empowered to adopt delegated acts in accordance with [Article 25 of this Regulation] to specify the requirements for the monitoring and reporting of CO₂ emissions from maritime transport pursuant to Articles 9 and 10 of Regulation (EU) No .../... (**) and taking into account, where applicable, relevant decisions adopted by the bodies of the UNFCCC and the Kyoto Protocol or agreements deriving from them or succeeding them or decisions adopted in the context of the International Maritime Organisation.
 3. The Commission shall adopt implementing acts to set out the structure, format and process for the Member states’ submission of CO₂ emissions from maritime transport pursuant to Articles 9 and 10 of Regulation (EU) No .../... (***) . These implementing acts shall be adopted in accordance with the examination procedure referred to in [Article 26(2)].
- 3a. The Commission shall biennially assess the maritime transport sector’s overall impact on the global climate including through non-CO₂ emissions or effects, based on the emission data provided by Member States pursuant to Article 7 and/or provided under Regulation (EU) No .../... (****) and improve that assessment by reference to scientific advancements and maritime traffic data.’ [Am. 82]**

(*) Number of this Regulation.

(**) Number of this Regulation.

(***) Number of this Regulation.

(****) Number of this Regulation.

3. In Article 25(2), (3) and (5) the following reference shall be inserted:

‘21a’

(+) Number and reference of this Regulation.

Wednesday 16 April 2014

Article 27

Entry into force

This Regulation shall enter into force on 1 July 2015.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

The President

For the Council

The President

Wednesday 16 April 2014

ANNEX I

Methods for monitoring and reporting greenhouse gas emissions and other climate relevant information

A. CALCULATION OF FUEL CONSUMPTION (Article 9)

For the purposes of calculating fuel consumption companies shall respect the following formula:

Fuel consumption x Emission factor

Fuel consumption shall include fuel consumed by main engines, auxiliary engines, boilers and inert gas generators.

Fuel consumption within ports at berth shall be calculated separately.

In principle, default values for emission factors of fuels shall be used unless the company decides using data on fuel quality set out in the Bunker Fuel Delivery Notes and used for demonstrating compliance with applicable regulations of sulphur emissions.

Default emission factors shall be based on latest available IPCC values. They can be derived from Annex VI to Commission Regulation (EU) No 601/2012⁽¹⁾.

Appropriate emission factors shall be applied in respect of biofuels and alternative non-fossil fuel fuels.

B. METHODS FOR DETERMINING EMISSIONS

The company shall define in the monitoring plan which monitoring methodology is used to calculate fuel consumption for each ship type under its responsibility and ensure that once it has been chosen, is consistently applied.

In selecting a monitoring methodology, the improvements from greater accuracy shall be balanced against the additional costs.

Actual fuel consumption for each voyage shall be used and be calculated using one of the following methods:

- (a) Bunker Fuel Delivery Note (BDN) and periodic stocktakes of fuel tanks;
- (b) Bunker fuel tank monitoring on board;
- (c) Flow meters for applicable combustion processes;
- (d) Direct emissions measurements;

(da) Modelling with ship movement information (AIS) and ship specific data. [Am. 83]

Any combination of the above methods, approved by the verifier may be used if it enhances the overall accuracy of the measurement. [Am. 84]

1. Method A: BDN (Bunker Delivery Notes) and periodic stock-takes of fuel tanks

This method is based on the quantity and type of fuel as defined on the BDN combined with periodic stock-takes of fuel tanks based on tank readings. The fuel at the beginning of the period, plus deliveries, minus fuel available at the end of the period and de-bunkered fuel between the beginning of the period and the end of the period together constitute the fuel consumed over the period.

⁽¹⁾ Commission Regulation (EU) No 601/2012 of 21 June 2012 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council (OJ L 181, 12.7.2012, p. 30).

Wednesday 16 April 2014

The period includes time between two port calls or time within a port. For the fuel used during a period, the fuel type and the sulphur content need to be specified.

~~This approach shall not be used when BDN~~ **Where BDNs** are not available on board of ships, especially when cargo is used as a fuel, for example, liquefied natural gas (LNG) boil-off, **only the stock takes of fuel tanks and bunker fuel tank readings shall be used.** [Am. 85]

The BDN is mandated under existing MARPOL Annex VI Regulations and relevant records are retained on board for 3 years after the delivery of the bunker fuel and be readily available. The periodic stock-take of fuel tanks on-board is based on fuel tank readings. It uses tank tables relevant to each fuel tank to determine the volume at the time of the fuel tank reading. The uncertainty associated with the BDN shall be specified in the monitoring plan referred to in Article 6. Fuel tank readings shall be carried out by appropriate methods such as automated systems, soundings and dip tapes. The method for tank sounding and uncertainty associated shall be specified in the monitoring plan referred to in Article 6.

Where BDNs are not available on board ships, especially when cargo is used as a fuel, for example, liquefied natural gas (LNG) boil-off, only the stock takes of fuel tanks and bunker fuel tank readings shall be used. [Am. 86]

Where the amount of fuel uplift or the amount of fuel remaining in the tanks is determined in units of volume, expressed in litres, the company shall convert that amount from volume to mass by using actual density values. The company shall determine the actual density by using one of the following:

- (a) on-board measurement systems;
- (b) the density measured by the fuel supplier at fuel uplift and recorded on the fuel invoice or delivery note.

The actual density shall be expressed in kg/litre and determined for the applicable temperature for a specific measurement. In cases for which actual density values are not available, a standard density factor for the relevant fuel type shall be applied upon approval by the verifier.

2. Method B: Bunker fuel tank monitoring on-board

This method is based on fuel tank readings for all fuel tanks on-board. The tank readings shall occur daily when the ship is at sea and each time the ship is bunkering or de-bunkering.

The cumulative variations of the fuel tank level between two readings constitute the fuel consumed over the period.

The period means time between two port calls or time within a port. For the fuel used during a period, the fuel type and the sulphur content need to be specified.

Fuel tank readings shall be carried out by appropriate methods such as automated systems, soundings and dip tapes. The method for tank sounding and uncertainty associated shall be specified in the monitoring plan referred to in Article 6.

Where the amount of fuel uplift or the amount of fuel remaining in the tanks is determined in units of volume, expressed in litres, the company shall convert that amount from volume to mass by using actual density values. The company shall determine the actual density by using one of the following:

- (a) on-board measurement systems;
- (b) the density measured by the fuel supplier at fuel uplift and recorded on the fuel invoice or delivery note;

(ba) the density measured in a test analysis conducted in an accredited fuel test laboratory, where available. [Am. 87]

Wednesday 16 April 2014

The actual density shall be expressed in kg/litre and determined for the applicable temperature for a specific measurement. In cases for which actual density values are not available, a standard density factor for the relevant fuel type shall be applied upon approval by the verifier.

3. Method C: Flow meters for applicable combustion processes

This method is based on measured fuel flows on-board. The data from all flow meters linked to relevant emission sources shall be combined to determine all fuel consumption for a specific period.

The period means time between two port calls or time within a port. For the fuel used during a period, the fuel type and the sulphur content need to be monitored.

The calibration methods applied and the uncertainty associated with flow meters used shall be specified in the monitoring plan referred to in Article 6.

Where the amount of fuel consumed is determined in units of volume, expressed in litres, the company shall convert that amount from volume to mass by using actual density values. The company shall determine the actual density by using one of the following:

- (a) on-board measurement systems;
- (b) the density measured by the fuel supplier at fuel uplift and recorded on the fuel invoice or delivery note.

The actual density shall be expressed in kg/litre and determined for the applicable temperature for a specific measurement. In cases for which actual density values are not available, a standard density factor for the relevant fuel type shall be applied upon approval by the verifier.

4. Method D: Direct emissions measurement

The direct emissions measurements may be used for voyages within the scope of this regulation and for emissions occurring in ports located in a Member State's jurisdiction. CO₂ emitted shall include CO₂ emitted by main engines, auxiliary engines, boilers and inert gas generators. For ships on which reporting is based on this method, the fuel consumption shall be calculated using the measured CO₂ emissions and the applicable emission factor of the relevant fuels.

This method is based on the determination of CO₂ emission flows in exhaust gas stacks (funnels) by multiplying the CO₂ concentration of the exhaust gas with the exhaust gas flow.

The calibration methods applied and the uncertainty associated with the devices used shall be specified in the monitoring plan referred to in Article 6.

4a. Method Da: Modelling with ship movement information (AIS) and ship specific data

The agency in charge of the modelling system makes a written agreement with the ship-owner of the ship in question. At the end of the monitoring period, the calculated CO₂ emissions are compared to the ship oil record book and BDNs in order to find and correct any discrepancies. [Am. 90]

Wednesday 16 April 2014

ANNEX II

Monitoring of other climate-relevant information

A. Monitoring on a per voyage basis (Article 9)

For the purposes of monitoring other climate-relevant information on a per-voyage basis (Article 9), companies shall respect the following rules:

The date and hour of departure and arrival shall be considered using Greenwich Mean Time (GMT). The time spent at sea shall be calculated based on port departure and arrival information and shall exclude ankering.

The distance travelled can be the distance of the most direct route between the port of departure and the port of arrival or the real distance travelled. In the event of the use of the distance of the most direct route between the port of departure and the port of arrival, conservative correction factor should be taken into account to ensure that the distance travelled is not significantly underestimated. The monitoring plan referred to in Article 6 shall specify which distance calculation is used and, if necessary, the correction factor used. The distance travelled shall be expressed in nautical-miles.

~~For passenger ships, the number of passengers shall be used to express cargo carried. For all other categories of ships, the amount of cargo carried shall be expressed as metric tonnes and cubic meters of cargo. [Am. 91]~~

~~Transport work shall be determined by multiplying the distance travelled with the amount of cargo carried. [Am. 92]~~

B. Monitoring on a yearly basis (Article 10)

For the purposes of monitoring other climate-relevant information on a yearly basis, companies shall respect the following rules:

The values to be monitored according to Article 10 should be determined by aggregation of the respective per voyage data.

Average energy efficiency shall be monitored by using ~~at least four~~ **two** indicators, fuel consumption per distance, ~~the fuel consumption per transport work,~~ **and** the CO₂ emissions per distance ~~and the CO₂ emissions per transport work,~~ which shall be calculated as follows:

Fuel consumption per distance = total annual fuel consumption / total distance travelled

~~Fuel consumption per transport work = total annual fuel consumption / total transport work~~

CO₂ emissions per distance = total annual CO₂ emissions / total distance travelled.

~~CO₂ emissions per transport work = total annual CO₂ emissions / total transport work [Am. 93]~~

Wednesday 16 April 2014

P7_TA(2014)0425

Invasive alien species *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species (COM(2013)0620 — C7-0264/2013 — 2013/0307(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/98)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0620),
 - having regard to Article 294(2) and Article 192(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0264/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Austrian Bundesrat, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 22 January 2014 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 19 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on International Trade and the Committee on Fisheries (A7-0088/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0307

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the prevention and management of the introduction and spread of invasive alien species

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 1143/2014.)

⁽¹⁾ Not yet published in the Official Journal.

Wednesday 16 April 2014

P7_TA(2014)0426

Technical implementation of the Kyoto Protocol to the UN Framework Convention on Climate Change *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 525/2013 as regards the technical implementation of the Kyoto Protocol to the United Nations Framework Convention on Climate Change (COM(2013)0769 — C7-0393/2013 — 2013/0377(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/99)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0769),
 - having regard to Article 294(2) and Article 192(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0393/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 26 February 2014 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 19 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0171/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0377

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EU) No 525/2013 as regards the technical implementation of the Kyoto Protocol to the United Nations Framework Convention on Climate Change

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 662/2014.)

⁽¹⁾ Not yet published in the Official Journal.

Wednesday 16 April 2014

P7_TA(2014)0427

Fight against fraud to the Union's financial interests by means of criminal law *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council on the fight against fraud to the Union's financial interests by means of criminal law (COM(2012)0363 — C7-0192/2012 — 2012/0193(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/100)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0363),
 - having regard to Article 294(2) and Article 325(4) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0192/2012),
 - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard the opinion of the Court of Auditors of 15 November 2012 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 10 October 2012 ⁽²⁾,
 - having regard to Rules 55 and 37 of its Rules of Procedure,
 - having regard to the joint deliberations of the Committee on Budgetary Control and the Committee on Civil Liberties, Justice and Home Affairs under Rule 51 of the Rules of Procedure,
 - having regard to the report of the Committee on Budgetary Control and the Committee on Civil Liberties, Justice and Home Affairs and the opinion of the Committee on Legal Affairs (A7-0251/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0193

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the fight against fraud to the Union's financial interests by means of criminal law

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article ~~325(4)~~ **83(2)** thereof, **[Am. 1]**

⁽¹⁾ OJ C 383, 12.12.2012, p. 1.

⁽²⁾ OJ C 391, 18.12.2012, p. 134.

Wednesday 16 April 2014

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Court of Auditors ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) The protection of the Union's financial interests concerns not only the management of budget appropriations, but extends to all measures negatively affecting or threatening to negatively affect its assets, and those of the Member States to the extent they are designated to support or stabilise the economy or public finances of Member States with relevance to Union policies.
- (2) In order to ensure effective, proportionate and dissuasive protection of the Union's financial interests, ~~criminal law in the Member States should continue to complement the protection under administrative and civil law for~~ **against** the most serious types of fraud-related conduct in this field, **and to ensure that the Union's financial interests are optimally protected, measures adopted under administrative and civil law should be complemented by legislation under criminal law in the Member States**, whilst avoiding inconsistencies, both within and among these areas of law. [Am. 2]
- (3) The protection of the Union's financial interests calls for a common definition of fraud covering fraudulent conduct with respect to expenditure ~~and~~ revenues, **assets and liabilities** at the expense of the ~~EU~~ **Union** budget, **including borrowing and lending activities**. [Am. 3]
- (4) Fraud affecting Value Added Tax (VAT) diminishes tax receipts of Member States and subsequently the application of a uniform rate to Member States' VAT assessment base. As confirmed by the case-law ⁽⁴⁾ of the Court of Justice of the European Union, there is a direct link between the collection of VAT revenue in compliance with the Union law applicable and the availability to the Union budget of the corresponding resources, since any lacuna in the collection of the first potentially causes a reduction in the second. The Directive therefore covers revenue resulting from VAT receipts in the Member States.
- (5) The consideration of the substantial impact on the EU's financial interests resulting from the illegal diminution of the VAT-based own resource and application of thresholds contained in this Directive shall be read in line with the principle of proportionality, given the specific nature and methodology used for calculating that own resource, including differentiated treatment of Member States.
- (6) The Union's financial interests can be negatively affected where individual tenderers provide information to contracting or grant awarding authorities based on information ~~and~~ **illegally** obtained directly or indirectly from the tendering body, with the aim of circumventing or ~~skewing~~ **violating** rules applicable to a public procurement or grant procedure. Such conduct is very similar to fraud, but does not necessarily need to ~~constitute~~ **bear all the hallmarks of** a full fraud offence on the side of the tenderer, since the provided bid may ~~be completely in line with all requirements~~ **meet all the necessary criteria**. Bid-rigging behaviour between tenderers violates Union competition rules and equivalent national laws; it is subject to public enforcement action and sanctions throughout the Union and should remain outside the scope of this Directive. [Am. 4]
- (7) The Union money laundering legislation is fully applicable to laundering the proceeds of the criminal offences referred to in this Directive. A reference made to that legislation should insure that the sanction regime introduced by this Directive applies to all criminal offences against the Union's financial interest.

⁽¹⁾ OJ C 383, 12.12.2012, p. 1.

⁽²⁾ OJ C 391, 18.12.2012, p. 134.

⁽³⁾ Position of the European Parliament of 16 April 2014.

⁽⁴⁾ Judgment of the Court of Justice of 15 November 2011 in Case C-539/09 *Commission v Germany* ([2011] ECR I-11235).

Wednesday 16 April 2014

- (8) Corruption constitutes a particularly serious threat against the Union's financial interests, which can in many cases also be linked to fraudulent conduct. A particular criminalisation in this area is therefore needed. It must be ensured that the relevant offences are covered by the definition irrespective of whether conduct is in breach of official duties or not. As regards the offences of passive corruption and misappropriation, there is a need to include a definition of public officials covering all relevant officials, whether appointed, elected or employed on the basis of a contract, **or holding a formal office, as well as persons exercising the function of providing service from government and other public bodies to citizens, or for the public interest in general, without holding in the Union, in the Member States or in third countries. Private persons are increasingly involved in the management of Union funds. In order to adequately protect Union funds from corruption and misappropriation, the definition of 'public official' for the purposes of this Directive therefore needs to cover also persons who do not hold a formal office, but who are none the less assigned, and who exercise, in a similar manner, a public-service function in relation to Union funds,** such as contractors involved in the management of ~~EU~~ **such** funds. [Am. 5]
- (9) The Union's financial interests can be negatively affected by certain types of conduct of a public official which aim at misappropriating funds or assets contrary to the purpose foreseen, and with the intention to damage the Union's financial interests. There is therefore a need to introduce a precise **and unambiguous** definition of offences covering such conduct. [Am. 6]
- (9a) **With regard to the criminal offences committed by natural persons as defined in this Directive, it is necessary to establish intent in respect of all the elements comprised in those offences. Offences committed by natural persons which do not require intent are not covered by this Directive.** [Am. 7]
- (10) Some offences against the Union's financial interests are in practice often closely related to the offences covered by Article 83(1) of the Treaty on the Functioning of the European Union (TFEU) and Union legislation based on that Article. Coherence with such legislation should therefore be ensured in the wording of the provisions.
- (11) In as much as the Union's financial interests can also be damaged or threatened by conduct attributable to legal persons, they should be liable for the criminal offences, as defined in this Directive, committed on their behalf.
- (12) In order to protect the Union's financial interests equivalently through measures which should act as a deterrent throughout the Union, Member States should further foresee certain minimum types and levels of sanctions when the criminal offences defined in this Directive are committed. The levels of sanctions should not go beyond what is proportionate for the offences and a threshold expressed in money, under which criminalisation is not necessary, should therefore be introduced.
- (13) This Directive does not affect the proper and effective application of disciplinary measures. Sanctions that can not be equated to criminal penalties can be taken into account in accordance with national law when sentencing a person for one of the offences defined under this Directive in individual cases; for other sanctions, the principle of *ne bis in idem* should be fully respected. This Directive does not criminalise behaviour which is not also subject to disciplinary sanctions or other measures concerning a breach of official duties, in cases where such disciplinary sanctions or other measures can be applied to the persons concerned.
- (14) The sanctions for natural persons in more serious cases should foresee imprisonment ranges. These serious cases should be defined by referring to a certain minimum overall damage, expressed in money, which must have been caused by the criminal behaviour to the Union's and, possibly, other budget. The introduction of minimum maximum imprisonment ranges is necessary in order to guarantee that the Union's financial interests are given an equivalent protection throughout Europe. The minimum sanction of six months ensures that a European Arrest Warrant can be issued and executed for the offences listed in Article 2 of the Framework Decision on the European Arrest Warrant, thus ensuring that judicial and law enforcement cooperation will be as efficient as possible. The

Wednesday 16 April 2014

sanctions will also serve as a strong deterrent for potential criminals, with effect all over Europe. More severe sanction levels should be imposed for cases when the offence was committed within a criminal organisation in the sense of Council Framework Decision 2008/841/JHA ⁽¹⁾.

- (15) Given in particular the mobility of perpetrators and of proceeds stemming from illegal activities at the expense of the Union's financial interests, as well as the complex cross-border investigations which this entails, all Member States should establish their jurisdiction and lay down rules concerning prescription periods necessary in order to enable them to counter these activities.
- (16) In order to ensure the coherence of Union law and safeguard the principle that no-one is punished twice for the same cause of action, there is a need to clarify the relation between penalties under this Directive and other relevant administrative measures under Union law. The Directive should be without prejudice to the application of specific administrative measures, penalties and fines under Union law.
- (17) Without prejudice to other obligations under Union law, there is a need for appropriate provision to be made for cooperation between Member States and the Commission to ensure effective action against the criminal offences defined in this Directive affecting the Union's financial interests, including exchange of information between the Member States, **Eurojust**, and the Commission. [Am. 10]
- (18) The Convention for the protection of the European Communities' financial interests of 26 July 1995 ⁽²⁾ and the Protocols thereto of 27 September 1996 ⁽³⁾ and 29 November 1996 ⁽⁴⁾ should be repealed and replaced by this Directive.
- (19) Proper implementation of this Directive by the Member States includes the processing of personal data among the competent national authorities, its exchange between Member States, on the one hand, and between competent Union bodies on the other hand. The processing of personal data at the national level between national competent authorities should be regulated by national law respecting the Convention of the Council of Europe on the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981 and its additional Protocol (ETS no 181). The exchange of personal data between Member States should meet the requirements of Council Framework Decision 2008/977/JHA ⁽⁵⁾. To the extent personal data are processed by Union institutions, bodies, agencies and offices, they should comply with Regulation (EC) No 45/2001 of the European Parliament and of the Council ⁽⁶⁾ and with the applicable rules concerning the confidentiality of judicial investigations.
- (20) The intended dissuasive effect of the application of criminal law penalties requires particular caution with regard to fundamental rights. This Directive respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably the right to liberty and security, the protection of personal data, the freedom to choose an occupation and right to engage in work, the freedom to conduct a business, the right to property, the right to an effective remedy and to a fair trial, the presumption of innocence and the right of defence, the principles of the legality and proportionality of criminal offences and penalties, as well as the prohibition of being tried or punished twice in criminal proceedings for the same criminal offence. This Directive seeks to ensure full respect for those rights and principles and must be implemented accordingly.
- (21) This Directive will apply without prejudice to the provisions on the lifting of the immunities contained in the TFEU, the Protocol on the Privileges and Immunities of the European Union, the Statute of the Court of Justice and the texts implementing them, or similar provisions incorporated in national law.
- (22) This Directive is without prejudice to the general rules and principles of national criminal law on the application and execution of sentences in accordance with the concrete circumstances in each individual case.

⁽¹⁾ Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime (OJ L 300, 11.11.2008, p. 42).

⁽²⁾ OJ C 316, 27.11.1995, p. 48.

⁽³⁾ OJ C 313, 23.10.1996, p. 1.

⁽⁴⁾ OJ C 151, 20.5.1997, p. 1.

⁽⁵⁾ Council Framework Decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters (OJ L 350, 30.12.2008, p. 60).

⁽⁶⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

Wednesday 16 April 2014

- (23) Since the objective of this Directive cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.

HAVE ADOPTED THIS DIRECTIVE:

Title I

Subject matter and definition

Article 1

Subject matter

This Directive establishes necessary measures in the field of prevention of and fight against fraud and other illegal activities affecting the Union's financial interests by defining criminal offences and sanctions **with a view to affording effective and equivalent protection in the Member States and in Union institutions, bodies, offices and agencies and boosting the credibility of Union institutions and initiatives.** [Am. 11]

Article 2

Definition of the Union's financial interest

For the purposes of this Directive, 'the Union's financial interests' means **all the assets and liabilities managed by or on behalf of the Union and its institutions, bodies and agencies; and all its financial operations, including borrowing and lending activities, as well as, in particular,** all revenues and expenditures covered by, acquired through, or due to: [Am. 12]

- (a) the Union budget;
- (b) the budgets of institutions, bodies, offices and agencies established ~~under~~ **pursuant to** the Treaties or budgets **directly or indirectly** managed and monitored by them. [Am. 13]

Title II

Criminal offences in the fields of prevention of and fight against fraud affecting the Union's financial interests

Article 3

Fraud affecting the Union's financial interests

Member States shall take the necessary measures to ensure that the following conduct, when committed intentionally, is punishable as a criminal offence:

- (a) in respect of expenditure, any act or omission relating to:
 - (i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds from the Union budget or budgets managed by the Union, or on its behalf,
 - (ii) non-disclosure of information in violation of a specific obligation, with the same effect, or
 - (iii) the misapplication of liabilities or expenditure for purposes other than those for which they were granted;
- (b) in respect of revenue, any act or omission relating to:
 - (i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the illegal diminution of the resources of the Union budget or budgets managed by the Union, or on its behalf,

Wednesday 16 April 2014

- (ii) non-disclosure of information in violation of a specific obligation, with the same effect, or
- (iii) misapplication of a legally obtained benefit, with the same effect.

Article 4

Fraud related criminal offences affecting the Union's financial interests

1. Member States shall take the necessary measures to ensure that any provision of information, or failure to provide such information, to contracting or grant awarding entities or authorities in a public procurement or grant procedure involving the Union's financial interests, by candidates or tenderers, or by persons responsible for or involved in the preparation of replies to calls for tenders or grant applications of such participants, when committed intentionally and with the aim of circumventing or skewing the application of the eligibility, exclusion, selection or award criteria, **or of distorting or destroying natural competition among bidders**, is punishable as a criminal offence. [Am. 14]

2. Member States shall take the necessary measures to ensure that money laundering as defined in Article 1(2) of Directive 2005/60/EC of the European Parliament and of the Council ⁽¹⁾ involving property **or income** derived from the offences covered by this Directive is punishable as a criminal offence. [Am. 15]

3. Member States shall take the necessary measures to ensure that ~~the following conduct,~~ **passive corruption and active corruption**, when committed intentionally, ~~are~~ **are** punishable as criminal ~~offence: offences.~~

(a) **For the purposes of this Directive, passive corruption shall consist of** the action of a public official, who, directly or through an intermediary, requests or ~~receives~~ **accepts in advance** advantages of any kind whatsoever **or a promise of such an advantage**, for himself or for a third party, ~~or accepts a promise of such an advantage, to act for acting, delaying action or refrain refraining~~ from acting in accordance with his duty or in the exercise of his functions, **whether or not in breach of his official obligations**, in a way which damages or is likely to damage the Union's financial interests ~~(passive corruption).~~

(b) **For the purposes of this Directive, active corruption shall consist of** the action of whosoever promises, **offers** or gives, directly or through an intermediary, an advantage of any kind whatsoever to a public official for himself or for a third party for him to act, **to delay action** or **to refrain** from acting in accordance with his duty or in the exercise of his functions in a way which damages or is likely to damage the Union's financial interests ~~(active corruption), or for having performed those conducts in the past.~~ [Am. 16]

4. Member States shall take the necessary measures to ensure that ~~the intentional~~ **misappropriation, when committed intentionally, is punishable as a criminal offence.**

For the purposes of this Directive, misappropriation shall consist of an act by a public official to commit or disburse funds, or appropriate or use assets, contrary to the purpose for which they were intended, and ~~with the intent to damage~~ **which damages** the Union's financial interests, ~~is punishable as a criminal offence (misappropriation).~~ [Am. 17]

5. For the purpose of this Article, 'public official' means:

- (a) ~~any person exercising a public service function for the Union or in Member States or third countries by holding a legislative, administrative or judicial office;~~ **Union or national official, including any national official of another Member State and any national official of a third country.**

The term 'Union official' means:

- (i) **any person who is an official or other contracted employee within the meaning of the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union ('Staff Regulations'),**

⁽¹⁾ Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing (OJ L 309, 25.11.2005, p. 15).

Wednesday 16 April 2014

(ii) *any person seconded to a Union institution, body, office or agency by the Member States or by any public or private body, who carries out functions equivalent to those performed by Union officials or other servants.*

Members of bodies, offices or agencies set up in accordance with the Treaties and the staff of such bodies, offices or agencies shall be treated as Union officials, inasmuch as the Staff Regulations do not apply to them.

The term 'national official' shall be understood by reference to the definition of 'official' or 'public official' in the national law of the Member State or third country in which the person in question performs the function.

Nevertheless, in the case of proceedings involving an official of a Member State, or a national official of a third country, initiated by another Member State, the latter shall not be bound to apply the definition of 'national official' except in so far as the definition is compatible with its national law;

(b) any other person **assigned and** exercising a public service function ~~for the Union or in Member States or third countries, not holding such an office, participating in~~ **involving** the management of, or decisions concerning, the Union's financial interests **in Member States or third countries.** [Am. 18]

Title III

General provisions relating to the criminal offences in the fields of prevention of and fight against fraud affecting the Union's financial interests

Article 5

Incitement, aiding and abetting, attempt

1. Member States shall take the necessary measures to ensure that inciting, aiding or abetting the **commission of any of the** criminal offences referred to in ~~Title II Articles 3 and 4~~ is punishable as a criminal offence. [Am. 19]
2. Member States shall take the necessary measures to ensure that an attempt to commit **any of the criminal offence offences** referred to in Article 3 ~~or~~ **and** in Article 4, ~~paragraph 4,~~ **(4)** is punishable as a criminal offence. [Am. 20]

Article 6

Liability of legal persons

1. Member States shall take the necessary measures to ensure that legal persons can be held liable for any of the criminal offences referred to in ~~Title II Articles 3, 4 and 5~~ committed for their benefit by any person, acting either individually or as part of an organ of the legal person, and having a leading position within the legal person, based on: [Am. 21]
 - (a) a power of representation of the legal person;
 - (b) an authority to take decisions on behalf of the legal person; or
 - (c) an authority to exercise control within the legal person.
2. Member States shall also take the necessary measures to ensure that legal persons can be held liable where the lack of supervision or control by a person referred to in paragraph 1 has made possible the commission of any of the criminal offences referred to in ~~Title II Articles 3, 4 and 5~~ for the benefit of that legal person by a person under its authority. [Am. 22]

Wednesday 16 April 2014

3. Liability of a legal person under paragraphs 1 and 2 shall not exclude criminal proceedings against natural persons who are perpetrators of the criminal offences referred to in ~~Title II~~ **Articles 3 and 4** or criminally liable under Article 5. **[Am. 23]**

4. For the purpose of this Directive, 'legal person' shall mean any entity having legal personality under the applicable law, except for States or public bodies in the exercise of State authority and for public international organisations.

Article 7

Penalties for natural persons

1. As regards natural persons, Member States shall ensure that the criminal offences referred to in ~~Title II~~ **Articles 3, 4 and 5** are punishable by effective, proportionate and dissuasive criminal penalties, including fines and imprisonment as specified in Article 8. **[Am. 24]**

2. In cases of ~~minor~~ offences involving damages of less than EUR ~~10,000~~ **5 000** and advantages of less than EUR ~~10,000~~ **5 000** and not involving ~~particularly serious~~ **aggravating** circumstances, Member States may provide instead for **the imposition of sanctions** other than criminal penalties. **[Am. 25]**

3. Paragraph 1 **of this Article** shall be without prejudice to the exercise of disciplinary powers by the competent authorities against public officials, **as defined in Article 4(5)**. **[Am. 26]**

4. Member States shall ensure that sanctions of another nature, that cannot be equated to criminal penalties, and which are already imposed on the same person for the same conduct, can be taken into account when sentencing that person for a criminal offence referred to in Title II.

Article 8

Imprisonment thresholds

1. Member States shall take the necessary measures to ensure that criminal offences as referred to in Articles 3 and 4, paragraphs 1 and 4, involving an advantage or damage of at least EUR ~~100,000~~ **50 000** shall be punishable by: **[Am. 43]**

(a) ~~a minimum penalty of at least 6 months imprisonment;~~ **[Am. 27]**

(b) a maximum penalty of at least 5 years of imprisonment.

Member States shall take the necessary measures to ensure that criminal offences as referred to in Article 4, paragraphs 2 and 3, involving an advantage or damage of at least EUR 30,000 shall be punishable by:

(a) ~~a minimum penalty of at least 6 months imprisonment;~~ **[Am. 28]**

(b) a maximum penalty of at least 5 years of imprisonment.

2. Member States shall take the necessary measures to ensure that the criminal offences referred to in ~~Title II~~ **Articles 3, 4 and 5** are punishable by a maximum penalty of at least 10 years of imprisonment where the offence was committed within a criminal organisation ~~in the sense~~ **within the meaning** of Framework Decision 2008/841/JHA. **[Am. 30]**

Article 8a

Aggravating circumstances

Member States shall take the necessary measures to ensure that, where it is established that a criminal offence as referred to in Articles 3, 4 or 5 has been committed within a criminal organisation within the meaning of Framework Decision 2008/841/JHA, that fact is treated as an aggravating circumstance for sentencing purposes. **[Am. 31]**

Wednesday 16 April 2014

Article 9

Minimum sanction types for legal persons

Member States shall take the necessary measures to ensure that a legal person held liable pursuant to Article 6 is subject to effective, proportionate and dissuasive sanctions, which shall include criminal or non-criminal fines and may include other sanctions, such as:

- (a) exclusion from entitlement to public benefits or aid;
- (aa) temporary or permanent exclusion from Union tender procedures; [Am. 32]**
- (b) temporary or permanent disqualification from the practice of commercial activities;
- (c) placing under judicial supervision;
- (d) judicial winding-up;
- (e) temporary or permanent closure of establishments which have been used for committing the offence.

Article 9a

Ne bis in idem rule

Member States shall apply in their national criminal law the 'ne bis in idem' rule, under which a person whose trial has been completed in a Member State may not be prosecuted in another Member State in respect of the same facts, provided that, if a penalty was imposed, it has been enforced, is in the process of being enforced or may no longer be enforced under the laws of the sentencing State. [Am. 33]

Article 10

Freezing and confiscation

Member States shall ensure freezing and confiscation of proceeds and instrumentalities from the offences referred to in Title II in accordance with Directive 2014/42/EU of the European Parliament and of the Council ⁽¹⁾.

Article 11

Jurisdiction

1. Member States shall take the necessary measures to establish their jurisdiction over the criminal offences referred to in ~~Title II~~ **Articles 3, 4 and 5** where:

- (a) the offence is committed in whole or in part within their territory; ~~or~~
- (b) the offender is one of their **own** nationals **or is resident in their territory; or**
- (c) the offender is subject to the Staff Regulations, or was subject to the Staff Regulations at the time of the offence. [Am. 34]**

2. For the case referred to in point (b) of paragraph 1, Member States shall take the necessary measures to ensure that their jurisdiction is not subordinated to the condition that the prosecution can only be initiated following a report made by the victim in the place where the offence was committed, or a denunciation from the State of the place where the offence was committed.

3. Member States shall ensure that their jurisdiction includes situations where an offence is committed by means of information and communication technology accessed from their territory.

Article 12

Prescription for offences affecting the Union's financial interests

1. Member States shall ensure a prescription period within which the investigation, prosecution, trial and judicial decision on offences referred to in Title II, and in Article 5, remain possible, of at least five years from the time when the offence was committed.

⁽¹⁾ Directive 2014/42/EU of the European Parliament and of the Council of 3 April 2014 on the freezing and confiscation of instrumentalities and proceeds of crime in the European Union (OJ L 127, 29.4.2014, p. 39).

Wednesday 16 April 2014

2. Member States shall ensure that the prescription period shall be interrupted and commence anew upon any act of a competent national authority, including in particular the effective beginning of investigation or prosecution, until at least ten years from the time when the offence was committed.

3. Member States shall take the necessary measures to enable the enforcement of a penalty imposed following a final conviction for a criminal offence referred to in Title II, and in Article 5, for a sufficient period of time that shall not be less than 10 years from the time of the final conviction.

Article 13

Recovery

This Directive shall be without prejudice to the recovery of sums unduly paid in the context of the commission of the criminal offences referred to in ~~Title II~~ **Articles 3, 4 and 5**.

Member States shall take the necessary measures to ensure the prompt recovery of such sums and their transfer to the Union budget, without prejudice to the relevant Union sector-specific rules on financial corrections and recovery of amounts unduly spent. Member States shall also keep regular records of the sums recovered and shall inform the relevant Union institutions or bodies about those sums, or, where they have not been recovered, of the reasons for such non-recovery. [Am. 35]

Article 14

Interaction with other applicable legal acts of the Union

The application of administrative measures, penalties and fines as laid down in Union law, in particular those within the meaning of Articles 4 and 5 of Council Regulation (EC, Euratom) No 2988/95 ⁽¹⁾, or in national law adopted in compliance with a specific obligation under Union law, shall be without prejudice to this Directive. Member States shall ensure that any criminal proceedings initiated on the basis of national provisions implementing this Directive shall not affect the proper and effective application of administrative measures, penalties and fines that cannot be equated to criminal proceedings, laid down in Union law or national implementing provisions.

Title IV

Final provisions

Article 15

Cooperation ~~between the Member States and the European Commission (European Anti-Fraud Office)~~ **[Am. 36]**

1. **Without prejudice to the rules on cross-border cooperation and mutual legal assistance in criminal matters**, the Member States, **Eurojust** and the Commission shall, **within their respective competences**, cooperate with each other in the fight against the criminal offences referred to in ~~Title II~~ **Articles 3, 4 and 5**. To that end, the Commission **and, where appropriate Eurojust**, shall lend such technical and operational assistance as the competent national authorities may need to facilitate coordination of their investigations. **[Am. 37]**

2. The competent authorities in the Member States may, **within their respective competences**, exchange information with the Commission **and with Eurojust** so as to make it easier to establish the facts and to ensure effective action against the criminal offences referred to in ~~Title II~~ **Articles 3, 4 and 5**. The Commission, **Eurojust** and the competent national authorities shall ~~take account~~ in each specific case **comply with Article 6** of the ~~requirements of investigation secrecy and data protection~~ **Treaty on the European Union, with the Charter of Fundamental Rights of the European Union and with the applicable Union legislation on the protection of personal data, and shall take into account the requirements of investigation secrecy**. To that end, a Member State, when supplying information to the Commission **and to Eurojust**, may set specific conditions covering the use of information, whether by the Commission, **by Eurojust**, or by another Member State to which that information may be passed. **[Am. 38]**

⁽¹⁾ Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interest (OJ L 312, 23.12.1995, p. 1).

Wednesday 16 April 2014

2a. The Court of Auditors, national audit institutions (for example when auditing transactions under shared management arrangements) and auditors responsible for auditing the budgets of the institutions, bodies and agencies established pursuant to the Treaties, or the budgets managed and audited by the institutions, shall disclose to OLAF any criminal offences of which they become aware during their mission. [Am. 39]

2b. Union officials shall disclose to OLAF any criminal offences of which they become aware during their mission. [Am. 40]

Article 16

Repeal of the criminal law conventions for the protection of the European Communities' financial interests

The Convention on the protection of the European Communities' financial interests of 26 July 1995, including the Protocols thereto of 27 September 1996, of 29 November 1996 and of 19 June 1997, shall be repealed with effect from [day of application under Art. 17 (1) second sub-paragraph].

Article 17

Transposition

1. Member States shall adopt and publish, by ... at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 17a

Reporting, statistics and evaluation

1. The Commission shall, by [24 months after the deadline for implementation of this Directive], and thereafter on a yearly basis, submit to the European Parliament and to the Council a report assessing the extent to which the Member States have taken the necessary measures to comply with this Directive and evaluating the effectiveness of this Directive in attaining its objectives.

Those reports shall refer to the information made available by Member States pursuant to paragraph 2.

2. Member States shall regularly collect and maintain comprehensive statistics from the relevant authorities in order to review the effectiveness of the systems established by them to protect the Union's financial interests. The statistics collected shall be sent to the Commission on a yearly basis and shall include:

(a) the number of criminal proceedings initiated, subdivided into the number of proceedings dismissed, the number resulting in an acquittal, the number resulting in a conviction and the number of ongoing proceedings;

(b) the amounts recovered, and the amounts not recovered, following criminal proceedings;

(c) the number of requests for assistance received from other Member States, subdivided into the number of requests acceded to and the number rejected.

3. The Commission shall, by [60 months after the deadline for implementation of this Directive], submit to the European Parliament and to the Council a full evaluation of this Directive, based on the experience gained and, in particular, on the reports and statistics provided pursuant to paragraphs 1 and 2. If appropriate, the Commission shall at the same time submit a proposal for amendment of this Directive, taking duly into account the outcome of the evaluation. [Am. 41]

Wednesday 16 April 2014

Article 18

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 19

Addressees

This Directive is addressed to the Member States.

Done at

For the European Parliament
The President

For the Council
The President

Wednesday 16 April 2014

P7_TA(2014)0432

System of own resources *

European Parliament legislative resolution of 16 April 2014 on the draft Council decision on the system of own resources of the European Union (05602/2014 — C7-0036/2014 — 2011/0183(CNS))

(Special legislative procedure — consultation)

(2017/C 443/101)

The European Parliament,

- having regard to the Council draft (05602/2014),
 - having regard to the third paragraph of Article 311 of the Treaty on the Functioning of the European Union and to Article 106a of the Treaty establishing the European Atomic Energy Community, pursuant to which the Council consulted Parliament (C7-0036/2014),
 - having regard to its resolution of 29 March 2007 on the future of the European Union's own resources ⁽¹⁾,
 - having regard to its resolution of 8 June 2011 on investing in the future: a new Multiannual Financial Framework (MFF) for a competitive, sustainable and inclusive Europe ⁽²⁾,
 - having regard to its resolution of 13 June 2012 on the Multiannual Financial Framework and own resources ⁽³⁾,
 - having regard to its resolution of 23 October 2012 in the interest of achieving a positive outcome of the Multiannual Financial Framework approval procedure ⁽⁴⁾,
 - having regard to its resolution of 13 March 2013 on the European Council conclusions of 7-8 February 2013 concerning the Multiannual Financial Framework ⁽⁵⁾,
 - having regard to its resolution of 3 July 2013 on the political agreement on the Multiannual Financial Framework 2014-2020 ⁽⁶⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Budgets (A7-0271/2014),
1. Approves the Council draft as amended;
 2. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 3. Asks the Council to consult Parliament again if it intends to substantially amend its draft;
 4. Calls on the High Level Group on Own resources to deliver its first assessment of the own resources system by the end of 2014 as indicated in the joint declaration annexed to this resolution ⁽⁷⁾; expects that this Group will deliver proposals for overcoming the deficiencies of the current system in order to pave the way for a reform -guided by the overall objectives of simplicity, transparency, equity and democratic accountability- to become operational in the next MFF;

⁽¹⁾ OJ C 27 E, 31.1.2008, p. 214.

⁽²⁾ OJ C 380 E, 11.12.2012, p. 89.

⁽³⁾ OJ C 332 E, 15.11.2013, p. 42.

⁽⁴⁾ OJ C 68 E, 7.3.2014, p. 1.

⁽⁵⁾ Texts adopted, P7_TA(2013)0078.

⁽⁶⁾ Texts adopted, P7_TA(2013)0304.

⁽⁷⁾ See also Text adopted, P7_TA(2013)0455.

Wednesday 16 April 2014

5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1**Draft decision****Recital 8 a (new)**

Council draft

Amendment

- (8a) *The European Parliament has continuously called for the Union budget to be financed wholly by own resources, as stipulated in the Treaty, and has regularly highlighted the shortcomings and limits of the existing system of own resources, which is non-transparent, unfair, not subject to parliamentary control, highly complex and totally incomprehensible to European citizens, who ultimately bear the consequences. The European Parliament considers that such a system violates, in essence, the letter and the spirit of the Treaty.*

Amendment 2**Draft decision****Recital 8 b (new)**

Council draft

Amendment

- (8b) *The European Parliament considers that the current system of Union financing, whereby some 74 % of revenues stem from GNI-based contributions and 11 % from the existing, statistical VAT-based contributions, has only reinforced the logic of 'fair return' that has prevailed in every debate in the Council, both on the revenue and the expenditure side of the Union budget and has led to the introduction of complex and opaque rebates and other correction mechanisms, and it contributes to the recurrent problem of shortage of payments in the annual budgetary procedure. The European Parliament considers also that the current system prevents the formation of a sufficient majority in Council to budgetise a sufficient level of payment appropriations in the annual budgets to meet EU legal obligations and political commitments.*

Wednesday 16 April 2014

Amendment 3
Draft decision
Recital 8 c (new)

Council draft

Amendment

- (8c) *The European Parliament has strongly advocated in favour of an in-depth reform of the own resources system that should return to a system of genuine, clear, simple and fair own resources. The European Parliament considered that the Commission legislative proposals on own resources of June 2011 were taking a step in the right direction and were, as such, supported by an overwhelming majority of the European Parliament from the outset; The European Parliament regrets that the Council was unable to make any progress on the reform of the own resources system on the basis of those legislative proposals. The European Parliament regrets that the final European Council political agreement on 8 February 2013 has even introduced new rebates and exceptions.*

Amendment 4
Draft decision
Recital 8 d (new)

Council draft

Amendment

- (8d) *A High Level Group on own resources is established by common accord of the three Union institutions, as set out in the Joint Declaration on Own Resources, forming part of the political agreement on the MFF 2014-2020. This high level group shall undertake a general review of the Own Resources system guided by the overall objectives of simplicity, transparency, equity and democratic accountability. All aspects of the reform of the own resources system should be examined. A first assessment will be available at the end of 2014.*

Wednesday 16 April 2014

Amendment 5
Draft decision
Recital 8 e (new)

Council draft

Amendment

- (8e) *The outcome of the work of the High Level Group shall be assessed in an inter-institutional conference during 2016, with the participation of national parliaments. On the basis of the results of this work, the Commission will assess if new Own Resources initiatives are appropriate. This assessment will be done in parallel to the MFF 2014-2020 post electoral review/revision, to be launched by the Commission by the end of 2016 at the latest. The European Parliament believes that the work of this High Level Group should pave the way for possible reforms be agreed and become operational for the period covered by the next MFF.*
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Wednesday 16 April 2014

ANNEX

Joint Declaration on Own Resources

1. According to Article 311 of the TFEU the Union shall provide itself with the means necessary to attain its objectives and carry through its policies; it also stipulates that, without prejudice to other revenue, the budget shall be financed wholly from own resources. Article 311 al. 3 indicates that the Council, acting in accordance with a special legislative procedure, shall unanimously and after consulting the European Parliament adopt a decision on the system of own resources and that, in that context, the Council may establish new categories of own resources or abolish an existing category.
 2. On this basis, the Commission presented in June 2011 a set of proposals to reform the Own Resources system of the Union. At its meeting of 7/8 February 2013, the European Council agreed that Own Resources arrangements should be guided by the overall objectives of simplicity, transparency and equity. In addition, the European Council called on the Council to continue working on the proposal of the Commission for a new own resource based on value added tax (VAT). It also invited the Member States participating in the enhanced cooperation in the area of financial transaction tax (FTT) to examine if it could become the base for a new own resource for the EU budget.
 3. The question of own resources requires further work. To this end, a high-level Group will be convened, composed of members appointed by the three institutions. It will take into account all existing or forthcoming input which may be brought by the three European institutions and by National Parliaments. It should draw on appropriate expertise, including from national budgetary and fiscal authorities as well as independent experts.
 4. The Group will undertake a general review of the Own Resources system guided by the overall objectives of simplicity, transparency, equity and democratic accountability. A first assessment will be available at the end of 2014. Progress of the work will be assessed at political level by regular meetings, at least once every six months.
 5. National Parliaments will be invited to an inter-institutional conference during 2016 to assess the outcome of this work.
 6. On the basis of the results of this work, the Commission will assess if new Own Resource initiatives are appropriate. This assessment will be done in parallel to the review referred to in Article 1a of the MFF Regulation with a view to possible reforms to be considered for the period covered by the next multiannual financial framework.
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Wednesday 16 April 2014

P7_TA(2014)0433

Traditional, VAT- and GNI based own resources and measures to meet cash requirements ***European Parliament legislative resolution of 16 April 2014 on the draft Council regulation on the methods and procedure for making available the traditional, VAT and GNI-based own-resources and on the measures to meet cash requirements (recast) (05603/2014 — C7-0037/2014 — 2011/0185(CNS))****(Special legislative procedure — consultation — recast)**

(2017/C 443/102)

The European Parliament,

- having regard to the Council draft (05603/2014),
- having regard to the Commission proposal to the Council (COM(2011)0742),
- having regard to Article 322(2) of the Treaty on the Functioning of the European Union and Article 106a of the Treaty establishing the European Atomic Energy Community, pursuant to which the Council consulted Parliament (C7-0037/2014),
- having regard to its resolution of 29 March 2007 on the future of the European Union's own resources ⁽¹⁾,
- having regards to its resolution of 8 June 2011 on investing in the future: a new Multiannual Financial Framework (MFF) for a competitive, sustainable and inclusive Europe ⁽²⁾,
- having regards to its resolution of 13 June 2012 on the Multiannual Financial Framework and own resources ⁽³⁾,
- having regard to its resolution of 23 October 2012 in the interest of achieving a positive outcome of the Multiannual Financial Framework approval procedure ⁽⁴⁾,
- having regard to its resolution of 13 March 2013 on the European Council conclusions of 7-8 February 2013 concerning the Multiannual Financial Framework ⁽⁵⁾,
- having regard to its resolution of 3 July 2013 on the political agreement on the Multiannual Financial Framework 2014-2020 ⁽⁶⁾,
- having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts ⁽⁷⁾,
- having regard to the letter of 6 March 2012 from the Committee on Legal Affairs to the Committee on Budgets in accordance with Rule 87(3) of its Rules of Procedure,
- having regard to Rules 87 and 55 of its Rules of Procedure,
- having regard to the report of the Committee on Budgets (A7-0268/2014),

⁽¹⁾ OJ C 27 E, 31.1.2008, p. 214.⁽²⁾ OJ C 380 E, 11.12.2012, p. 89.⁽³⁾ OJ C 332 E, 15.11.2013, p. 42.⁽⁴⁾ OJ C 68 E, 7.3.2014, p. 1.⁽⁵⁾ Texts adopted, P7_TA(2013)0078.⁽⁶⁾ Texts adopted, P7_TA(2013)0304.⁽⁷⁾ OJ C 77, 28.3.2002, p. 1.

Wednesday 16 April 2014

- A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;
1. Approves the Council draft as adapted to the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;
 2. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 3. Asks the Council to consult Parliament again if it intends to substantially amend the text approved by Parliament;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.
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Wednesday 16 April 2014

P7_TA(2014)0435

Public employment services *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a decision of the European Parliament and of the Council on enhanced co-operation between Public Employment Services (PES) (COM(2013)0430 — C7-0177/2013 — 2013/0202(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/103)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2013)0430),
 - having regard to Article 294(2) and 149 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0177/2013),
 - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 17 October 2013 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 28 November 2013 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 7 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 55 and 37 of its Rules of Procedure,
 - having regard to the report of the Committee on Employment and Social Affairs (A7-0072/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Approves its statement annexed to this resolution;
 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0202

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on enhanced co-operation between Public Employment Services (PES)

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 573/2014/EU.)

⁽¹⁾ OJ C 67, 6.3.2014, p. 116.

⁽²⁾ Not yet published in the Official Journal.

Wednesday 16 April 2014

ANNEX TO THE LEGISLATIVE RESOLUTION

STATEMENT BY THE EUROPEAN PARLIAMENT

ON

THE ESTABLISHMENT OF A NETWORK FOR PUBLIC EMPLOYMENT SERVICES

The European Parliament:

1. WELCOMES the agreement reached by the co-legislators on the Commission's proposal for a Decision on enhanced co-operation between Public Employment Services (PES), which is formalising and strengthening the existing informal network of cooperation between PES;
 2. RECALLS that Article 149 TFEU provides that the European Parliament and the Council may adopt incentive measures designed to encourage cooperation between Member States in the field of employment. Such acts are legislative acts and may provide for legally binding obligations, however, without harmonising laws and regulations of Member States;
 3. CONSIDERS that setting up the network of cooperation between PES is an incentive measure falling within the scope of Article 149 TFEU. Therefore, once the Decision is adopted, all Member States shall participate in the said network, as the non-participation of a Member State in a Union policy cannot be justified by the mere wish of Member States;
 4. UNDERLINES that, according to the recitals and the enacting articles, the primary objective of this Decision is to strengthen and enhance the effectiveness of the previously existing informal PES network, by formalising it through a legislative act. Such an objective can only be achieved if all Member States are participating in the network and engaging in the activities laid down in Article 3 of the Decision.
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Wednesday 16 April 2014

P7_TA(2014)0436

European Union Solidarity Fund *I****European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 2012/2002 establishing the European Union Solidarity Fund (COM(2013)0522 — C7-0231/2013 — 2013/0248(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/104)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0522),
 - having regard to Article 294(2) and the third paragraph of Article 175 and Article 212(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0231/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 10 December 2013 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 28 November 2013 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 12 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Regional Development and the opinion of the Committee on Budgets (A7-0078/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0248**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 2012/2002 establishing the European Union Solidarity Fund***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 661/2014.)*

⁽¹⁾ Not yet published in the Official Journal.

⁽²⁾ Not yet published in the Official Journal.

Wednesday 16 April 2014

P7_TA(2014)0437

Capital increase of the European Investment Fund *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a decision of the European Parliament and of the Council on the participation of the European Union in the capital increase of the European Investment Fund (COM(2014)0066 — C7-0030/2014 — 2014/0034(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/105)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2014)0066),
 - having regard to Article 294(2) and Article 173(3) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0030/2014),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 25 March 2014⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 12 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Budgets (A7-0156/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Approves the statement by Parliament and the Council annexed hereto, which will be published in the L series of the *Official Journal of the European Union* together with the final legislative act;
 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2014)0034

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council on the participation of the European Union in the capital increase of the European Investment Fund

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 562/2014/EU.)

⁽¹⁾ Not yet published in the Official Journal.

Wednesday 16 April 2014**ANNEX TO THE LEGISLATIVE RESOLUTION****Statement by the European Parliament and the Council**

The European Parliament and the Council agree to address the issue of the treatment of the Fund's dividends in the framework of the next revision of the financial rules applicable to the general budget of the Union or, at the latest, in the context of the interim report on the achievement provided for in Article 4.

Wednesday 16 April 2014

P7_TA(2014)0438

European Medicines Agency (conduct of pharmacovigilance activities in respect of medicinal products for human use)*I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (COM(2013)0472 — C7-0196/2013 — 2013/0222(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/106)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0472),
 - having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0196/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Greek Parliament and the Spanish Congress of Deputies and the Spanish Senate, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 16 October 2013 ⁽¹⁾,
 - after consulting the Committee of the Regions,
 - having regard to the undertaking given by the Council representative by letter of 19 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0476/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0222

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 658/2014.)

⁽¹⁾ OJ C 67, 6.3.2014, p. 92..

Wednesday 16 April 2014

P7_TA(2014)0439

Macro-financial assistance to the Republic of Tunisia *I****European Parliament legislative resolution of 16 April 2014 on the proposal for a decision of the European Parliament and of the Council providing macro-financial assistance to the Republic of Tunisia (COM(2013)0860 — C7-0437/2013 — 2013/0416(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/107)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0860),
 - having regard to Article 294(2) and Article 212 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0437/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the Committee on Budgets on the proposal's financial compatibility,
 - having regard to the undertaking given by the Council representative by letter of 26 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 55 and 38 of its Rules of Procedure,
 - having regard to the report of the Committee on International Trade (A7-0110/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0416**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Decision No .../2014/EU of the European Parliament and of the Council providing macro-financial assistance to the Republic of Tunisia**

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision No 534/2014/EU.)

Wednesday 16 April 2014

P7_TA(2014)0440

Recovery plan for Bluefin tuna in the eastern Atlantic and Mediterranean *I**

European Parliament legislative resolution of 16 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 302/2009 concerning a multiannual recovery plan for Bluefin tuna in the eastern Atlantic and Mediterranean (COM(2013)0250 — C7-0117/2013 — 2013/0133(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/108)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0250),
 - having regard to Article 294(2) and Article 43(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0117/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 16 October 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 7 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Fisheries (A7-0102/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0133

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Regulation (EC) No 302/2009 concerning a multiannual recovery plan for Bluefin tuna in the eastern Atlantic and Mediterranean

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 544/2014.)

⁽¹⁾ OJ C 67, 6.3.2014, p. 157.

Wednesday 16 April 2014

P7_TA(2014)0441

Protection of the euro and other currencies against counterfeiting by criminal law *I****European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council on the protection of the euro and other currencies against counterfeiting by criminal law, and replacing Council Framework Decision 2000/383/JHA (COM(2013)0042 — C7-0033/2013 — 2013/0023(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/109)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0042),
 - having regard to Article 294(2) and Article 83(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0033/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 23 May 2013 ⁽¹⁾,
 - having regard to the opinion of the European Central Bank of 28 May 2013 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 19 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs and the opinion of the Committee on Economic and Monetary Affairs (A7-0018/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0023**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on the protection of the euro and other currencies against counterfeiting by criminal law, and replacing Council Framework Decision 2000/383/JHA***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/62/EU.)*⁽¹⁾ OJ C 271, 19.9.2013, p. 42.⁽²⁾ OJ C 179, 25.6.2013, p. 9.

Wednesday 16 April 2014

P7_TA(2014)0442

Honey ***I

European Parliament legislative resolution of 16 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Council Directive 2001/110/EC relating to honey (COM(2012)0530 — C7-0304/2012 — 2012/0260(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/110)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0530),
 - having regard to Article 294(2) and Article 43(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0304/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 14 November 2012 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 7 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A7-0440/2013),
1. Adopts its position at first reading hereinafter set out ⁽²⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2012)0260

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Council Directive 2001/110/EC relating to honey

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/63/EU.)

⁽¹⁾ OJ C 11, 15.1.2013, p. 88.

⁽²⁾ This position replaces the amendments adopted on 15 January 2014 (Texts adopted P7_TA(2014)0028).

Wednesday 16 April 2014

P7_TA(2014)0443

European Maritime and Fisheries Fund *I**

European Parliament legislative resolution of 16 April 2014 on the amended proposal for a regulation of the European Parliament and of the Council on the European Maritime and Fisheries Fund repealing Council Regulation (EC) No 1198/2006 and Council Regulation (EC) No 861/2006 and Council Regulation No XXX/2011 on integrated maritime policy (COM(2013)0245 — C7-0108/2013 — 2011/0380(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/111)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2011)0804) and the amended proposal COM(2013)0245),
 - having regard to Article 294(2) and Articles 42, 43(2), 91(1), 100(2), 173(3), 175, 188, 192(1), 194(2) and 195(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0108/2013),
 - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinions of the European Economic and Social Committee of 11 July 2012 ⁽¹⁾ and of 22 May 2013 ⁽²⁾,
 - having regard to the opinion of the Committee of the Regions of 9 October 2012 ⁽³⁾,
 - having regard to the undertaking given by the Council representative by letter of 12 February 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 55 and 37 of its Rules of Procedure,
 - having regard to the report of the Committee on Fisheries and the opinions of the Committee on Budgets, the Committee on Employment and Social Affairs, the Committee on the Environment, Public Health and Food Safety and the Committee on Regional Development (A7-0282/2013),
1. Adopts its position at first reading hereinafter set out ⁽⁴⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

⁽¹⁾ OJ C 299, 4.10.2012, p. 133.

⁽²⁾ OJ C 271, 19.9.2013, p. 154.

⁽³⁾ OJ C 391, 18.12.2012, p. 84.

⁽⁴⁾ This position replaces the amendments adopted on 23 October 2013 (Texts adopted, P7_TA(2013)0441)

Wednesday 16 April 2014

P7_TC1-COD(2011)0380

Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on the European Maritime and Fisheries Fund and repealing Council Regulations (EC) No 2328/2003, (EC) No 861/2006, (EC) No 1198/2006 and (EC) No 791/2007 and Regulation (EU) No 1255/2011 of the European Parliament and of the Council

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 508/2014.)

Wednesday 16 April 2014

P7_TA(2014)0444

European Police College *I****European Parliament legislative resolution of 16 April 2014 on the draft regulation of the European Parliament and of the Council amending Decision 2005/681/JHA establishing the European Police College (CEPOL) (17043/2013 — C7-0435/2013 — 2013/0812(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/112)

The European Parliament,

- having regard to the initiative emanating from a group of Member States submitted to Parliament and the Council (17043/2013),
 - having regard to Article 76(b) and Article 87(2)(b) of the Treaty on the Functioning of the European Union, pursuant to which the draft act was submitted to Parliament (C7-0435/2013),
 - having regard to Article 294(3) and (15) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the Commission (COM(2014)0007),
 - having regard to the undertaking given by the Council representative by letter of 5 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rules 44 and 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs (A7-0146/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Regrets that the European Parliament was not fully involved in the evaluation of the applications and that only one candidate was presented to the relevant committee, although seven applications had been submitted further to the Council Presidency's call in July 2013 for applications to provisionally host the European Police College until a long-term solution for the future of the Agency could be found. The Member States submitting candidatures were Ireland, Greece, Spain, Italy, Hungary, the Netherlands and Finland. The political agreement was confirmed at the JHA Council meeting of 8 October 2013; intends to request more information on the impact assessment of the exact location before taking its final position;
 3. Calls on the budgetary authorities to ensure that the additional costs relating to the change in the seat of CEPOL will be fully covered by the current host country and by additional Union budget and thus will not adversely affect the regular budget of CEPOL so as not to jeopardise the normal operational needs of CEPOL;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0812**Position of the European Parliament adopted at first reading on 16 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Council Decision 2005/681/JHA establishing the European Police College (CEPOL)***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 543/2014.)*

Thursday 17 April 2014

P7_TA(2014)0445

EC-Albania Stabilisation and Association Agreement (Protocol to take account of the accession of Croatia) ***

European Parliament legislative resolution of 17 April 2014 on the draft Council decision on the conclusion, on behalf of the European Union and its Member States, of the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Albania, of the other part, to take account of the accession of the Republic of Croatia to the European Union (14783/2013 — C7-0075/2014 — 2013/0311(NLE))

(Consent)

(2017/C 443/113)

The European Parliament,

- having regard to the draft Council decision (14783/2013),
 - having regard to the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Albania, of the other part, to take account of the accession of the Republic of Croatia to the European Union (14782/2013),
 - having regard to the request for consent submitted by the Council in accordance with Article 217, in conjunction with point (a)(i) of Article 218(6) and the second subparagraph of Article 218(8) of the Treaty on the Functioning of the European Union (C7-0075/2014),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2), Rule 90(7) and Rule 46(1) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Foreign Affairs (A7-0266/2014),
1. Gives its consent to conclusion of the Protocol;
 2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Republic of Albania.
-

Thursday 17 April 2014

P7_TA(2014)0446

Arrangement with the Kingdom of Norway on the modalities of its participation in the European Asylum Support Office *****European Parliament legislative resolution of 17 April 2014 on the draft Council decision on the conclusion of the Arrangement between the European Union and the Kingdom of Norway on the modalities of its participation in the European Asylum Support Office (18141/2013 — C7-0107/2014 — 2013/0427(NLE))****(Consent)**

(2017/C 443/114)

The European Parliament,

- having regard to the draft Council decision (18141/2013),
 - having regard to the draft Arrangement between the European Union and the Kingdom of Norway on the modalities of its participation in the European Asylum Support Office (18140/2013),
 - having regard to the request for consent submitted by the Council in accordance with Articles 74 and 78(1) and (2) and Article 218(6), second subparagraph, point (a), of the Treaty on the Functioning of the European Union (C7-0107/2014),
 - having regard to Rule 81(1), first and third subparagraphs, Rule 81(2), and Rule 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Civil Liberties, Justice and Home Affairs (A7-0257/2014),
1. Gives its consent to the conclusion of the Arrangement;
 2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Kingdom of Norway.
-

Thursday 17 April 2014

P7_TA(2014)0447

Arrangement with the Principality of Liechtenstein on the modalities of its participation in the European Asylum Support Office ***

European Parliament legislative resolution of 17 April 2014 on the draft Council decision on the conclusion of the Arrangement between the European Union and the Principality of Liechtenstein on the modalities of its participation in the European Asylum Support Office (18116/2013 — C7-0091/2014 — 2013/0423(NLE))

(Consent)

(2017/C 443/115)

The European Parliament,

- having regard to the draft Council decision (18116/2013),
 - having regard to the draft Arrangement between the European Union and the Principality of Liechtenstein on the modalities of its participation in the European Asylum Support Office (18115/2013),
 - having regard to the request for consent submitted by the Council in accordance with Articles 74 and 78(1) and (2) and Article 218(6), second subparagraph, point (a), of the Treaty on the Functioning of the European Union (C7-0091/2014),
 - having regard to Rules 81 and 90(7) of its Rules of Procedure,
 - having regard to the recommendation of the Committee on Civil Liberties, Justice and Home Affairs (A7-0168/2014),
1. Consents to the conclusion of the Arrangement;
 2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Principality of Liechtenstein.

Thursday 17 April 2014

P7_TA(2014)0448

European long-term investment funds *I**

Amendments adopted by the European Parliament on 17 April 2014 on the proposal for a regulation of the European Parliament and of the Council on European Long-term Investment Funds (COM(2013)0462 — C7-0209/2013 — 2013/0214(COD))⁽¹⁾

(Ordinary legislative procedure: first reading)

(2017/C 443/116)

[Amendment No 1 unless otherwise stated]

AMENDMENTS BY THE EUROPEAN PARLIAMENT (*)

to the Commission proposal

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on European Long-term Investment Funds
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Long-term finance is a crucial enabling tool for putting the European economy on a path of sustainable, smart and inclusive growth, **in accordance with the Europe 2020 strategy, high employment and competitiveness** for building tomorrow's economy in a way that is less prone to systemic risks and is more resilient. European long-term investment funds (ELTIFs) provide finance to various infrastructure projects, unlisted companies **or listed small and medium-sized enterprises (SMEs)** of lasting duration that issue equity or debt instruments for which there is no readily identifiable buyer. By providing finance to such projects, ELTIFs contribute to the financing of the **Union's real economy and the implementation of its policies.**

⁽¹⁾ The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0211/2014).

(*) Amendments: new or amended text is highlighted in bold italics; deletions are indicated by the symbol ▬.

⁽¹⁾ OJ C 67, 6.3.2014, p. 71.

Thursday 17 April 2014

- (2) On the demand side, ELTIFs can provide a steady **and safe** income stream for pension administrators, insurance companies, **foundations, municipalities** and other entities that face regular and recurrent liabilities **and are seeking long-term returns within well-regulated structures**. While providing less liquidity than investments in transferable securities, ELTIFs can provide a steady **and safe** income stream for individual investors that rely on the regular cash flow that an ELTIF can produce. ELTIFs can also offer good opportunities for capital appreciation over time for those investors not receiving a steady income **and safe** stream. **It should be possible to authorise an ELTIF to reduce its capital on a pro rata basis in the event that it has divested itself of one of its assets.**
- (3) Financing for projects, regarding transport infrastructure, sustainable energy generation or distribution, social infrastructure (housing or hospitals), **the** roll-out of new technologies and systems that reduce use of resources and energy or the further growth of SMEs, can be scarce. As the financial crisis has shown, complementing bank financing with a wider variety of financing sources that better mobilise capital markets could help tackle financing gaps. ELTIFs can play a crucial role in this respect. **For certain projects they could make use of resources such as innovative financial instruments to supplement public funding eroded by the sovereign debt crisis.**
- (4) **Given that** investors may be interested in investing in an ELTIF, **the fact that investors should be given the right incentives to invest in them and the fact that in particular retail investors may not have the necessary resources or a sufficiently diversified portfolio that would allow them to lock-up their capital for a long period of time, an ELTIF should be able to offer redemption rights** to its investors. **Therefore, the ELTIF manager should be given discretion to decide whether to establish ELTIFs with or without redemption rights according to the ELTIF's investment strategy. When a redemption rights regime is in place, those rights and their main features should be clearly predefined and disclosed in the rules or instruments of incorporation of the ELTIF. In addition, the Commission's impact assessment found at national level cases of long-term funds that have been structured as listed entities. That allows investors to trade their shares or units in the fund on a secondary market. When the shares of the fund are listed on an exchange, investors are able to buy and sell shares of the fund directly on the exchange like any other listed security. The secondary market can also be operating when the shares or units of the fund are not listed. In that case the investors can exchange directly their holding with another investor. Intermediaries like banks or distributors can play a facilitating role in this secondary market. They can collect the buy and sell orders and can match those orders between their clients. If long-term investing is really supposed to become attractive for smaller-scale investors or the retail community at large, secondary markets will be the principal venue in which you can buy into or leave the long-term fund.** A report, three years after the adoption of this Regulation, **will** investigate whether this rule will have achieved the expected results in terms of ELTIF distribution.■
- (4a) **In order to make ELTIFs a feasible and attractive choice for professional investors such as institutions for occupational retirement provision, pension funds, and insurance companies, it is important that necessary adjustments are made to their regulatory own funds requirements, within the framework of Directive 2003/41/EC of the European Parliament and of the Council⁽¹⁾ and of Directive 2009/138/EC of the European Parliament and of the Council⁽²⁾ in order to provide flexibility in the case of ELTIFs as regards the high capital requirements for investments in illiquid assets. Moreover, any additional national regulatory constraints should be thoroughly assessed, if necessary.**
- (5) Long-term asset classes within the meaning of this Regulation should comprise **equity or debt instruments issued by non-listed undertakings and listed SMEs** where there is no readily identifiable buyer for those. **They should also comprise equity or debt instruments issued by listed undertakings of maximum capitalisation of EUR 1 billion.** This Regulation should also **cover** real assets that require significant up-front capital expenditure **and that produce recurrent and foreseeable cash flow through their duration.**

⁽¹⁾ Directive 2003/41/EC of the European Parliament and of the Council of 3 June 2003 on the activities and supervision of institutions for occupational retirement provision (OJ L 235, 23.9.2003, p. 10).

⁽²⁾ Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1).

Thursday 17 April 2014

- (6) In the absence of a Regulation setting out rules on ELTIFs, diverging measures might be adopted at national level, which are likely to cause distortions of competition resulting from differences in investment protection measures. Diverging requirements on portfolio composition, diversification and eligible assets, in particular the investment in commodities, create obstacles to the cross-border marketing of funds that focus on non-listed undertakings and real assets because investors cannot easily compare the different investment propositions offered to them. Divergent national requirements also lead to different levels of investor protection. Furthermore, different national requirements pertaining to investment techniques, such as the permitted levels of borrowing, use of derivative financial instruments, rules applicable to short selling or securities financing transactions lead to discrepancies in the level of investor protection. In addition, different requirements on redemption and/or holding periods impede the cross-border selling of funds investing in non-listed assets. **By increasing legal uncertainty, those divergences can undermine the confidence of investors when considering investments in such funds, and reduce the scope for investors to choose effectively between various long-term investment opportunities. Member States should therefore not be allowed to lay down additional requirements in the area covered by this Regulation and the appropriate legal basis for this Regulation should be Article 114 of the Treaty, as interpreted by consistent case law of the Court of Justice of the European Union.**
- (7) Uniform rules across the Union are necessary to ensure that ELTIFs display a coherent **and stable** product profile across the Union. In order to ensure the smooth functioning of the internal market and a high level of investor protection, it is necessary to establish uniform rules regarding the operation of ELTIFs, in particular on the composition of the portfolio of ELTIFs and the investment instruments that they are allowed to use in order to gain exposure to **long-term assets such as equity or debt instruments issued by listed SMEs, and by** non-listed undertakings, as well as real assets. Uniform rules on the portfolio of an ELTIF are also required to ensure that ELTIFs that aim to generate regular income maintain a diversified portfolio of investment assets suitable to maintain the regular cash flow. **Moreover, coordination among tax frameworks of Member States is necessary to ensure a level playing field in terms of investor attractiveness and convergence of national policies is required to establish similar conditions in terms of investment climate in order to address imbalances among Member States.**
- (8) It is essential to ensure that the definition of the operation of ELTIFs, in particular on the composition of the portfolio of ELTIFs and the investment instruments that they are allowed to use be directly applicable to the managers of ELTIFs and therefore these new rules need to be adopted as a Regulation. This also ensures uniform conditions for the use of the designation ELTIF by preventing diverging national requirements. Managers of ELTIFs should follow the same rules across the Union, in order to also enhance the confidence of investors in ELTIFs and ensure sustainable trustworthiness of the designation. At the same time, by adopting uniform rules, the complexity of the regulatory requirements applicable to ELTIFs is reduced. By means of uniform rules, the managers' cost of compliance with divergent national rules governing funds that invest in **listed SMEs and** non-listed **long-term assets** and comparable real asset classes is also reduced. This is especially true for managers that wish to raise capital on a cross-border basis. It also contributes to eliminate competitive distortions.
- (9) The new rules on ELTIFs are closely linked to Directive 2011/61/EU of the European Parliament and of the Council ⁽¹⁾ since that Directive forms the legal framework governing the management and marketing of alternative investment funds (AIFs) in the Union. By definition ELTIFs are EU AIFs that are managed by alternative investment fund managers (AIFMs) authorised in accordance with Directive 2011/61/EU.
- (10) Whereas Directive 2011/61/EU also provides for a staged third country regime governing non-EU AIFMs and non-EU AIFs, the new rules on ELTIFs have a more limited scope emphasising the European dimension of the new long term investment product. Hence, only an EU AIF as defined in Directive 2011/61/EU *should be* eligible to become an

⁽¹⁾ Directive 2011/61/EU of the European Parliament and of the Council of 8 June 2011 on Alternative Investment Fund Managers and amending Directives 2003/41/EC and 2009/65/EC and Regulations (EC) No 1060/2009 and (EU) No 1095/2010 (OJ L 174, 1.7.2011, p. 1).

Thursday 17 April 2014

authorised ELTIF and only if it is managed by an EU AIFM that has been authorised in accordance with Directive 2011/61/EU. **However, third-country investors should also be encouraged to invest in ELTIFs given the valuable capital that they can contribute towards projects in the Union.**

- (11) The new rules applicable to ELTIFs should build on the existing regulatory framework established through Directive 2011/61/EU and the acts adopted for its implementation. Therefore, the product rules concerning ELTIFs should apply in addition to the rules laid down in the existing Union legislation. Particularly, the management and marketing rules laid down in Directive 2011/61/EU should apply to ELTIFs. Equally, the rules on the cross-border provision of services and freedom of establishment laid down in Directive 2011/61/EU should apply accordingly to the cross-border activities of ELTIFs. These should be supplemented by the specific marketing rules designed for the cross-border marketing of ELTIFs to both retail and professional investors across the Union.
- (12) Uniform rules should apply to all those EU AIFs that wish to market themselves as ELTIFs. EU AIFs that do not wish to market themselves as ELTIFs should not be bound by these rules, thereby also consenting not to benefit from the advantages that ensue. On the other hand, undertakings for collective investment in transferable securities (UCITS) and non-EU AIFs would not be eligible for marketing as ELTIFs.
- (13) In order to ensure the compliance of ELTIFs with the harmonised rules governing the activity of these funds, it is necessary to require that competent authorities authorise ELTIFs. The harmonised authorisation and supervision procedures for AIFMs under Directive 2011/61/EU should therefore be supplemented with a special authorisation procedure for ELTIFs. Procedures should be established to ensure that only EU AIFMs authorised in accordance with Directive 2011/61/EU and capable of managing an ELTIF may manage ELTIFs. All appropriate steps are taken to ensure that the ELTIF shall be able to comply with the harmonised rules governing the activity of these funds.
- (14) Given that EU AIFs may take different legal forms that do not necessarily endow them with legal personality, the provisions requiring ELTIFs to take action should be understood to refer to the manager of the ELTIF in cases where the ELTIF is constituted as an EU AIF that is not in a position to act by itself because it has no legal personality of its own.
- (15) In order to ensure that ELTIFs target long-term investments **and contribute to finance a sustainable growth of the EU's economy**, rules on the portfolio of ELTIFs should require a clear identification of the categories of assets that should be eligible for investment by ELTIFs and of the conditions under which they should be eligible. An ELTIF should invest at least 70 % of its capital in eligible investment assets **and at least 60 % of its capital in securities issued by an eligible portfolio undertaking established in the Union**. To ensure the integrity of ELTIFs it is also desirable to prohibit an ELTIF from engaging in certain financial transactions that might endanger its investment strategy and objectives by raising additional risks different to those that might be expected for a fund targeting long-term investments. In order to ensure a clear focus on long term investments, as may be useful for retail investors unfamiliar with less conventional investment strategies, an ELTIF should not be allowed to invest in financial derivative instruments other than for the purpose of hedging the **risks inherent to its own investments**. Given the liquid nature of commodities and financial derivative instruments that give an indirect exposure to them, investments in commodities do not require a long-term investor commitment and therefore should be excluded. This rationale does not apply to investments in infrastructure or companies related to commodities or whose performance is linked indirectly to the performance of commodities, such as farms in the case of agricultural commodities or power plants in the case of energy commodities.
- (15a) **In order for ELTIF to contribute effectively to a sustainable, smart and inclusive growth in the Union, each ELTIF should take into account the social impact of eligible investments, taking into account its environmental, social and governance characteristics. In particular, the ELTIF manager should consider the inherent contribution of the selected asset to the objectives of the European model of growth, namely enhancing social infrastructures, sustainable mobility, renewable energy production and distribution, energy efficiency processes, as well as firms operating in sectors fostering environmental and social solutions, or having a high potential of innovation.**

Thursday 17 April 2014

- (16) The definition of what constitutes a long-term investment is broad. Without necessarily requiring long-term holding periods for the ELTIF manager, eligible investment assets are generally illiquid, require commitments for a certain period of time, and have an economic profile of a long-term nature. Eligible investment assets are non-transferable securities and therefore do not have access to the liquidity of secondary markets. They often require fixed term commitments which restrict their marketability. **However, as listed SMEs may face problems of liquidity and access to the secondary market, equity or debt instruments issued by listed SMEs should be included in the eligible investment assets of the ELTIF as they need to maintain a stable shareholding structure. Consequently, eligible investment assets may be transferable securities and therefore may have access to the liquidity of secondary markets.** The economic cycle of the investment sought by ELTIFs is essentially of a long-term nature due to the high capital commitments and the length of time required to produce returns. As a result such assets do not suit investments with redemption rights, **apart from specific cases and under certain conditions.**
- (17) An ELTIF should be allowed to invest in assets other than eligible investment assets, as may be necessary to efficiently manage its cash flow, but only so long as this is consistent with the ELTIF's long term investment strategy.
- (18) Eligible investment assets must be understood to include participations, such as equity or quasi-equity instruments, debt instruments in qualifying portfolio undertakings and loans provided to them. They should also include participation in other funds that are focused on assets such as investments in non-listed undertakings that issue equity or debt instruments for which there is not always a readily identifiable buyer. Direct holdings of real assets, unless they are securitised, should also form a class of eligible assets **under strict conditions regarding their acquisition value and cash-flow profile.**
- (19) Quasi-equity instruments must be understood to comprise a type of financing instrument, which is a combination of equity and debt, where the return on the instrument is linked to the profit or loss of the qualifying portfolio undertaking, and where the repayment of the instrument in the event of default is not fully secured. Such instruments include a variety of financing instruments such as subordinated loans, silent participations, participating loans, profit participating rights, convertible bonds and bonds with warrants.
- (20) To reflect existing business practices, an ELTIF should be allowed to buy existing shares of a qualifying portfolio undertaking from existing shareholders of that undertaking. Also, for the purposes of ensuring the widest possible opportunities for fundraising, investments into other ELTIFs should be permitted. To prevent dilution of the investments into qualifying portfolio undertakings, ELTIFs should only be permitted to invest in other ELTIFs, provided that those ELTIFs have not themselves invested more than 10 % of their capital in other ELTIFs.
- (21) The use of financial undertakings **is** necessary in order to **effectively market ELTIFs to investors as well as** pool and organise the contributions of different investors, including investments of a public nature, into infrastructure projects. ELTIFs should therefore be permitted to invest in eligible investment assets by means of financial undertakings, so long as these undertakings are dedicated to financing long-term projects **and the growth of SMEs.**
- (22) **■** Qualifying portfolio undertakings **should** include infrastructure projects, investment in unlisted companies **and listed SMEs** seeking growth **■** that could be suitable for long term investment purposes.
- (23) Due to the scale of infrastructure projects, these require large amounts of capital that have to remain invested for long periods of time. Such infrastructure projects **should** include public building infrastructure such as schools, hospitals or prisons, social infrastructure such as social housing, transport infrastructure such as roads, mass transit systems or airports, energy infrastructure such as energy grids, climate adaptation and mitigation projects, power plants or pipelines, water management infrastructure such as water supply systems, sewage or irrigation systems, communication infrastructure such as networks and waste management infrastructure such as recycling or collection systems.

Thursday 17 April 2014

- (24) Unlisted undertakings can face difficulties accessing capital markets and financing further growth and expansion. Private financing through equity stakes or loans are typical ways of raising financing. Because such instruments are by their nature long-term investments they require patient capital that ELTIFs can provide. **Moreover, listed SMEs, often face significant obstacles in acquiring long-term financing and ELTIFs may provide valuable alternative sources of funding.**
- (25) Investments in **infrastructure** require patient capital due to the absence of liquid secondary markets. Investment funds represent an essential source of financing for assets that require large capital expenditure. For these assets, capital pooling is often necessary to achieve the desired level of funding. Such investments require long periods of time due to the generally long economic cycle attached to these assets. It generally takes several years to *amortise* the investment in large real assets. In order to facilitate the development of such large assets, ELTIFs should be able to invest directly in **infrastructure** with a value of more than EUR 10 million **and which deliver foreseeable and recurrent cash-flows throughout their term.** ■ For these reasons it is necessary to treat direct holdings in **infrastructure** in qualifying portfolio undertakings in like manner.
- (26) Where the manager holds a stake in a portfolio undertaking, there is a risk that the manager puts its interests ahead of the interests of investors in the fund. To avoid such conflict of interests, the ELTIF should only invest in assets that are unrelated to the manager **to ensure sound corporate governance, unless they invest in units or shares or assets managed by the ELTIF manager that are eligible under this Regulation.**
- (27) In order to allow managers of ELTIFs a certain degree of flexibility in the investment of their funds, trading in assets other than long-term investments should be permitted up to a maximum threshold of 30 % of their capital.
- (28) In order to limit risk-taking by ELTIFs it is essential to reduce counterparty risk by subjecting the portfolio of ELTIFs to clear diversification requirements. All over-the counter (OTC) derivatives should be subject to Regulation (EU) No 648/2012 of the European Parliament and of the Council [...] ⁽¹⁾.
- (29) In order to prevent the exercise of significant influence by an investing ELTIF over the management of another ELTIF or of an issuing body, it is necessary to avoid excessive concentration by an ELTIF in the same investment.
- (30) In order to allow ELTIF managers to raise further capital during the life of the fund, they should be permitted to borrow cash amounting to up to **40** % of the capital of the fund. This should serve to provide additional return to the investors. In order to eliminate the risk of currency mismatches, the ELTIF should only borrow in the currency the manager expects to acquire the asset in.
- (31) Due to the long-term and illiquid nature of the investments of an ELTIF, the managers should have sufficient time to apply the investment limits. The time required to implement these limits should take account of the peculiarities and characteristics of the investments but should not exceed five years.
- (31a) **Under exceptional circumstances specified within the rules of incorporation, the lifecycle of ELTIF could be extended or reduced to allow for more flexibility, where, for instance, a project is completed later or earlier than expected, to put it in line with its long term investment strategy.**
- (31b) **The European Investment Bank (EIB), given its expertise in Union infrastructure financing, as well as other similar national institutions should actively cooperate with the ELTIF managers and the investors, particularly retail investors who may lack the relevant experience. Furthermore, the EIB's Project Bonds Initiative and other similar activities, such as the Connecting Europe Facility, should be directly linked to the ELTIF, with the EIB assuming risk and providing guarantees, to reduce risks inherent to this type of investments and encourage investors to trust the ELTIF as a safe investment vehicle.**

⁽¹⁾ Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories (OJ L 201, 27.7.2012, p. 1).

Thursday 17 April 2014

- (32) **Nothing should prevent an ELTIF from seeking admission of these shares or units to a regulated market as defined in Article 4(21) of Directive 2014/.../EU of the European Parliament and of the Council⁽¹⁾ [new MIFID], to a multilateral trading facility as defined in Article 4(22) of Directive 2014/.../EU [new MIFID], or to an organised trading facility as defined in Article 4(23) of Directive 2014/.../EU [new MIFID], thus providing investors with an opportunity to sell their units or shares before the end of life of the ELTIF. The rules or instruments of incorporation of an ELTIF should therefore not prevent units or shares from being admitted to or from being dealt in regulated markets, nor should they prevent investors from freely transferring their shares or units to third parties who wish to purchase those shares or units. **However, according to experiences in national markets to date, trading in secondary markets may work in some markets but in others this option may entail high premiums or important discounts on the units or shares of ELTIFs that are admitted to or dealt on regulated markets, which would prevent, in practice, investors from using this alternative. Therefore, that option may not be sufficient to substitute for the option of more regular redemptions.****
- (33) In order for investors to effectively redeem their units or shares at the end of the fund's life, the manager should start to sell the portfolio of assets of the ELTIF in good time to ensure the value is properly realised. In determining an orderly disinvestment schedule, the ELTIF manager should take into account the different maturity profiles of the investments and the length of time necessary to find a buyer for the assets in which the ELTIF is invested. Due to the impracticality of maintaining the investment limits during this liquidation period, they should cease to apply when the liquidation period starts.
- (34) The assets in which an ELTIF is invested may obtain a listing on a regulated market during the life of the fund. Where this happens, the asset would no longer comply with the non-listing requirement of this Regulation. In order to allow managers to disinvest from such an asset in an orderly manner, this asset could continue to count towards the 70 % limit of eligible investment assets for up to three years.
- (35) Given the specific characteristics of ELTIFs, as well as the targeted retail and professional investors it is important that solid transparency requirements be put in place that are capable of allowing prospective investors to make an informed judgement and be fully aware of the risks implied. In addition to the transparency requirements contained in Directive 2011/61/EU, ELTIFs should publish a prospectus the content of which should necessarily include all information required to be disclosed by collective investment undertakings of the closed-end type in accordance with Directive 2003/71/EC of the European Parliament and of the Council⁽²⁾ and Commission Regulation (EC) No 809/2004⁽³⁾. For the marketing of an ELTIF to retail investors it should be mandatory to publish a key information document (KID) in accordance with Regulation (EU) No .../... of the European Parliament and the Council⁽⁴⁾ [PRIIPS]. Furthermore, any marketing documents should explicitly draw attention to the risk profile of the ELTIF **and mention any participation in instruments involving Union budgetary funds.**
- (36) As ELTIFs target both professional and retail investors across the Union, it is necessary that certain requirements be added to the marketing requirements laid down in Directive 2011/61/EU in order to ensure an appropriate degree of investor protection, **particularly for retail investors.** Thus, facilities should be made available for making subscriptions, making payments to unit- or shareholders, repurchasing or redeeming units or shares and making available the information which the ELTIF and its managers are required to provide. Moreover, in order to ensure that retail investors are not disadvantaged with respect to experienced professional investors certain safeguards have to be put in place when ELTIFs are marketed to retail investors.

⁽¹⁾ Directive 2014/.../EU of the European Parliament and of the Council of ... on markets in financial instruments and amending Directive 2011/61/EU and Directive 2002/92/EC [new MIFID].(OJ L ...).

⁽²⁾ Directive 2003/71/EC of the European Parliament and of the Council of 4 November 2003 on the prospectus to be published when securities are offered to the public or admitted to trading and amending Directive 2001/34/EC (OJ L 345, 31.12.2003, p. 64).

⁽³⁾ Commission Regulation (EC) No 809/2004 of 29 April 2004 implementing Directive 2003/71/EC of the European Parliament and of the Council as regards information contained in prospectuses as well as the format, incorporation by reference and publication of such prospectuses and dissemination of advertisements (OJ L 149, 30.4.2004, p. 1).

⁽⁴⁾ Regulation (EU) No .../... of the European Parliament and the Council on ... [PRIIPS] (OJ ...).

Thursday 17 April 2014

- (37) The competent authority of the ELTIF should verify whether an ELTIF is able to comply with this Regulation on an on-going basis. As the competent authorities are already provided with extensive powers under Directive 2011/61/EU, it is necessary that such powers be extended in order to be exercised by reference to the new common rules on ELTIFs.
- (38) ESMA should be able to exercise all the powers conferred under Directive 2011/61/EU with respect to this Regulation **and should be provided with all resources necessary for this purpose, in particular human resources.**
- (39) The European Supervisory Authority (European Securities and Markets Authority) (ESMA), established by Regulation (EU) No 1095/2010 of the European Parliament and of the Council ⁽¹⁾, should play a central role in the application of the rules concerning ELTIFs by ensuring consistent application of Union rules by national competent authorities. As a body with highly specialised expertise regarding securities and securities markets, it is efficient and appropriate to entrust ESMA with the elaboration of draft regulatory technical standards which do not involve policy choices, for submission to the Commission, in respect of the circumstances in which the life of an ELTIF will be sufficient in length to cover the life-cycle of each of the individual assets of the ELTIF, the features of the schedule for the orderly disposal of ELTIF assets, the definitions, calculation methodologies and presentation of cost disclosures, and the characteristics of the facilities to be set up by ELTIFs in each Member State where they intend to market units or shares.
- (39a) **The provision of tax incentives, at national level, relating to long-term investments via ELTIFs can play an important role in directing the currently available resources to the financing of long-term projects in the Union, particularly focusing on projects which are beneficial to society and to the environment. For that reason, it could be assessed whether project bonds should also be considered to be eligible assets, with the aim of ensuring economies of scale and encouraging synergies between Union investment tools. Member States that are facing the consequences of fiscal adjustment are encouraged to provide state guarantees and favourable tax treatments such as tax deductions for investors who participate in ELTIFs. Member States should take all necessary legislative and institutional measures to ensure implementation of this Regulation.**
- (39b) **Member States, as well as regional and local authorities have a significant responsibility in effectively promoting and marketing ELTIFs to investors, as well as providing specific information to citizens and consumers about the benefits offered by that new framework.**
- (39c) **It is crucial to encourage a number of semi-professional investors in the Union, such as mid-tier pension schemes, insurance companies, municipalities, churches, charities and foundations, that may have sufficient capital and certain expertise, to invest in ELTIFs.**
- (40) The new uniform rules on ELTIFs should comply with the provisions of Directive 95/46/EC of the European Parliament and of the Council [...] ⁽²⁾ and with Regulation (EC) No 45/2001 of the European Parliament and of the Council [...] ⁽³⁾.
- (40a) **An ELTIF should not invest in an eligible investment asset in which the ELTIF manager has or takes a direct or indirect interest other than by holding units or shares of the ELTIF it manages. Guarantees should also be in place in order to avoid practices that distort competition or create barriers to entry.**

⁽¹⁾ Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority) (ESMA), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

⁽²⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽³⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and of the free movement of such data (OJ L 8, 12.1.2001, p. 1).

Thursday 17 April 2014

- (41) Since the objectives of this Regulation, namely to ensure uniform requirements on the investments and operating conditions for ELTIFs throughout the Union, while taking full account of the need to balance safety and reliability of ELTIFs with the efficient operation of the market for long-term financing and the cost for its various stakeholders, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (42) The new uniform rules on ELTIFs respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably **access to services of general economic interest**, consumer protection, the freedom to conduct a business, the right to remedy and to a fair trial, and the protection of personal data. The new uniform rules on ELTIFs should be applied in accordance with those rights and principles,

HAVE ADOPTED THIS REGULATION:

Chapter I
General provisions

Article 1
Subject matter *and objective*

1. This Regulation lays down uniform rules on the authorisation, investment policies and operating conditions of EU alternative investment funds (AIFs), **or compartments of AIFs**, that are marketed in the Union as European long-term investment funds (ELTIFs). [Am. 2]

1a. The objective of this Regulation is to raise and channel capital towards the real economy, in line with the objectives of a smart, sustainable and inclusive growth.

2. Member States shall not add any additional requirements in the field covered by this Regulation.

Article 2
Definitions

For the purposes of this Regulation the following definitions apply:

- (1) 'capital' means aggregate capital contributions and uncalled committed capital, calculated on the basis of amounts investible after deduction of all fees, charges and expenses which are directly or indirectly borne by investors;
- (1a) '**retail investor**' means an investor who is not a professional client, in accordance with Section I of Annex II to Directive.../.../EU [new Mifid];
- (1b) '**professional investor**' means an investor who is a professional client, in accordance with Section I of Annex II to Directive .../.../EU [new Mifid], or who may, on request, be treated as a professional client in accordance with that Directive;
- (1c) '**semi-professional investor**' means any retail investor who commits to investing a minimum of EUR 100 000 and who provides a written statement, separate from the contract to be concluded for the commitment to invest, to the effect that the investor is aware of the risks associated with the envisaged commitment or investment;
- (2) 'equity' means ownership interest in an undertaking, represented by the shares or other forms of participation in the capital of the qualifying portfolio undertaking issued to its investors;

Thursday 17 April 2014

- (3) 'quasi-equity' means any type of financing instrument where the return on the instrument is linked to the profit or loss of the qualifying portfolio undertaking and where the repayment of the instrument in the event of default is not fully secured;
- (4) 'financial undertaking' means any of the following:
- (a) a credit institution as defined in point (1) of Article 4(1) of Regulation (EU) No 575/2013 of the European Parliament and of the Council ⁽¹⁾;
 - (b) an investment firm as defined in point (2) of Article 4(1) of Regulation (EU) No 575/2013;
 - (c) an insurance undertaking as defined in point (1) of Article 13 of Directive 2009/138/EC of the European Parliament and of the Council ⁽²⁾;
 - (d) a financial holding company as defined in point (20) of Article 4(1) of Regulation (EU) No 575/2013;
 - (e) a mixed-activity holding company as defined in point (22) of Article 4(1) of Regulation (EU) No 575/2013;
- (4a) 'professional ELTIF' means an ELTIF eligible to be marketed only to professional and semi-professional investors;**
- (4b) 'EU AIF' means EU AIF as defined in Article 4(1)(k) of Directive 2011/61/EU;**
- (4c) 'EU AIFM' means EU AIFM as defined in Article 4(1)(l) of Directive 2011/61/EU;**
- (5) 'competent authority of the ELTIF' means the competent authority of the home Member State of the EU AIF as defined in Article 4(1)(p) of Directive 2011/61/EU;
- (6) 'ELTIF home Member State' means the Member State where the ELTIF is authorised;
- 'competent authority of the ELTIF manager' means the competent authority of the home Member State of the EU AIFM as defined in Article 4(1)(q) of Directive 2011/61/EU;**
- (6a) 'repurchase agreement' means any agreement in which one party transfers securities or any rights related to that title to a counterparty, subject to a commitment to repurchase them at a specified price on a future date specified or to be specified;**
- (6b) 'short selling' means the uncovered sale of assets;**
- (6c) 'retail ELTIF' means an ELTIF whose investors include retail investors;**
- (6d) 'securities lending' and 'securities borrowing' mean a transaction in which an institution or its counterparty transfers securities subject to a commitment that the borrower will return equivalent securities at some future date or when requested to do so by the transferor, that transaction constituting securities lending to the transferor and securities borrowing to the transferee;**
- (6e) 'infrastructure' means basic physical and intangible organisational structures and facilities needed for the operation of a society or enterprise.**

⁽¹⁾ Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (OJ L 177, 30.6.2006, p. 1).

⁽²⁾ Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1).

Thursday 17 April 2014

Article 3

Authorisation and use of designation

1. Only EU AIFs shall be eligible **to apply for and to be granted** authorisation as an ELTIF.
2. An ELTIF **may** be marketed in the **whole** Union **or in any Member State provided that** it has been authorised in accordance with this Regulation.

The authorisation as an ELTIF shall be valid for all Member States.

3. A collective investment undertaking shall only use the designation 'ELTIF' or '**European** long-term investment fund' in relation to itself or the units or shares it issues where it has been authorised in accordance with this Regulation.
4. The competent authorities of the ELTIF shall, on a quarterly basis, inform ESMA **on a confidential basis**, of authorisations granted or withdrawn pursuant to this Regulation **and provide all necessary details on the ELTIF activities that ensure compliance with the provisions laid down in this Regulation.**

ESMA shall keep a central public register identifying each ELTIF authorised under this Regulation, its manager, **the information provided under Article 4** and the competent authority of the ELTIF. The register shall be made available in electronic format.

Article 4

Application for authorisation as ELTIF

1. An **EU AIF** shall apply for authorisation **as ELTIF** to its competent authority.

The application for authorisation as an ELTIF shall include the following:

- (a) the fund rules or instruments of incorporation;
 - (b) information on the identity of the *proposed ELTIF* manager, **its current and previous fund management history and experience relevant to long term investment**;
 - (c) information on the identity of the depositary;
 - (d) a description of the information to be made available to investors;
 - (da) **for retail ELTIFs, a description of the procedures and arrangements in place to deal with retail investors' complaints**;
 - (e) any other information or document requested by the competent authority of the ELTIF to verify compliance with the requirements of this Regulation.
2. An **EU** AIFM authorised under Directive 2011/61/EU **is entitled to** manage an ELTIF, **and shall make a simplified application to the competent authority of the ELTIF for approval to manage an ELTIF** that has submitted an application for authorisation in accordance with paragraph 1. **Such an application for approval shall refer to the application (including documentation submitted) and authorisation under Directive 2011/61/EU.**

3. The ELTIF and the EU AIFM shall be informed within [two months] from the date of submission of a complete application whether authorisation of the ELTIF **and the approval to manage the ELTIF** has been granted.

4. Any subsequent modifications of the documentation referred to in **paragraph 1** shall be immediately notified to the competent authority of the ELTIF.

Article 5

Conditions for granting the authorisation

1. An applicant ELTIF shall be authorised only where its competent authority:
 - (a) is satisfied that the applicant ELTIF is able to meet all the requirements of this Regulation **and has approved the fund rules or instruments of incorporation and the choice of the depositary**;

Thursday 17 April 2014

(b) has approved the application of an EU AIFM authorised in accordance with Directive 2011/61/EU to manage the ELTIF ;

(ba) **is satisfied that the proposed ELTIF manager or a person exercising a management function within the proposed ELTIF manager has not previously been the subject of penalties for infringements of national or Union law governing fund management.**

1a. The competent authority shall provide the applicant ELTIF with an answer within [two] month.

2. The competent authority of the ELTIF may refuse the application of the EU AIFM to manage the ELTIF only where:

(a) the EU AIFM does not comply with this Regulation;

(b) the EU AIFM does not comply with Directive 2011/61/EU, **as established in cooperation with the competent authority of the ELTIF manager in accordance with this Regulation and with the supervisory cooperation arrangements laid down in Directive 2011/61/EU;**

(c) the EU AIFM is not authorised by its competent authority to manage AIFs that include funds of the type covered in this Regulation, **as established in cooperation with the competent authority of the ELTIF manager in accordance with this Regulation;**

(d) the EU AIFM has not provided the documentation referred to in Article 4(2), **or any clarification or information requested thereunder.**

Before refusing an application the competent authority of the ELTIF shall consult the competent authority of the EU AIFM.

3. The competent authority shall not grant authorisation as an ELTIF if the applicant ELTIF is legally prevented from marketing its units or shares in its home Member State. **The competent authority shall communicate to the applicant ELTIF the reason for its refusal to grant authorisation. The refusal shall apply in all Members States.**

4. Authorisation as an ELTIF shall not be subject to a requirement that the ELTIF be managed by an EU AIFM authorised in the ELTIF home Member State or that the EU AIFM pursue or delegate any activities in the ELTIF home Member State

Article 6

Applicable rules and liability

1. An ELTIF shall comply at all times with the provisions of this Regulation.

2. An ELTIF and an *ELTIF manager* shall comply at all times with the requirements of Directive 2011/61/EU.

3. The *ELTIF manager* shall be responsible for ensuring compliance with this Regulation. The *ELTIF manager* shall be liable for any loss or damage resulting from non-compliance with this Regulation.

Chapter II

Obligations concerning the investment policies of ELTIFs

SECTION 1

GENERAL RULES AND ELIGIBLE ASSETS

Article 7

Investment compartments

Where an ELTIF comprises more than one investment compartment, each **ELTIF** compartment shall be regarded as a separate ELTIF for the purposes of this Chapter.

Thursday 17 April 2014

Article 8

Eligible investments

1. **In accordance with the objectives of a smart, sustainable and inclusive growth**, an ELTIF shall only invest in the following categories of assets and only under the conditions specified in this Regulation:

- (a) eligible investment assets;
- (b) assets referred to in Article 50(1) of Directive 2009/65/EC of the European Parliament and of the Council ⁽¹⁾.

2. An ELTIF shall not undertake any of the following activities:

- (a) short-selling of assets;
- (b) taking direct or indirect exposure to commodities, including via derivatives, certificates representing them, indices based on them or any other means or instruments that would give an exposure to them;

(d) using financial derivative instruments, except where it solely serves the purpose of hedging risks inherent to other investments of the ELTIF.

2a. In order to ensure consistent application of this Article, ESMA shall, after conducting an open public consultation, develop draft regulatory technical standards specifying criteria for establishing the circumstances where derivative contracts solely serve the purpose of hedging the risks inherent to the investments referred to in paragraph 2 (d).

ESMA shall submit those draft regulatory technical standards to the Commission by [3 months after entry into force of this Regulation].

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.

Article 9

Eligible investment assets

An asset referred to in Article 8(1)(a) shall be eligible for investment by an ELTIF only where it falls into one of the following categories:

- (a) equity or quasi-equity instruments which have been:
 - (i) issued by a qualifying portfolio undertaking and acquired directly by the ELTIF from the qualifying portfolio undertaking;
 - (ii) issued by a qualifying portfolio undertaking in exchange for an equity instrument previously acquired directly by the ELTIF from the qualifying portfolio undertaking;
 - (iii) issued by an undertaking of which the qualifying portfolio undertaking is a majority-owned subsidiary, in exchange for an equity instrument acquired in accordance with points (i) or (ii) by the ELTIF from the qualifying portfolio undertaking;
- (b) debt instruments issued by a qualifying portfolio undertaking **with a maturity aligned to the life of the ELTIF**;
- (c) loans granted by the ELTIF to a qualifying portfolio undertaking **with a maturity aligned to the life of the ELTIF**;

⁽¹⁾ Directive 2009/65/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) (OJ L 302, 17.11.2009, p. 32).

Thursday 17 April 2014

- (d) units or shares of one or several other ELTIFs, European Venture Capital Funds (EuVECFs) and European Social Entrepreneurship Funds (EuSEFs) provided that those ELTIFs, EuVECFs and EuSEFs have not themselves invested more than 10 % of their capital in ELTIFs;
- (e) direct holdings **or indirect holdings via qualifying portfolio undertakings** of individual **infrastructure** that require up-front capital expenditure of at least EUR 10 million or its equivalent in the currency, and at the time, in which the expenditure is incurred **and provide regular predictable returns**.

In accordance with the objectives of a smart, sustainable and inclusive growth or with the Union regional policy, projects financed by a public-private partnership shall be granted priority by the competent authorities when examining an application.

Article 10

Qualifying portfolio undertaking

1. A qualifying portfolio undertaking referred to in Article 9(1) shall be a portfolio undertaking other than a collective investment undertaking that fulfils all of the following requirements:

(a) it is not a financial undertaking **other than the European multilateral development banks referred to in Regulation (EU) No 575/2013 [CRR] Article 117(2)(f), (i), (j) and (k)**;

(b) it is not admitted to trading:

(i) on a regulated market as defined in point 21 of Article 4(1) of Directive 2014/.../EU [new MIFID];

(ii) on a multilateral trading facility as defined in point 22 of Article 4(1) of Directive 2014/.../EU [new MIFID];

■

(ba) **it is admitted to trading on a regulated market or on a multilateral trading facility and has a market capitalisation of no more than EUR 1 billion;**

(bb) **it is admitted to trading on a regulated market or on a multilateral trading facility and is considered to be an SME in accordance with Article 2(1) of the Annex to Commission Recommendation 223/361/EC⁽¹⁾;**

(c) it is established in a Member State, or in a third country provided that the third country:

(i) is not a high-risk and non-cooperative jurisdictions identified by the Financial Action Task Force (FATF); or

(ii) has signed an agreement with the home Member State of the *ELTIF manager* and with every other Member State in which the units or shares of the ELTIF are intended to be marketed which **provides** that the third country **is not a country:**

— **where there are no or nominal taxes,**

— **where there is a lack of effective exchange of information with foreign tax authorities,**

— **where there is a lack of transparency in legislative, judicial or administrative provisions,**

— **where there is no requirement for a substantive local presence,**

— **which acts as an offshore financial centre.**

⁽¹⁾ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

Thursday 17 April 2014

2. By way of derogation from paragraph 1(a) [...], a qualifying portfolio undertaking may be a financial undertaking **or a collective investment undertaking** that, **in accordance with the objectives of a smart, sustainable and inclusive growth**, exclusively finances qualifying portfolio undertakings referred to in paragraph 1 of this Article or real assets referred to in Article 9.

Article 11

Conflicts of interest

An ELTIF shall not invest in an eligible investment asset in which the manager has or takes a direct or indirect interest, other than by holding units or shares of the **ELTIFs, EUSEFs or EuVECAs or collective investment undertakings within the meaning of Article 10(2)** it manages.

SECTION 2

PROVISIONS ON INVESTMENT POLICIES

Article 12

Portfolio composition and diversification

1. An ELTIF shall invest at least 70 % of its capital in eligible investment assets **and at least 60 % of its capital in assets listed in Article 9(a), (b) and (c) in qualifying portfolio undertakings established within the territory of a Member State.**

1a. Where the rules or instruments of incorporation of ELTIF provide for regular redemption rights, the ELTIF shall maintain at the predefined redemption periods a liquidity reserve taking into account the requirements and conditions for exercise of the redemption rights, commensurate with the management of liquidity for the exercise of redemption rights.

1b. ESMA shall develop regulatory technical standards to further specify the structure of the liquidity reserves.

ESMA shall submit those draft regulatory technical standards to the Commission by ...*.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.

2. An ELTIF shall invest no more than:

(a) 10 % of its capital in assets issued by any single qualifying portfolio undertaking;

(b) 10 % of its capital **directly or indirectly** in an individual **infrastructure according to Article 9(e)**;

(c) 10 % of its capital in units or shares of any single ELTIF, EuVECA, EuSEF **or AIFs**;

(d) 5 % of its capital in assets referred to in Article 8(1)(b) where those assets have been issued by any single body.

3. The aggregate value of units or shares of ELTIFs, EuVECAs and EuSEFs in an ELTIF portfolio shall not exceed 20 % of the value of its capital.

4. The aggregate risk exposure to a counterparty of the ELTIF stemming from over the counter (OTC) derivative transactions or **repurchase agreements or** reverse repurchase agreements shall not exceed 5 % of its capital.

5. By way of derogation from paragraph 2(a) and 2(b), the ELTIF may raise the 10 % limit referred to therein to 20 %, provided that the aggregate value of the assets held by the ELTIF in qualifying portfolio undertakings and in individual real assets in which it invests more than 10 % of its capital does not exceed 40 % of the value of its capital.

Thursday 17 April 2014

6. Companies which are included in the same group for the purposes of consolidated accounts, as regulated by Seventh Council Directive 83/349/EEC ⁽¹⁾ or in accordance with recognised international accounting rules, shall be regarded as a single qualifying portfolio undertaking or a single body for the purpose of calculating the limits referred to in paragraphs 1 to 5.

Article 12a

In circumstance where the ELTIF breaches the diversification requirements as stipulated in Article 12 and the contravention is beyond the control of the ELTIF manager, competent authorities shall provide a period of six months for the manager to take such measures as are necessary to rectify the position.

Article 13

Concentration

1. An ELTIF may acquire no more than 25 % of the units or shares of a single ELTIF, EuVECA or EuSEF.
2. The concentration limits laid down in Article 56(2) of Directive 2009/65/EC shall apply to investments in the assets referred to in Article 8(1)(b) of this Regulation.

Article 14

Borrowing of cash

An ELTIF may borrow cash provided that such borrowing fulfils all of the following conditions:

- (a) it represents no more than **40** % of the capital of the ELTIF;
- (b) it serves the purpose of acquiring a participation in eligible investment assets;
- (c) it is contracted in the same currency as the assets to be acquired with the borrowed cash;

(ea) it encumbers the assets that represent no more than 30 % of the capital of the ELTIF.

(eb) its duration is aligned with the life of the ELTIF.

The ELTIF manager shall inform the investors in advance about future borrowing needs that arise within the investment strategy.

Article 15

Application of portfolio composition and diversification rules

1. The investment limits laid down in Article 12(1) shall:
 - (a) apply by the date specified in the ELTIF rules or instruments of incorporation, where this date shall take account of the peculiarities and characteristics of the assets to be invested by the ELTIF and shall not be later than five years **or half the life of the ELTIF as determined in accordance with Article 16(2), whichever is the earlier**, after the authorisation of the ELTIF. In exceptional circumstances, the competent authority of the ELTIF, upon submission of a duly justified investment plan, may approve an extension of this time limit by no more than one additional year;
 - (b) cease to apply once the ELTIF starts to sell assets in accordance with its redemption policy as set out in Article 16;

⁽¹⁾ OJ L 193, 18.7.1983, p. 1.

Thursday 17 April 2014

(c) be temporarily suspended where the ELTIF raises additional capital, so long as such a suspension lasts no longer than 12 months, **in particular in the case of an infrastructure investment.**

2. Where a long-term asset in which the ELTIF has invested is issued by a qualifying portfolio undertaking that no longer complies with Article 10(1)(b), the long-term asset may continue to be counted for the purpose of calculating the 70 % referred to in Article 12(1) for a maximum of three years as of the date when the portfolio undertaking no longer fulfils the requirements in Article 10.

Chapter III

Redemption, trading and issue of ELTIF shares or units and distributions of income

Article 16

Redemption policy

1. **The ELTIF manager may set up a professional ELTIF with no participation for retail investors or he may decide to set up an ELTIF where retail, professional and semi-professional investors can participate.**

1a. The ELTIF rules or instruments of incorporation **may indicate a specific date as the end of life of the ELTIF as well as the right for temporary extension of its life-cycle and the conditions to exercise the right. Where no specific date is indicated, the life of the ELTIF shall not be limited.**

1b. **When the ELTIF manager decides to let retail investors participate in the ELTIF, all investors shall be able to ask for redemption of their units or shares before the end of life of the ELTIF. However, redemption of units and shares by institutional or retail investors can only take place after the life of ELTIF is halfway and for a total maximum of 20 % of the total amount of the fund. If no redemption rights are foreseen in the rules or instruments of incorporation of the ELTIF, redemption to investors shall be possible as of the day following the date defining the end of life of the ELTIF.**

ESMA shall develop draft regulatory technical standards to further specify the conditions and requirements of the redemption policy structures of ELTIFs, to achieve clarity and consistency across the Union.

2. The life of the ELTIF shall be **consistent with the long-term nature of the ELTIF and shall be** sufficient in length to cover the life-cycle of each of the individual assets of the ELTIF, measured according to the illiquidity profile and economic life-cycle of the asset, and the stated investment objective of the ELTIF.

3. Investors may request the winding down of the ELTIF if their redemption requests **made in accordance with the ELTIF's redemption policy** have not been satisfied within one year after the **date when they have been made.**

3a. **The ELTIF rules or instruments of incorporation and disclosures to investors shall lay down the procedures for reinvesting the proceeds from investment in qualifying portfolio undertakings, either in further qualifying portfolio undertakings or high-quality liquid assets, where such investments mature prior to the end of life of the ELTIF.**

4. Investors shall always have the option to be repaid in cash.

5. Repayment in kind out of the ELTIF's assets shall be possible only where all of the following conditions are met:

(a) the ELTIF rules or instrument of incorporation foresees this possibility, under the condition that all investors receive fair treatment;

(b) the investor asks in writing to be repaid through a share of the assets of the fund;

(c) no specific rules restrict the transfer of those assets.

Thursday 17 April 2014

6. ESMA shall develop draft regulatory technical standards specifying the circumstances in which the life of an ELTIF is sufficient in length to cover the life-cycle of each of the individual assets of the ELTIF.

ESMA shall submit those draft regulatory technical standards to the Commission by **2015**.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.

Article 17

Secondary market

1. The ELTIF rules or instrument of incorporation shall not prevent units or shares of an ELTIF from being admitted to trading on a regulated market as defined in Article 4(14) of Directive 2004/39/EC or on a multilateral trading facility as defined in Article 4(15) of Directive 2004/39/EC **■**.

2. The ELTIF rules or instrument of incorporation shall not prevent investors from freely transferring their shares or units to third parties.

2a. The ELTIF shall regularly publish an explanation of any significant difference between the market value of listed shares or units and its own estimate of its net asset value.

Article 18

Issuance of new shares or units

1. An ELTIF may offer new issues of shares or units in accordance with its fund rules or instruments of incorporation.

2. An ELTIF shall not issue new shares or units at a price below its net asset value without a prior offering of those shares or units at that price to existing investors.

Article 19

Disposal of ELTIF assets

1. Each ELTIF shall adopt an itemised schedule for the orderly disposal of its assets in order to redeem investors after the end of life of the ELTIF.

2. The schedule referred to in paragraph 1 shall **be at least annually reviewed and shall** include:

(a) an assessment of the market for potential buyers;

(b) an assessment and comparison of potential sales prices;

(c) a valuation for the assets to be divested;

(d) a precise timeframe for the disposal schedule.

3. ESMA shall develop draft regulatory technical standards specifying the criteria to be used for the assessments in point (a) and valuation in point (c) of paragraph 2.

ESMA shall submit those draft regulatory technical standards to the Commission by [...].

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.

Article 20

Distribution of **proceeds**

1. An ELTIF may regularly distribute to investors the **proceeds** generated by the assets contained in the portfolio. **Those proceeds** shall be composed of:

(a) any **proceeds** that the assets are regularly producing;

Thursday 17 April 2014

(b) the capital appreciation realized after the disposal of an asset ■.

2. The income **distribution policy shall be designed to minimise the volatility of returns to investors. The income** shall not be distributed to the extent that it is required for future commitments of the ELTIF.

2a. An ELTIF shall be authorised to reduce its capital on a pro rata basis in the event that it has disposed of one of its portfolio assets.

3. The ELTIF shall state in its fund rules or instruments of incorporation the distribution policy that it will adopt during the life of the fund.

Chapter IV

Transparency requirements

Article 21

Transparency

1. The units or shares of an authorised ELTIF shall not be marketed in the Union without prior publication of a prospectus.

The units or shares of an authorised ELTIF shall not be marketed to retail investors in the Union without prior publication of a key information document (KID) in accordance with Regulation (EU) No .../... [PRIPS].

2. The prospectus shall include the information necessary for investors to be able to make an informed judgement regarding the investment proposed to them, and, in particular, the risks attached thereto.

3. The prospectus shall contain at least the following:

(a) a statement setting out how the ELTIF's investment objectives and strategy for achieving these objectives qualify the fund as long term in nature;

(b) information to be disclosed by collective investment undertakings of the closed-end type in accordance with Directive 2003/71/EC of the European Parliament and of the Council ⁽¹⁾ and Commission Regulation (EC) No 809/2004 ⁽²⁾;

(c) information to be disclosed to investors pursuant to Article 23 of Directive 2011/61/EU, if it is not already covered under point(b) of this paragraph;

(d) prominent indication of the categories of assets the ELTIF is authorised to invest in;

(da) **a cash flow statement.**

■

4. The prospectus, the KID and any other marketing documents shall prominently notify investors about the illiquid nature of the ELTIF.

In particular, the prospectus, the KID, and any other marketing documents shall clearly:

(a) inform investors about the long-term nature of the ELTIF's investments;

(b) **where applicable according to Article 16(1)** inform investors about the end of life of the ELTIF **and any right of temporary expansion or any right of intervention of the life of the ELTIF and the specific conditions provided for;**

(c) state whether the ELTIF is intended to be marketed to retail investors;

⁽¹⁾ OJ L 345, 31.12.2003, p. 64.

⁽²⁾ OJ L 149, 30.4.2004, p. 1.

Thursday 17 April 2014

- (d) state **the rights of investors** to redeem their investment **in accordance with Article 16(1) and with the rules or instruments of incorporation** of the ELTIF;
- (e) state the frequency and the timing of any income payments, if any, to the investors during the life of the fund;
- (f) advise investors that only a small proportion of their overall investment portfolio should be invested in an ELTIF.
- (fa) **inform investors about the strategy for qualifying unlisted companies to be admitted to trading in regulated markets;**
- (fb) **inform investors about the strategy regarding the use of derivatives taking into account specific characteristics and aspects of the project in question;**
- (fc) **mention any participation in instruments involving Union budgetary funds.**
- (fd) **inform investors regularly, at least once a year, of the progress of each investment project, the value of the individual qualifying portfolio investments and the value of other assets in which spare cash is placed as well as the nature, purpose and value of any derivatives used.**

4a. The prospectus of professional ELTIFs shall contain the information required under Article 23 of Directive 2011/61/EU. In addition, it shall also contain any deviation from the provisions of Article 12 on portfolio composition.

Article 22

Cost disclosure

1. The prospectus shall prominently inform investors as to the level of the different costs borne directly or indirectly by the investor. The different costs shall be grouped according to the following headings:

- (a) costs of setting-up the ELTIF;
- (b) the costs related to the acquisition of assets;
- (c) management costs;
- (d) distribution costs;
- (e) other costs, including administrative, regulatory, **depository**, custodial, **professional service** and audit costs.

2. The prospectus shall disclose an overall ratio of the costs to the capital of the ELTIF.

3. The key information document shall reflect all of the costs outlined in the prospectus within its expression of total costs in monetary and percentage terms.

4. ESMA shall develop draft regulatory technical standards to specify:

- (a) the common definitions, calculation methodologies and presentation formats of the costs referred to in paragraph 1 and the overall ratio referred to in paragraph 2;
- (b) the common definition, calculation methodology and presentation format of the expression of total costs in paragraph 3.

Thursday 17 April 2014

When developing these draft regulatory technical standards, ESMA shall take into account the draft regulatory standards referred to in point (...) of Regulation (EU) No .../... [PRIPS].

ESMA shall submit those draft regulatory technical standards to the Commission by [...].

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.

Chapter V

Marketing of units or shares of ELTIFs

Article 23

Facilities available to investors

1. **Where the rules or instruments of incorporation of a retail ELTIF provide for redemption rights, the ELTIF manager** shall, in each Member State where it intends to market units or shares of that ELTIF, put in place facilities available for making subscriptions, making payments to unit- or shareholders, repurchasing or redeeming units or shares and making available the information which the ELTIF and its managers are required to provide.

2. ESMA shall develop draft regulatory technical standards to specify the types and characteristics of the facilities, their technical infrastructure and of the content of their tasks in respect of ELTIF investors referred to in paragraph 1.

ESMA shall submit those draft regulatory technical standards to the Commission by [...].

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.

2a. For professional ELTIFs, the paragraph 1 of this Article shall not apply.

Article 24

Additional requirements for marketing to retail investors

The ELTIF manager **may** market the units or shares of that ELTIF to retail investors provided that all of the following additional requirements are fulfilled:

- (a) the ELTIF's rules or instruments of incorporation provide that all investors benefit from equal treatment and no preferential treatment or specific economic benefits are granted to individual investors or groups of investors;
- (b) the ELTIF **may be** structured as a partnership **if this does not require additional commitments for the investor apart from the original capital commitment;**
- (c) retail investors may, during the subscription period ■ of units or shares of the ELTIF, cancel their subscription and have the money returned without penalty;
- (ca) **the ELTIF manager has established appropriate procedures and arrangements to deal with retail investor complaints, which allow retail investors to file complaints in the official language or one of the official languages of their Member State;**
- (cb) **the legal form of the ELTIF is such that retail investors cannot lose more than the amount that they have invested into the fund;**
- (cc) **the ELTIF invests in units or shares of EuVECA and EuSEF only where those funds have a depositary;**

ESMA shall develop standards further specifying the provisions for retail investors to be included in the rules or instruments of incorporation.

Thursday 17 April 2014

Article 25

Marketing of units or shares of ELTIFs

1. The *ELTIF manager* shall be able to market the units or shares of that authorised ELTIF to professional, **semi-professional** and retail investors in its home Member State upon notification in accordance with Article 31 of Directive 2011/61/EU.
2. The *ELTIF manager* **may** market the units or shares of that authorised ELTIF to professional, **semi-professional** and retail investors in Member States other than in the home Member State of the ELTIF manager upon notification in accordance with Article 32 of Directive 2011/61/EU.
3. The *ELTIF manager* shall in respect of each ELTIF specify to its competent authority whether or not it intends to market it to retail investors.
4. In addition to the documentation and information required pursuant **Article** 32 of Directive 2011/61/EU the manager of the ELTIF shall provide to its competent authority all of the following:
 - (a) the prospectus of the ELTIF;
 - (b) the key information document of the ELTIF in case of marketing to retail investors;
 - (c) information on the facilities referred to in Article 22.
5. The competences and powers of the the competent authorities pursuant to **Article** 32 of Directive 2011/61/EU shall be understood to also refer to the marketing of ELTIFs to retail investors and to cover the additional requirements laid down in this Regulation.
6. **■ The** competent authority of the home Member State of the ELTIF manager shall **prohibit** the marketing of an authorised ELTIF if the ELTIF manager does not comply with this Regulation.
7. In addition to its powers in accordance with *the first subparagraph of Article 32(3) [...]* of Directive 2011/61/EU, the competent authority of the home Member State of the ELTIF manager shall also refuse the transmission of a complete notification file to the competent authorities of the Member State where the ELTIF is intended to be marketed, if the ELTIF manager does not comply with this Regulation.

Chapter VI

Supervision

Article 26

Supervision by the competent authorities

1. The competent authorities shall supervise compliance with this Regulation on an on-going basis.
2. The competent authority of the ELTIF shall be responsible for supervising compliance with the rules laid down in Chapters II, III and IV.
3. The competent authority of the ELTIF shall be responsible for supervising compliance with the obligations set out in the fund rules or in the instruments of incorporation, and the obligations set out in the prospectus, which shall be consistent with this Regulation.
4. The competent authority of the *ELTIF manager* shall be responsible for supervising the adequacy of the arrangements and organisation of the manager so that the manager of the ELTIF is in a position to comply with the obligations and rules which relate to the constitution and functioning of all the ELTIFs it manages.

The competent authority of the manager shall be responsible for supervising compliance of the ELTIF manager with this Regulation.

5. Competent authorities shall monitor collective investment undertakings established or marketed in their territories to verify that they do not use the ELTIF designation or suggest that they are an ELTIF unless they are authorised and comply with this Regulation.

Thursday 17 April 2014

Article 27

Powers of competent authorities

1. Competent authorities shall have all supervisory and investigatory powers that are necessary for the exercise of their functions pursuant to this Regulation.

1a. The competent authority of the ELTIF shall, while respecting the principle of proportionality, take the appropriate measures, in particular where ELTIF manager:

- (a) ***fails to comply with the requirements that apply portfolio composition and diversification in breach of Articles 12 and 15;***
- (b) ***markets, the units of shares of a ELTIF to retail investors in breach of Article 24 and 25;***
- (c) ***uses the designation ELTIF but is not authorised to do so in accordance with Article 3;***
- (d) ***uses the designation ELTIF for the marketing of funds which are not established in accordance with Article 3(1);***
- (e) ***fails to comply with the applicable rules and liability in breach of Article 6.***

1b. In the cases referred to in paragraph 1a, the competent authority of the home Member State of the ELTIF shall, as appropriate:

- (a) ***take measures to ensure that the ELTIF manager complies with Articles 3, 6, 12, 15, 24, and 25.***
- (b) ***prohibit the use of the designation ELTIF and withdraw the approval given to the ELTIF manager concerned from the authorisation.***

2. The powers conferred on competent authorities in accordance with Directive 2011/61/EU shall be exercised also with respect to this Regulation.

Article 28

Powers and competences of ESMA

1. ESMA shall have the powers **and resources** necessary to carry out the tasks attributed to it by this Regulation.
2. ESMA's powers in accordance with Directive 2011/61/EU shall be exercised also with respect to this Regulation and in compliance with Regulation (EC) No 45/2001.
3. For the purposes of Regulation (EU) No 1095/2010, this Regulation shall be included under any further legally binding Union act which confers tasks on the Authority as referred to in Article 1(2) of Regulation (EU) No 1095/2010.

Article 29

Cooperation between authorities

1. The competent authority of the ELTIF and the competent authority of the manager, if different, shall cooperate with each other and exchange information for the purpose of carrying out their duties under this Regulation.
2. Competent authorities and ESMA shall cooperate with each other for the purpose of carrying out their respective duties under this Regulation in accordance with Regulation (EU) No 1095/2010.
3. **Competent authorities and ESMA shall exchange** all information and documentation necessary to **carry out their respective duties under this Regulation in accordance with Regulation (EU) No 1095/2010, in particular to identify and remedy breaches of this Regulation.**

Thursday 17 April 2014

Chapter VII

Final provisions

Article 30

Review

The Commission shall start a review of the application of this Regulation at the same time as or immediately after the review provided for in Article 69 of the Directive 2011/61/EU. The review shall analyse in particular:

- (a) the impact of Article 16(1);
- (b) the impact on asset diversification of the application of the minimum threshold of 70 % of eligible investment assets laid down in Article 12(1), in particular whether increased measures on liquidity would be necessary;
- (c) the extent to which ELTIFs are marketed in the Union, including whether AIFMs within the meaning of Article 3(2) of Directive 2011/61/EU might have an interest in marketing ELTIFs;
- (ca) **the extent to which the list of eligible assets and investments should be updated, as well as the diversification rules, portfolio composition and limits regarding the borrowing of cash.**

The results of that review shall be communicated to the European Parliament and to the Council accompanied, where necessary, by appropriate proposals for amendments.

Article 31

Entry into force

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

The President

For the Council

The President

Thursday 17 April 2014

P7_TA(2014)0449

Maritime spatial planning and integrated coastal management *I****European Parliament legislative resolution of 17 April 2014 on the proposal for a directive of the European Parliament and of the Council establishing a framework for maritime spatial planning and integrated coastal maritime spatial planning and integrated coastal management (COM(2013)0133 — C7-0065/2013 — 2013/0074(COD))****(Ordinary legislative procedure: first reading)**

(2017/C 443/117)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0133),
 - having regard to Article 294(2) and Articles 43(2) and 100(2), 192(1) and 194(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0065/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by a Parliament of the Kingdom of Belgium, the German Bundesrat, the Irish House of Representatives, the Irish Senate, the Lithuanian Parliament, the Netherlands Senate, the Netherlands House of Representatives, the Polish Senate, the Finnish Parliament and the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 18 September 2013 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 9 October 2013 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 12 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Transport and Tourism and the opinions of the Committee on the Environment, Public Health and Food Safety and the Committee on Fisheries (A7-0379/2013),
1. Adopts its position at first reading hereinafter set out ⁽³⁾;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0074**Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council establishing a framework for maritime spatial planning***(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/89/EU.)*⁽¹⁾ OJ C 341, 21.11.2013, p. 67.⁽²⁾ OJ C 356, 5.12.2013, p. 124.⁽³⁾ This position replaces the amendments adopted on 12 December 2013 (Texts adopted P7_TA(2013)0588).

Thursday 17 April 2014

P7_TA(2014)0450

Estimates of revenue and expenditure for the financial year 2015 — Section I — Parliament

European Parliament resolution of 17 April 2014 on Parliament's estimates of revenue and expenditure for the financial year 2015 (2014/2003(BUD))

(2017/C 443/118)

The European Parliament,

- having regard to Article 314 of the Treaty on the Functioning of the European Union,
 - having regard to Regulation (EU, Euratom) No 966/2012 of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 ⁽¹⁾, and in particular Article 36 thereof,
 - having regard to Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 ⁽²⁾,
 - having regard to the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management ⁽³⁾, and in particular point 27 thereof,
 - having regard to Regulation (EU, Euratom) No 1023/2013 of the European Parliament and of the Council of 22 October 2013 amending the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union ⁽⁴⁾,
 - having regard to the cooperation agreement of 5 February 2014 between the European Parliament and the European Economic and Social Committee and the Committee of Regions,
 - having regard to its resolution of 23 October 2013 on the draft general budget of the European Union for the financial year 2014 ⁽⁵⁾,
 - having regard to the Secretary-General's report to the Bureau on drawing up Parliament's preliminary draft estimates for the financial year 2015,
 - having regard to the preliminary draft estimates drawn up by the Bureau on 2 April 2014 pursuant to Rules 23(7) and 79(1) of Parliament's Rules of Procedure,
 - having regard to its positions of 11 March 2014 on the adjustment of the remuneration and pension of the officials and other servants of the European Union and the correction coefficients applied thereto ⁽⁶⁾,
 - having regard to the draft estimates drawn up by the Committee on Budgets pursuant to Rule 79(2) of Parliament's Rules of Procedure,
 - having regard to Rule 79 of its Rules of Procedure,
 - having regard to the report of the Committee on Budgets (A7-0277/2014),
- A. whereas the 2015 budgetary procedure will run during a European election year, when the estimates of the Parliament for the financial year 2015 will be adopted by the current Parliament and the final budget will be approved by the new Parliament in the autumn;
- B. whereas the ceiling of heading V (Administration), set by the new Multiannual Financial Framework for 2014-2020 period, amounts to EUR 9 076 million for the 2015 budget; whereas the sub-ceiling for overall administrative expenditure of the institutions has been set at EUR 7 351 million;

⁽¹⁾ OJ L 298, 26.10.2012, p. 1.

⁽²⁾ OJ L 347, 20.12.2013, p. 884.

⁽³⁾ OJ C 373, 20.12.2013, p. 1.

⁽⁴⁾ OJ L 287, 29.10.2013, p. 15.

⁽⁵⁾ Texts adopted, P7_TA(2013)0437.

⁽⁶⁾ Texts adopted, P7_TA(2014)0186 and P7_TA(2014)0187.

Thursday 17 April 2014

- C. whereas the following three priorities have been proposed by the Secretary-General for the 2015 financial year, namely: to mobilise all necessary resources and support in order to empower the Members of the new Parliament to fulfil their mandate, to consolidate and reinforce structural changes in order to strengthen the Parliament's capacities to comply with all its powers and to assign the necessary means for the implementation of the multiannual projects;
- D. whereas the Secretary-General has proposed to continue and further strengthen the four activity areas adopted after the consultation of the Joint Bureau-Committee on Budgets Working Group in 2014, namely strengthening independent scientific advice and the capacity for scrutiny and improving logistical and local support for Members;
- E. whereas the Parliament will continue to exercise, in a transparent manner, a high degree of budgetary responsibility, control and self-restraint, while at the same time striking a delicate balance between budgetary rigour and structural savings on one hand and a concerted drive for efficiency on the other hand;
- F. whereas despite little room for manoeuvre and the need to counterbalance savings in other areas, certain investments should be considered in order to strengthen the institutional role of the Parliament and to improve the sustainability of the budget;
- G. whereas cooperation between the Bureau and the Committee on Budgets on Parliament's budget has proven its role in the process of structural reforms by identifying efficiency gains and possible savings in the Parliament's budget throughout the annual budget procedures; whereas possible savings, which affect the work of the Parliament and its Members, need to be discussed in the political groups and decided by a vote in plenary in the context of the budget procedure;
- H. whereas the agreement reached on 11 March 2014 on remuneration and pensions adjustments for 2011 and 2012 and its impact on the Parliament's budget for 2015 emerged as a new element of negotiations during the conciliation phase between the Bureau and the Committee on Budgets;

General framework and overall budget

1. Stresses that the 2015 budget should be set on a realistic basis and should be in line with the principles of budgetary discipline and sound financial management; notes that 2015 will be a full year for the new Parliament in office;
2. Believes that the Parliament's budget should reflect the current economic situation experienced by citizens across the Union, as well as the fiscal constraints faced by many Member States, some of whom are engaged in serious efforts to bring their budgets onto a more sustainable long-term footing;
3. Stresses that in order to allow the Members of the new Parliament to fulfil their mandate and to empower the Parliament's capacity to comply with all its powers, a sufficient level of resources should be ensured;
4. Welcomes the priorities set for the financial year 2015 and emphasises that they are fully in line with the priorities identified by the Secretary-General and discussed by the Joint Bureau — Committee on Budgets Working Group; stresses that these reforms should continue in order to bring substantial efficiency gains and free up resources, without jeopardising legislative excellence, budgetary powers and powers of scrutiny, the relations with national parliament and the quality of working conditions;
5. Recalls that the level of the preliminary draft estimates for the 2015 budget, as suggested by the Secretary-General's Report, amounted to EUR 1 822 929 112 (20,09 % of heading V); takes into account the rate of increase of 3,83 %, compared with the 2014 budget; notes that 0,67 % of this increase corresponds to the Members' allocation for the end of their mandate, which are statutory and obligatory costs and 1,42 % to long term investments in the construction of the KAD building; notes that the level of the increase for the other expenditure would thus correspond to + 1,74 %;
6. Takes note of the Preliminary Draft Estimates of the European Parliament for the financial year 2015 as adopted by the Bureau on 2 April 2014; welcomes the level of preliminary draft estimates, as adopted by the Bureau, which are significantly lower than the initial proposal; regrets however the lengthy and difficult procedure;
7. Approves the draft estimates for the year 2015 at EUR 1 794 929 112, corresponding to an overall rate of increase of 1,8 % over the 2014 budget and agrees furthermore to include in its draft estimates the obligatory extraordinary expenditure of 0,4 % resulting from the new agreement on the coefficient for the adjustment of the remunerations and pensions;

Thursday 17 April 2014

8. Believes that further savings could be achieved by having a critical look at the ICT budget lines, the expenditures on vehicles and the contingency reserve;
9. Believes that the next legislature will have the possibility to reconsider and adapt the budgetary priorities and will take the final decision in October 2014;
10. Invites the Secretary-General to present before the reading of the budget an estimate of the costs of the construction of the KAD building over the coming years in order to foresee the correct amount in the 2015 budget; furthermore invites the Secretary General to evaluate, at the end of the year, the funds not used in the 2014 budget and to commit them to the KAD project;
11. Emphasises, that as statutory and obligatory expenditure, such as rental and energy costs as well as expenditure for wages, is subject to annual indexations, the level for the other expenditure has been reduced in nominal terms; notes that this was possible due to structural reforms and savings achieved in the previous years;
12. Calls for the potential savings identified by the Joint Bureau and Committee on Budgets Working Group to be explored further in order to generate substantial organisational savings, such as the scope for interinstitutional cooperation arrangements between the Parliament, the European Economic and Social Committee and the Committee of the Regions, which reflects the will to strengthen the institutional, political and legislative role of the Parliament and the two advisory Committees; notes that restructuring the Committees' Translation Service should improve their respective political core work and strengthen the new Research Service for Members; emphasises that according to this organisational reform, the Parliament can become the standard provider for the interpretation of these two Committees; supports the idea of offering interpretation capacities to other institutions during off-peak times;
13. Takes note of the interinstitutional cooperation arrangement between the Parliament, the European Economic and Social Committee and the Committee of the Regions, signed on 5 February 2014; requests detailed information on the financial impact and the progress of the implementation of this agreement to be provided to the Committee on Budgets by early 2015, having regard to the preparation of the estimates for the budget 2016;
14. Welcomes internal measures leading to efficiency savings in the Parliament's budget, such as the development of a system of translation based on Members' demands for committee amendments, a system of on-request interpretation for meetings other than the Plenary, the implementation of a paperless Parliament, proposals for a more efficient structure of the working rhythm of the Parliament and migration from Streamline to Sysper2 system;
15. Underlines that the statutory and compulsory expenditure needed for 2015 must be covered; considers that a final decision can only be taken by the new legislature, in autumn, once the exact amounts will be known;

Specific issues

16. Stresses that structural economic measures undertaken throughout the seventh legislature have led to significant savings in the Parliament's budget, such as EUR 15 million and EUR 10 million annually in the field of interpretation and translation respectively, an additional EUR 4 million in travel expenses and EUR 28 million of savings of interest by pre-financing buildings; notes that further savings are anticipated in 2015, namely EUR 1,9 million from the transfer of the management of the Members' pensions to the Commission and EUR 1,5 million in buildings;
17. Emphasises the fact that institutional self-restraint in the seventh legislature, considering the level of relevant inflation rates, has resulted in a reduction of Parliament's budget in real terms for 2012 and 2014; notes that once exceptional and non-recurrent expenditure, such as Union enlargements or other expenditure linked to the entry in force of the Treaty of Lisbon, European elections and the financing of building projects were taken out, it showed a decrease in five years out of six (2009, 2011, 2012, 2013 and 2014); stresses, furthermore, that the Members' allowances have been frozen since 2011, the travel expenditure for Members and staff have been reduced by 5 % and the staff mission allowances have not been indexed since 2007;

Thursday 17 April 2014

18. Considers the note of the Secretary-General of November 2013 on the Implementation of the Staff Regulations and the reform and revision of the rules and procedures deriving from them; insists that the rules on parental leave are implemented correctly;

19. With reference to its abovementioned resolution of 23 October 2013 on the draft general budget of the European Union for the financial year 2014, notes that in order to comply with the 1 % annual staffing level reduction, the General Secretariat of the Parliament will decrease its number of staff and that any new tasks will be met through available human resources and redeployment;

20. Reiterates Parliaments' responsibility to act in a sustainable way; welcomes the efforts made in order to achieve a paperless environment and the on-going valuable work realised through the EMAS approach; believes that the EMAS process needs continued support;

21. Takes into consideration the conclusions of the Joint Bureau — Committee on Budgets Working Group on the Parliament budget to pursue structural and organisational reforms; notes, in that regard, that the provision of independent scientific advice and the capacity to exercise scrutiny, as well as support to the Members, should be further improved to strengthen Parliament's work as an institution vested with legislative and democratic scrutiny powers; stresses that these objectives shall be implemented in a financially responsible manner and that the Secretary-General should set out clearly a detailed plan, to be presented to the Committee on Budgets, on how these objectives will be met and the budgetary impact they will have before the Parliament's reading of the budget for 2015;

22. Regrets the freezing of allocations for political groups; political groups are indispensable contributors when it comes to Parliament's legislative and non-legislative work and its exercise of scrutiny;

23. Stresses that in order to address the development of these four areas of activities in a financially responsible manner, the Joint Working Group has identified seven areas where Parliament can improve its efficiency:

- (i) Develop a system of translation on demand by Members of committee amendments,
- (ii) Explore possibilities for interinstitutional cooperation with the Committee of the Regions and the European Economic and Social Committee,
- (iii) Explore the offer of interpretation capacities to other institutions during off-peak times,
- (iv) Migration from the present human resources management system, Streamline, to Sysper2,
- (v) Prepare for the more efficient structure of the working rhythm of the Parliament,
- (vi) Prepare for a paperless Parliament, wherever possible, through best practice and the full implementation of the e-meetings project,
- (vii) Develop a system of on-request interpretation for meetings other than the Plenary;

24. Admitting the importance of efficiency and cost-effectiveness in the field of interpretation, recalls that these aspects must not erode the availability of live and accessible information across the Union, considering that multilingualism and interpretation for web-streaming and Parliament transparency are of key importance for the public and thus for the Members of the Parliament;

25. Believes that some of the ICT expenditure benefitting Members directly could be financed through the Members' general expenditure allowance;

26. Reiterates that long-term investments, such as Parliament's building projects, need to be handled prudently and transparently; insists on strict cost management, project planning and supervision; reiterates its call for a transparent decision-making process in the field of buildings policy, based on early information; calls for a detailed analysis and update of the Parliament's property policy adopted by the Bureau in March 2010 and an overview of the investments made per year and per building under the 2009-2014 legislature to be presented to the Committee on Budgets by August 2014 at the latest, reiterates its request for precise information on the progress of buildings projects and its financial implication to be provided every six months;

Thursday 17 April 2014

27. Takes note of the fact that the opening of the European House of History is foreseen at the end of 2015; awaits the updated information on the state-of-play of the project from the Secretary-General and the Bureau to be presented in due time before the Parliament's reading in autumn 2014; reiterates the commitment that the final cost outturn should not exceed the figures set out in its business plan;

28. Recalls that on 10 June 2013, the Bureau endorsed the Secretary-General's proposals for immediate and phase-in measures in order to modernise the Parliament's 2014-2019 catering policy; calls, therefore, on the Bureau to present to the Committee on Budgets a clear evaluation of possible budgetary implications of this reform for the 2015 budget and beyond in due time for the preparation of the Parliament's reading of the budget for 2015;

29. Calls on the Secretary-General to report to the Committee on Budgets on the implementation and the financial impact of the new global security concept by spring 2015; requests detailed information on the financial consequences of the creation of the new Directorate-General for Security in 2013; calls for information on the financial consequences of the interinstitutional administrative cooperation arrangements in the field of security;

30. Takes note of the creation of the new Directorate-General for Parliamentary Research Services on 1 November 2013; recalls that it was created in a budgetary neutral way by redeployments from DGs PRES and IPOL and that the new Directorate-General will not require new human or financial resources in 2015; calls for information on the number of posts in the new Directorate in August/September 2014, including the planned transfer of posts from the two European Advisory Committees, as compared to the situation in January 2014 and asks for a breakdown of how its external expertise resources are to be used, which should be presented to the Committee on Budgets in due time for the preparation of the Parliament's reading of the budget for 2015;

Final considerations

31. Adopts the estimates for the financial year 2015;

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32. Instructs its President to forward this resolution and the estimates to the Council and the Commission.

Thursday 17 April 2014

P7_TA(2014)0451

Infringements of competition law *I**

European Parliament legislative resolution of 17 April 2014 on the proposal for a directive of the European Parliament and of the Council on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union (COM(2013)0404 — C7-0170/2013 — 2013/0185(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/119)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0404),
 - having regard to Article 294(2) and Articles 103 and 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0170/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 16 October 2013 ⁽¹⁾,
 - having regard to the undertaking given by the Council representative by letter of 26 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Economic and Monetary Affairs and the opinions of the Committee on Legal Affairs and the Committee on the Internal Market and Consumer Protection (A7-0089/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0185

Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2014/104/EU.)

⁽¹⁾ OJ C 67, 6.3.2014, p. 83.

Thursday 17 April 2014

P7_TA(2014)0452

Shipments of waste ***I

European Parliament legislative resolution of 17 April 2014 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1013/2006 on shipment of waste (COM(2013)0516 — C7-0217/2013 — 2013/0239(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/120)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0516),
 - having regard to Article 294(2) and Article 192(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0217/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of European Economic and Social Committee of 10 December 2013 ⁽¹⁾,
 - having regard to the opinion of the Committee of the Regions of 30 January 2014 ⁽²⁾,
 - having regard to the undertaking given by the Council representative by letter of 12 March 2014 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0069/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Takes note of the Commission statement annexed to this resolution;
 3. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0239

Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council amending Regulation (EC) No 1013/2006 on shipments of waste

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) No 660/2014.)

⁽¹⁾ Not yet published in the OJ.

⁽²⁾ Not yet published in the OJ.

Thursday 17 April 2014

ANNEX TO THE LEGISLATIVE RESOLUTION

Commission statement

The Commission intends to make use of its prerogative to adopt guidance including on risk assessment for inspection plans and, as necessary, electronic data interchange.

Thursday 17 April 2014

P7_TA(2014)0453

New psychoactive substances *I**

European Parliament legislative resolution of 17 April 2014 on the proposal for a regulation of the European Parliament and of the Council on new psychoactive substances (COM(2013)0619 — C7-0272/2013 — 2013/0305(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/121)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0619),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0272/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the United Kingdom House of Commons and the United Kingdom House of Lords, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 21 January 2014 ⁽¹⁾,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0172/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0305

Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on new psychoactive substances

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

⁽¹⁾ OJ C 177, 11.6.2014, p. 52.

Thursday 17 April 2014

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) New psychoactive substances, which may have numerous commercial and industrial uses, as well as scientific uses, can pose health, social and safety risks when consumed by humans.
- (2) During the past years, Member States have notified an increasing number of new psychoactive substances via the mechanism for rapid exchange of information which was established by Joint Action 97/396/JHA ⁽³⁾ and was further strengthened by the Council Decision 2005/387/JHA ⁽⁴⁾. A large majority of these new psychoactive substances were reported by more than one Member State. Many such new psychoactive substances were sold to consumers without appropriate labelling and instructions of use.
- (3) Member States' competent public authorities introduce various restriction measures on these new psychoactive substances to address the risks that they pose or may pose when consumed. As new psychoactive substances are often used **for scientific research and development purposes and** in the production of various goods or of other substances which are used for manufacturing goods, such as medicines, industrial solvents, cleaning agents, goods in the hi-tech industry, restricting their access for this use can have an important impact on economic operators, potentially disrupting their business activities in the internal market **and can also impede sustainable scientific research and development.** [Am. 1]
- (4) The increasing number of new psychoactive substances available in the internal market, their growing diversity, the speed with which they emerge on the market, the different risks that they may pose when consumed by humans, ~~and~~ the growing number of individuals who consume them **and the lack of general public knowledge and awareness about the risks associated with their consumption**, challenge the capacity of public authorities to provide effective responses to protect public health and safety without hampering the functioning of the internal market. [Am. 2]
- (5) ~~Restriction~~ **As conditions and circumstances differ in Member States with regard to psychoactive substances, restriction** measures vary ~~significantly~~ **accordingly** in different Member States, meaning that economic operators that use them in the production of various goods must comply, in the case of the same new psychoactive substance, with different requirements, such as pre-export notification, export authorisation, or import and export licences. Consequently, the differences between the Member States' laws, regulations and administrative provisions on new psychoactive substances **could potentially hinder to some extent** the functioning of the internal market, by causing obstacles to trade, market fragmentation, lack of legal clarity and of an even level playing field for economic operators, making it **more** difficult for companies to operate across the internal market. [Am. 3]
- (6) Restriction measures **could** not only cause barriers to trade in the case of new psychoactive substances that already have commercial, industrial or scientific uses, but ~~can~~ **could** also impede the development of such uses, and are likely to cause obstacles to trade for economic operators that seek to develop such uses, by making access to those new psychoactive substances more difficult. [Am. 4]

⁽¹⁾ OJ C 177, 11.6.2014, p. 52.

⁽²⁾ Position of the European Parliament of 17 April 2014.

⁽³⁾ Joint Action 97/396/JHA of 16 June 1997 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, concerning the information exchange, risk assessment and the control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

⁽⁴⁾ Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

Thursday 17 April 2014

- (7) The disparities between the various restriction measures applied to new psychoactive substances ~~can~~, **while they are legitimate since they respond to each Member State's particularities with regard to psychoactive substances, could** also lead to displacement of harmful new psychoactive substances between the Member States, hampering efforts to restrict their availability to consumers and undermining consumer protection across the Union, **if efficient information exchange and coordination among Member States is not strengthened.** [Am. 5]
- (7a) **Such disparities facilitate illegal trafficking in such substances by criminals, in particular organised criminal gangs.** [Am. 6]
- (8) Such disparities are expected to ~~increase~~ **continue** as Member States ~~continue to pursue~~ **adopt** divergent approaches to addressing **challenges with regard to** new psychoactive substances. Therefore, the obstacles to trade and market fragmentation, and the lack of legal clarity and of a level playing field are expected to ~~increase~~ **continue**, further hindering the functioning of the internal market **if Member States do not coordinate and cooperate more efficiently.** [Am. 7]
- (9) ~~These~~ **Where** distortions to the functioning of the internal market **are identified they** should be ~~eliminated~~ **addressed** and, to that end, the rules relating to new psychoactive substances that are of concern at Union level should be approximated, while, at the same time, ensuring a high level of health, safety and consumer protection **and flexibility for Member States to respond to local situations.** [Am. 8]
- (10) New psychoactive substances and mixtures should be able to move freely in the Union when intended for commercial and industrial use, as well as for scientific research and development, **by duly authorised persons in establishments which are directly under the control of Member States' authorities or specifically approved by them.** This Regulation should ~~establish rules for introducing restrictions to this free movement.~~ [Am. 9]
- (11) New psychoactive substances that pose health, social and safety risks across the Union should be addressed at the Union level. Action on new psychoactive substances under this Regulation should contribute to a high level of protection of human health and safety, as enshrined in the Charter of Fundamental Rights of the European Union.
- (12) This Regulation should not apply to drug precursors because the diversion of those chemical substances for the purpose of manufacturing narcotic drugs or psychotropic substances is addressed under Regulation (EC) No 273/2004 of the European Parliament and of the Council ⁽¹⁾ and Council Regulation (EC) No 111/2005 ⁽²⁾.
- (13) Any Union action on new psychoactive substances should be based on scientific evidence and subject to a specific procedure. Based on the information notified by Member States, a report should be drawn up on new psychoactive substances that give rise to concerns across the Union. The report should indicate whether it is necessary to carry out a risk assessment. Following the risk assessment, the Commission should determine whether the new psychoactive substances should be subjected to any restriction measures. In case of immediate public health concerns, the Commission should subject them to temporary consumer market restriction before the conclusion of the risk assessment. In case new information emerges on a new psychoactive substance, the Commission should re-assess the level of risks that it poses. Reports on new psychoactive substances should be made publicly available.
- (14) No risk assessment should be conducted under this Regulation on a new psychoactive substance if it is subject to an assessment under international law, or if it is an active substance in a medicinal product or in a veterinary medicinal product, **unless there are sufficient data available at Union level to suggest the need for a joint report of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol.** [Am. 10]

⁽¹⁾ Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

⁽²⁾ Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).

Thursday 17 April 2014

- (15) Where the new psychoactive substance on which a report is drawn up is an active substance in a medicinal product or in a veterinary medicinal product, the Commission should assess with the European Medicines Agency the need for further action.
- (16) The measures taken on new psychoactive substances at Union level should be proportionate to the health, social and safety risks that they pose.
- (17) Certain new psychoactive substances pose immediate public health risks, requiring urgent action. Therefore, their availability to consumers should be restricted for a ~~limited~~ **sufficient period of** time, pending their risk assessment **and until the level of risk posed by a new psychoactive substance has been determined and, if justified, a decision introducing permanent market measures has entered into force.** [Am. 11]
- (18) ~~No~~ **On the basis of existing evidence and on predefined criteria, no** restriction measures should be introduced at Union level on new psychoactive substances which pose low health, social and safety risks, **but Member States may introduce further measures that are deemed appropriate or necessary depending on the specific risks that a substance poses in their territories taking into account national circumstances and any social, economic, legal, administrative or other factor they may consider relevant.** [Am. 12]
- (19) ~~These~~ **On the basis of the existing evidence and of predefined criteria, those** new psychoactive substances which pose moderate health, social and safety risks should not be made available to consumers. [Am. 13]
- (20) ~~These~~ **On the basis of the existing evidence and of predefined criteria, those** new psychoactive substances which pose severe health, social and safety risks should not be made available on the market. [Am. 14]
- (21) This Regulation should provide for exceptions in order to ensure the protection of human and animal health, to facilitate scientific research and development, and to allow the use of new psychoactive substances in industry, provided that they **are not liable to have adverse effects and that they** cannot be abused or recovered. [Am. 15]
- (21a) **Member States should take appropriate measures to prevent the diversion to the illicit market of new psychoactive substances used for research and development purposes or for any other authorised uses.** [Am. 16]
- (22) In order to ensure the efficient implementation of this Regulation, the Member States should lay down rules on the sanctions applicable to infringements of restriction measures. Those sanctions should be effective, proportionate and dissuasive.
- (23) The EMCDDA established by Regulation (EC) No 1920/2006 of the European Parliament and of the Council⁽¹⁾ should have a central role in the exchange **and coordination** of information on new psychoactive substances and in the assessment of the health, social and safety risks that they pose. **Given that within the scope of this Regulation there is an increase in the amount of information expected to be collected and managed by EMCDDA, specific support should be envisaged and provided.** [Am. 17]
- (24) The mechanism for rapid exchange of information on new psychoactive substances (**the ‘European Union Early Warning System on New Psychoactive Substances’ (‘EWS’)**) has proved to be a useful channel for sharing information on new psychoactive substances, on new trends in the use of controlled psychoactive substances and on related public health warnings. ~~That mechanism should be further strengthened to~~ **To** enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union, **the mechanism should be maintained and further developed, in particular as regards to the collection and management of data on the detection and identification of new psychoactive substances, adverse events associated with their use, and the involvement of criminal groups in the market through the Union new psychoactive substances database (the ‘European Database on New Drugs’).** **The media, particularly scientific and medical literature, can be an important source of information on adverse event case reports. In order to enhance the efficiency of reporting, the**

⁽¹⁾ Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (OJ L 376, 27.12.2006, p. 1).

Thursday 17 April 2014

EMCDDA should monitor all new psychoactive substances and enter this information in the European Database on New Drugs. Data sets essential to the functioning of this Regulation include data on the detection and identification of new psychoactive substances, adverse events associated with their use, and the involvement of criminal groups in the market. A core data set should be defined. The core data set should be reviewed on a regular basis to ensure that it reflects the information required for the effective functioning of this Regulation. Suspected serious adverse events, including fatal adverse events, should be subject to expedited reporting. [Am. 18]

- (24a) *In order to allow Member States to receive, access simultaneously and share information on new psychoactive substances in the Union, the European Database on New Drugs should be fully and permanently accessible to the Member States, the EMCDDA, Europol and the Commission. [Am. 19]*
- (24b) *The EMCDDA should issue health alerts to all Member States, through the system for rapid exchange of information on new psychoactive substances if, on the basis of information received on a new psychoactive substance, that substance seems to cause public health concerns. Those health alerts should also contain information regarding prevention, treatment and harm reduction measures that could be taken to address the risks associated with the substance. [Am. 20]*
- (24c) *In order to protect public health, the EWS activities of EMCDDA and Europol should be adequately funded. [Am. 21]*
- (25) Information from Member States is crucial for the effective functioning of the procedures leading to decision on market restriction of new psychoactive substances. Therefore, Member States should **monitor and** collect, on a regular basis, data on the **emergence and** use of **any** new psychoactive substances, related health, safety and social problems and policy responses, in accordance with the EMCDDA framework for data collection for the key epidemiological indicators and other relevant data. They should share ~~this~~ **those** data **notably with the EMCDDA, Europol and the Commission.** [Am. 22]
- (25a) *Information on new psychoactive substances provided by and exchanged among Member States is crucial for their national health policies, both in terms of drug prevention and of the treatment for psychoactive drug users in recovery services. Member States should make use of all the available information in an effective manner and monitor the relevant developments. [Am. 23]*
- (26) A lack of capacity to identify and anticipate the emergence and spread of new psychoactive substances and a lack of evidence about their health, social and safety risks hamper the provision of an effective response. Therefore, support **and the necessary resources** should be provided, including at Union **and national** level, to facilitate **regular and systematic** cooperation between the EMCDDA, **National Focal Points, health care and law enforcement representatives at national and regional level**, research institutes and forensic laboratories with relevant expertise, in order to increase the capacity to assess and address effectively new psychoactive substances. [Am. 24]
- (26a) *Appropriate safeguards, such as data anonymisation, should be put in place in order to ensure a high level of protection of personal data, in particular when sensitive data are collected and shared. [Am. 25]*
- (27) The procedures for information exchange, risk assessment and adoption of temporary and permanent restriction measures on new psychoactive substances established by this Regulation should enable swift action. Market restriction measures should be adopted without undue delay, not later than eight weeks from receipt of the joint report or risk assessment report.

Thursday 17 April 2014

- (28) As long as the Union has not adopted measures to subject a new psychoactive substance to market restriction under this Regulation, Member States may adopt technical regulations on that new psychoactive substance in compliance with the provisions of Directive 98/34/EC of the European Parliament and of the Council ⁽¹⁾. In order to preserve the unity of the Union's internal market and to prevent the emergence of unjustified barriers to trade, Member States should immediately communicate to the Commission any draft technical regulation on new psychoactive substances, in accordance with the procedure established by Directive 98/34/EC.
- (28a) Children and adolescents are particularly vulnerable to the dangers presented by such substances, the risks of which are still largely unknown. [Am. 26]**
- (29) Prevention, **early detection and intervention**, treatment, **risk** and harm reduction measures are important for addressing the growing use of new psychoactive substances and their potential risks. **Member States should improve the availability and effectiveness of prevention programmes and raise awareness about the risk of the use of new psychoactive substances and related consequences. To that end, prevention measures should include early detection and intervention, promotion of healthy lifestyles and targeted prevention directed also at families and communities.** The internet, which is one of the important **and rapidly developing** distribution channels through which new psychoactive substances are **advertised and** sold, should be used for disseminating information on the health, social and safety risks that they pose, **and for the prevention of misuse and abuse. It is essential for children, adolescents and young adults to be made aware of those risks, including by means of information campaigns in schools and other educational environments.** [Am. 27]
- (29a) The Commission and the Member States should also promote educational and awareness-raising activities, initiatives and campaigns, targeting the health, social and safety risks associated with the misuse and abuse of new psychoactive substances. [Am. 28]**
- (30) Medicinal products and veterinary medicinal products are addressed under Directive 2001/82/EC of the European Parliament and of the Council ⁽²⁾, Directive 2001/83/EC of the European Parliament and of the Council ⁽³⁾ and Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽⁴⁾. Their abuse or misuse should, therefore, not be covered by this Regulation.
- (30a) The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the criteria regarding low, moderate and severe risk substances. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. [Am. 29]**

⁽¹⁾ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society Services (OJ L 204, 21.7.1998, p. 37).

⁽²⁾ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 67).

⁽³⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 1).

⁽⁴⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Thursday 17 April 2014

- (31) In order to ensure uniform conditions for the implementation of temporary and permanent market restrictions, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (32) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to a rapid increase in the number of reported fatalities **and severe health consequences or incidents posing a grave threat to health** in several Member States associated with the consumption of the new psychoactive substance concerned, imperative grounds of urgency so require. [Am. 30]
- (33) In the application of this Regulation, the Commission should consult Member States' experts, relevant Union agencies, **in particular the EMCDDA**, civil society ~~and~~, economic operators **and any other relevant stakeholder**. [Am. 31]
- (34) Since the objectives of the proposed action cannot be sufficiently achieved by the Member States, but can rather, by reason of the effects of the envisaged action, be better achieved at the Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (35) In order to establish uniform rules and ensure clarity of concepts and procedures, as well as to provide legal certainty for economic operators, it is appropriate to adopt this act in the form of a Regulation.
- (36) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union **and of the European Convention for the Protection of Human Rights and Fundamental Freedoms**, including the freedom to conduct a business, the right to property, **the right of access to preventive healthcare** and the right to ~~an effective remedy~~ **benefit from medical treatment**, [Am. 32]

HAVE ADOPTED THIS REGULATION:

CHAPTER I

Subject matter, scope, definitions

Article 1

Subject matter and scope

1. This Regulation establishes rules for restrictions to the free movement of new psychoactive substances in the internal market. For that purpose it sets up a mechanism for information exchange on, risk assessment and submission to market restriction measures of new psychoactive substances at Union level.
2. This Regulation shall not apply to scheduled substances as defined in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

Article 2

Definitions

For the purpose of this Regulation, the following definitions apply:

- (a) 'new psychoactive substance' means a natural or synthetic substance that, when consumed by a human, has the capacity to produce central nervous system stimulation or depression, resulting in hallucinations, alterations in motor function, thinking, behaviour, perception, awareness or mood, ~~which~~ **whether or not it** is intended for human consumption ~~or is~~

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Thursday 17 April 2014

~~likely to be consumed by humans even if not intended for them with the purpose of inducing one or more of the effects mentioned above, which is neither controlled under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, nor the 1971 United Nations Convention on Psychotropic Substances; it excludes alcohol, caffeine and tobacco, as well as tobacco products within the meaning of Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products⁽¹⁾; [Am. 33]~~

- (b) 'mixture' means a mixture or solution containing one or more new psychoactive substances;
- (c) 'medicinal product' means a product as defined in point 2 of Article 1 of Directive 2001/83/EC;
- (d) 'veterinary medicinal product' means a product as defined in point 2 of Article 1 of Directive 2001/82/EC;
- (e) 'marketing authorisation' means an authorisation to place a medicinal product or a veterinary medicinal product on the market, in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004;
- (f) 'making available on the market' means any supply of a new psychoactive substance for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (g) 'consumer' means any natural person who is acting for purposes which are outside his/her trade, business or profession;
- (h) 'commercial and industrial use' means any manufacture, processing, formulation, storage, mixing, production and sale to natural and legal persons other than consumers;
- (i) 'scientific research and development' means any scientific experimentation, analysis or research carried out under strictly controlled conditions, in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁽²⁾;
- (j) 'United Nations system' means the World Health Organisation, the Commission on Narcotic Drugs and the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances.

CHAPTER II

Free movement

Article 3

Free movement

New psychoactive substances and mixtures shall move freely in the Union for commercial and industrial use, as well as for scientific research and development purposes.

Article 4

Prevention of barriers to free movement

Inssofar as the Union has not adopted measures to subject a new psychoactive substance to market restriction under this Regulation, **or when the Commission pursuant to Article 11 has not adopted a restriction measure**, Member States may adopt technical regulations on such new psychoactive substance in accordance with Directive 98/34/EC.

⁽¹⁾ *Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products* (OJ L 194, 18.7.2001, p. 26).

⁽²⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.)

Thursday 17 April 2014

Member States shall immediately communicate to the Commission any such draft technical regulation on new psychoactive substances, in accordance with Directive 98/34/EC. [Am. 34]

CHAPTER III

Exchange and collection of information

Article 5

Information exchange

If a Member State has information relating to what appears to be a new psychoactive substance or mixture, its National Focal Points within the European Information Network on Drugs and Drug Addiction ('Reitox') and Europol National Units shall collect and provide in a timely manner to the EMCDDA and Europol the available information on the detection and identification, consumption and its patterns, serious intoxication or deaths, possible risks as well as the toxicity level, data concerning manufacture, extraction, importation, trade, distribution and its channels, trafficking, commercial and scientific use of substances that appear to be new psychoactive substances or mixtures.

The EMCDDA and Europol shall communicate that information immediately to Reitox and the Europol National Units ***and the European Medicines Agency.***

To enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union, the information exchange mechanism ('EWS') shall be maintained and further developed, in particular as regards to the collection and management of data on the detection and identification of new psychoactive substances. [Am. 35]

Article 6

Joint report

1. Where the EMCDDA and Europol, or the Commission, consider that the information shared on a new psychoactive substance notified by several Member States gives rise to concerns across the Union because of the health, social and safety risks that the new psychoactive substance may pose, ***or in response to a reasoned request from more than one Member State,*** the EMCDDA and Europol shall draw up a joint report on the new psychoactive substance.

2. The joint report shall contain the following information:

- (a) the nature of the risks that the new psychoactive substance poses when consumed by humans, ***including contraindications with other substances when available,*** and the scale of the risk to public health, as referred to in Article 9(1);
- (b) the chemical and physical identity of the new psychoactive substance, the methods and, if known, the chemical precursors used for its manufacture or extraction, and other new psychoactive substances with a similar chemical structure that have emerged ***or which may reasonably be expected to emerge, on the basis of scientific assessment;***
- (c) the commercial and industrial use of the new psychoactive substance, as well as its use for scientific research and development purposes;
- (d) the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product or veterinary medicinal product;
- (e) the involvement of criminal groups in the manufacture, distribution or trade in the new psychoactive substance, and any use of the new psychoactive substance in the manufacture of narcotic drugs or psychotropic substances;

Thursday 17 April 2014

- (f) whether the new psychoactive substance is currently under assessment, or has been under assessment, by the United Nations system;
- (g) whether the new psychoactive substance is subject to any restriction measures in the Member States;
- (h) any existing prevention and treatment measure in place to address the consequences of the use of the new psychoactive substance.

3. The EMCDDA and Europol shall request the National Focal Points and the Europol National Units to provide additional information on the new psychoactive substance. They shall provide that information within four weeks from receipt of the request.

4. The EMCDDA and Europol shall request the European Medicines Agency **which should consult the competent authorities for medicines of Member States**, to provide information on whether, in the Union or in any Member State, the new psychoactive substance is:

- (a) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation;
- (b) an active substance in a medicinal product or a veterinary medicinal product that is the subject of an application for a marketing authorisation;
- (c) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation, but the marketing authorisation has been suspended by the competent authority;
- (d) an active substance in an unauthorised medicinal product in accordance with Article 5 of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with point (c) of Article 10 of Directive 2001/82/EC.

Member States shall provide the European Medicines Agency with the above information **without undue delay**, if so requested by it.

The European Medicines Agency shall provide the information at its disposal within four weeks from receipt of the request from the EMCDDA.

5. The EMCDDA shall request the European Chemicals Agency, **the European Centre for Disease Prevention and Control (ECDC)** and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance. The EMCDDA shall respect the conditions on use of the information, which are communicated to the EMCDDA by the European Chemicals Agency, **the ECDC** and the European Food Safety Authority, including conditions on information and data security and protection of confidential **data, including sensitive data or** business information.

The European Chemicals Agency, **the ECDC** and the European Food Safety Authority shall provide the information and data at their disposal within four weeks from receipt of the request.

6. The EMCDDA and Europol shall submit the joint report to the Commission within eight weeks from the request for additional information referred to in paragraph 3.

When the EMCDDA and Europol collect information on mixtures or on several new psychoactive substances with similar chemical structure, they shall submit individual joint reports to the Commission within ten weeks from the request for additional information referred to in paragraph 3. **[Am. 36]**

CHAPTER IV

Risk assessment

Article 7

Risk assessment procedure and report

1. Within four weeks from the receipt of the joint report referred to in Article 6, the Commission may request the EMCDDA to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report. The risk assessment shall be conducted by the Scientific Committee of the EMCDDA.

Thursday 17 April 2014

2. The risk assessment report shall include an analysis of the criteria and of the information referred to in Article 10(2) to enable the Commission to determine the level of health, social and safety risks that the new psychoactive substance poses.
3. The Scientific Committee of the EMCDDA shall assess the risks during a special meeting. The Committee may be extended by not more than five experts, **including a psychologist specialising in addiction**, representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance. The Director of the EMCDDA shall designate them from a list of experts. The Management Board of the EMCDDA shall approve the list of experts every three years. The **European Parliament, the Council, the Commission, the EMCDDA, Europol and the European Medicines Agency** shall each have the right to nominate two observers.
4. The Scientific Committee of the EMCDDA shall carry out the risk assessment on the basis of information on the risks of the substance and on its uses, **such as its patterns and dosage**, including commercial and industrial uses, provided by the Member States, the Commission, the EMCDDA, Europol, the European Medicines Agency, the European Chemicals Agency, **the ECDC**, the European Food Safety Authority and on the basis of any other relevant scientific evidence. It shall take into consideration all opinions held by its members. The EMCDDA shall support the risk assessment and shall identify information needs, including targeted studies or tests.
5. The EMCDDA shall submit the risk assessment report to the Commission within twelve weeks from the date when it received the request from the Commission.
6. Upon request of the EMCDDA, the Commission may extend the period to complete the risk assessment by no more than twelve weeks to allow for additional research and data collection to take place. The EMCDDA shall submit such a request to the Commission within six weeks from the launch of the risk assessment. If within two weeks of such request being made the Commission has not objected to such request, the risk assessment shall be so extended. [Am. 37]

Article 8

Exclusion from risk assessment

1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation expert committee on drug dependence has published its critical review together with a written recommendation, except where there is significant **and concrete** information that is new or of particular relevance for the Union and that has not been taken into account by the United Nations system, **which is to be mentioned in the assessment report**. [Am. 38]
2. No risk assessment shall be carried out where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule it under the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or the 1971 Convention on Psychotropic Substances, except where there is significant **and concrete** information that is new or of particular relevance for the Union, **the reasons for which shall be indicated in the assessment report**. [Am. 39]
3. No risk assessment shall be carried out where the new psychoactive substance is:
 - (a) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation;
 - (b) an active substance in a medicinal product or a veterinary medicinal product that is the subject of an application for a marketing authorisation;
 - (c) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation, but the marketing authorisation has been suspended by the competent authority.
4. **However, the risk assessment shall be carried out if at Union level there are sufficient data available to suggest the need for a joint report of the EMCDDA and Europol**. [Am. 40]

Thursday 17 April 2014

CHAPTER V

Market restrictions

Article 9

Immediate risks to public health and temporary consumer market restriction

1. Where it requests a risk assessment of a new psychoactive substance pursuant to Article 7(1), the Commission shall, by means of a Decision, prohibit the making available on the market to consumers of the new psychoactive substance if, based on existing information, it poses immediate risks to public health, evidenced by:

- (a) reported fatalities and severe health consequences associated with the consumption of the new psychoactive substance, **including contraindications with other substances when available**, in ~~several~~ Member States, related to the ~~serious acute~~ toxicity of the new psychoactive substance;
- (b) the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, in particular frequency, quantities and modality of use, its availability to consumers and the potential for diffusion, which indicate that the scale of the risk is considerable.

2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

On duly justified imperative grounds of urgency relating to a rapid increase in the number of reported fatalities in several Member States associated with the consumption of the new psychoactive substance concerned, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure laid down in Article 19(3).

3. The market restriction contained in the Decision referred to in paragraph 1 shall not exceed a period of twelve months. **If the level of health, social and safety risks posed by the new psychoactive substance justifies the introduction of permanent restriction measures, the duration of the temporary market restriction may be extended by a further 12 months, in the absence of permanent market restriction.** [Am. 41]

Article 10

Determination of the level of health, social and safety risks following the risk assessment

1. The Commission shall, **without undue delay**, determine the level of the health, social and safety risks posed by the new psychoactive substance on which a risk assessment report was drafted. It shall do so on the basis of all available evidence, in particular the risk assessment report.

2. The Commission shall take the following criteria into account when determining the level of risk of a new psychoactive substance:

- (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, **contraindications with other substances when available**, abuse liability and dependence-producing potential, in particular injury, disease, ~~and~~ **aggression, as well as** physical and mental impairment;
- (b) the social harm caused to individuals and to society, in particular **based on** its impact on social functioning, public order and criminal activities, organised crime activity associated with the new psychoactive substance, illicit profits generated by the production, trade and distribution of the new psychoactive substance, and associated economic costs of the social harm;
- (c) the risks to **public** safety, in particular **based on** the spread of diseases, including transmission of blood borne viruses, the consequences of physical and mental impairment on the ability to drive, the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment.

Thursday 17 April 2014

The Commission shall also take into account the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, its availability to consumers, its potential for diffusion, the number of Member States where it poses health, social and safety risks, the extent of its commercial and industrial use, and its use for scientific research and development purposes. [Am. 42]

Article 11

Low risks *at Union level*

The Commission shall not adopt restriction measures on a new psychoactive substance if, on the basis of *the* existing evidence *and of the following criteria*, it poses, overall, low health, social and safety risks, ~~in particular~~ *at Union level*:

- (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is ~~limited, as it provokes minor injury and disease, and minor physical or mental impairment~~ *insignificant*;
- (b) the social harm caused to individuals and to society is limited, in particular ~~regarding~~ *on the basis of* its impact on social functioning and public order, criminal activities associated with the new psychoactive substance are low, illicit profits generated by the production, trade and distribution of the new psychoactive substance and associated economic costs are non-existent or negligible;
- (c) the risks to *public* safety are limited, in particular *on the basis of a* low risk of spread of diseases, including transmission of blood borne viruses, non-existent or low consequences of physical and mental impairment on the ability to drive, and the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment is low.

Where the decision to not adopt restriction measures in relation to a new psychoactive substance that is considered to pose overall low health, social and safety risk at Union level was based on a partial or total lack of evidence, it shall include an appropriate reference in the justification. [Am. 43]

Article 12

Moderate risks and permanent consumer market restriction *at Union level*

1. The Commission shall, by means of a decision, without undue delay, prohibit the making available on the market to consumers of the new psychoactive substance if, on *the* basis of existing evidence *and of the following criteria*, it poses, overall, moderate health, social and safety risks, ~~in particular~~:

- (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is moderate, as it generally provokes non-lethal injury and disease, and moderate physical or mental impairment;
- (b) the social harm caused to individuals and to society is moderate, in particular ~~regarding~~ *on the basis of* its impact on social functioning and public order, producing public nuisance; criminal activities and organised crime activity associated with the substance are sporadic, illicit profits and economic costs are moderate;
- (c) the risks to *public* safety are moderate, in particular *on the basis of a* sporadic spread of diseases, including transmission of blood borne viruses, moderate consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials results in environmental nuisance.

2. The Commission shall adopt the decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

Thursday 17 April 2014

3. ~~Where the information or evidence available shows that the new psychoactive substance subject to the decision referred to in paragraph 1 poses a higher level of health, social and safety risks in a given Member State, in particular because of the modalities or scale of consumption of that substance or given the specific risks that the substance poses in its territory taking into account national circumstances and any social, economic, legal, administrative or other factor, Member States may maintain or introduce more stringent measures to ensure a high level of protection of public health.~~

4. ~~A Member State intending to maintain a more stringent measure concerning the new psychoactive substance in accordance with paragraph 3 shall immediately communicate the relevant laws, regulations or administrative provisions to the Commission and shall inform the other Member States thereof.~~

5. ~~A Member State willing to introduce a more stringent measure concerning the new psychoactive substance in accordance with paragraph 3 shall immediately communicate the relevant draft laws, regulations or administrative provisions to the Commission and shall inform the other Member States thereof.~~ [Am. 44]

Article 13

Severe risks and permanent market restriction **at Union level**

1. The Commission shall, by means of a decision, without undue delay, prohibit the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of the new psychoactive substance if, ~~based on existing evidence, it poses, overall, severe health, social and safety risks, in particular it poses severe health, social and safety risks, based on the existing evidence and on the following criteria:~~

- (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is ~~life-threatening~~ **severe**, as it generally provokes death or lethal injury, severe disease, and severe physical or mental impairment;
- (b) the social harm caused to individuals and to society is severe, in particular ~~regarding~~ **on the basis of** its impact on social functioning and public order, resulting in public order disruption, violent and anti-social behaviour causing damage to the user, to others and to property; criminal activities and organised crime activity associated with the new psychoactive substance are systematic ~~illicit profits, and economic costs are high;~~
- (c) the risks to **public** safety are severe, in particular **on the basis of a** significant spread of diseases, including transmission of blood borne viruses, severe consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials result in environmental harm.

2. The Commission shall adopt the decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2). [Am. 45]

Article 13a

Delegation of power

The Commission shall be empowered to adopt delegated acts in accordance with Article 20a to amend the criteria listed in Articles 11, 12 and 13. [Am. 46]

Article 14

Authorised uses

1. The Decisions referred to in Article 9(1) and Article 12(1) shall not impede the free movement in the Union and the making available on the market to consumers of new psychoactive substances that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation.

Thursday 17 April 2014

2. The Decisions referred to in Article 13(1) shall not impede the free movement in the Union and the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances:

- (a) for scientific research and development purposes, **by duly authorised persons in establishments which are directly under the control of Member States' authorities or specifically approved by them;**
- (b) for uses authorised under Union legislation;
- (c) that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation;
- (d) for use in the manufacture of substances and products provided that the new psychoactive substances are transformed in such a condition that they cannot be abused or recovered, **that the amount of each substance used is included in the information about the substance or the product.**

2a. For all authorised uses, new psychoactive substances and products containing new psychoactive substances shall include directions for use, including cautions, warnings and contraindications with other substances, to be either indicated on the label or included in the accompanying leaflet for the safety of the user.

3. The Decisions referred to in Article 13(1) may set requirements and conditions for the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances posing severe health, social and safety risks for the uses listed in paragraph 2.

4. Member States shall take any appropriate measures to prevent the diversion to the illicit market of new psychoactive substances used for research and development purposes or for any other authorised uses. [Am. 47]

CHAPTER VI

Monitoring and re-examination

Article 15

Monitoring

The EMCDDA and Europol, with the support of Reitox, shall monitor all new psychoactive substances on which a joint report has been drawn up.

Article 16

Re-examination of level of risks

Where new information and evidence is available on the risks posed by a new psychoactive substance the health, social and safety risks of which have already been determined in accordance with Article 10, the Commission shall request the EMCDDA to update the risk assessment report drafted on the new psychoactive substance and shall re-examine the level of risks that the new psychoactive substance poses.

CHAPTER VII

Sanctions and remedy

Article 17

Sanctions

Member States shall lay down the rules on sanctions applicable to infringements of the Decisions referred to in Article 9(1), Article 12(1) and Article 13(1) and shall take all necessary measures to ensure that they are implemented. The sanctions provided for shall be effective, proportionate and dissuasive. Member States shall notify those rules on sanctions and any subsequent amendment affecting those provisions to the Commission without delay.

Thursday 17 April 2014

Article 18

Remedy

Any person whose rights are affected by the implementation of a sanction taken by a Member State in accordance with Article 17 shall have the right to an effective remedy before a tribunal in that Member State.

CHAPTER VIII

PROCEDURES

Article 19

Committee

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

CHAPTER IX

Final Provisions

Article 20

Research and analysis, ~~and~~ prevention and funding

1. ~~The Commission and the Member States shall support~~ **Financial support and the necessary resources shall be provided at Union and national level for** the development, sharing and dissemination of information and knowledge on new psychoactive substances. ~~They~~ **The Commission and the Member States** shall do so by facilitating cooperation between the EMCDDA, other Union agencies, ~~and~~ scientific and research centres **and other bodies with relevant expertise, and by regularly providing those bodies with up-to-date information on such substances.**
2. **The Commission and the Member States shall also promote and support the research, including applied research into new psychoactive substances and ensure cooperation and coordination between networks at Union and national level in order to strengthen understanding of the phenomenon. They shall do so by facilitating cooperation between the EMCDDA, other Union agencies (in particular European Medicines Agency and European Chemicals Agency) and scientific and research centres. Emphasis shall be placed on developing forensic and toxicological capacity as well as on improving the availability of epidemiological information.**
3. **The Member States shall promote prevention schemes as well as, together with the Commission, measures to raise awareness of the risks posed by psychoactive substances, such as educational information campaigns.** [Am. 48]

Article 20a

Exercise of the delegation

1. **The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.**
2. **The power to adopt delegated acts referred to in Article 13a shall be conferred on the Commission for a period of ten years from ... (*)**. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the ten-year period. The delegation of powers shall be tacitly extended for a further period of ten years, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. **The delegation of powers referred to in Article 13a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.**

(*) Date of the entry into force of this Regulation.

Thursday 17 April 2014

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 13a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council. [Am. 49]

Article 21

Reporting

1. The EMCDDA and Europol shall report annually to the European Parliament, the Commission and Member States on the implementation of this Regulation. **The implementation reports shall be published on a website and made publicly available.**

2. **The Commission shall by ... (*) present to the European Parliament and Member States a report and, if justified, followed by a proposal for closing any identified loop-holes between Regulation (EC) No 1907/2006, Directive 2001/83/EC, Regulation (EC) No 726/2004 and this Regulation in order to make sure that psychotropic substances are properly regulated.** [Am. 50]

Article 22

Evaluation

By ..(**) at the latest and every five years thereafter, the Commission shall assess the implementation, application and effectiveness of this Regulation and shall publish a report. **In this respect, the Commission, the EMCDDA and Europol shall conduct post-risk assessments of new psychoactive substances.**

By ... (**) the Commission shall evaluate and, if appropriate, present a proposal for a possible classification of groups of new psychoactive substances in order to counteract the practice of bypassing the legislation in force by slight modifications of the chemical structure of the psychoactive substances. [Am. 51]

Article 23

Replacement of Decision 2005/387/JHA

Decision 2005/387/JHA is hereby repealed and replaced, without prejudice to the obligations of the Member States relating to the time limit for transposition of that Decision into national law. References to Decision 2005/387/JHA shall be construed as reference to this Regulation.

Article 24

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

The President

For the Council

The President

(*) Five years after entry into force of this Regulation.

(**) Five years after entry into force of this Regulation.

Thursday 17 April 2014

P7_TA(2014)0454

Criminal acts and penalties in the field of illicit drug trafficking *I**

European Parliament legislative resolution of 17 April 2014 on the proposal for a directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug (COM(2013)0618 — C7-0271/2013 — 2013/0304(COD))

(Ordinary legislative procedure: first reading)

(2017/C 443/122)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0618),
 - having regard to Article 294(2) and Article 83(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0271/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the United Kingdom House of Commons and the United Kingdom House of Lords, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0173/2014),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2013)0304

Position of the European Parliament adopted at first reading on 17 April 2014 with a view to the adoption of Directive 2014/.../EU of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 83(1) thereof,

Thursday 17 April 2014

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

- (1) Council Framework Decision 2004/757/JHA ⁽²⁾ provides a common approach to the fight against illicit drug trafficking, which poses a threat to the health, safety and quality of life of citizens of the Union, and to the legal economy, stability and security of the Member States. It sets out minimum common rules on the definition of drug trafficking offences and sanctions, to avoid that problems may arise in cooperation between the judicial authorities and law enforcement agencies of Member States, owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State.
- (1a) **Setting out minimum common rules across the Union on the definition of drug trafficking offences and sanctions should ultimately contribute to the protection of public health and the reduction of harm related to drug trafficking and consumption. [Am. 1]**
- (2) Framework Decision 2004/757/JHA applies to the substances covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the 1971 United Nations Convention on Psychotropic Substances ('UN Conventions'), as well as to the synthetic drugs subjected to control across the Union pursuant to Joint Action 97/396/JHA ⁽³⁾, which pose public health risks comparable to those posed by the substances scheduled under the UN Conventions.
- (3) Framework Decision 2004/757/JHA should also apply to the substances subjected to control measures and criminal penalties pursuant to Council Decision 2005/387/JHA ⁽⁴⁾, which pose public health risks comparable to those posed by the substances scheduled under the UN Conventions.
- (4) New psychoactive substances **such as products containing synthetic cannabinoid receptor agonists (CRAs)**, which imitate the effects of substances scheduled under the UN Conventions, are emerging frequently and are spreading fast in the Union. Certain new psychoactive substances pose severe **public** health, social and safety risks, as ascertained by Regulation (EU) No .../... of the European Parliament and of the Council ⁽⁵⁾. Under that Regulation, measures may be taken to prohibit the production, manufacture, making available on the market, including importation to the Union, transport, and exportation from the Union of new psychoactive substances posing severe health, social and safety risks. To effectively reduce the availability of new psychoactive substances that pose severe risks to individuals and society, and to deter trafficking in those substances across the Union, as well as the involvement of criminal organisations, **often generating considerable profit from illicit drug trafficking**, permanent market restriction measures adopted under that Regulation should be underpinned by **proportionate** criminal law provisions, **aimed solely at producers, suppliers and distributors rather than individual consumers**. [Am. 2]
- (4a) **To effectively reduce the demand for new psychoactive substances that pose severe health, social and safety risks, dissemination of evidence-based, public health information and early warnings to consumers should be an integral part of an inclusive and participatory strategy to prevent and reduce harm. [Am. 3]**

⁽¹⁾ Position of the European Parliament of 17 April 2014.

⁽²⁾ Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).

⁽³⁾ Joint Action 97/396/JHA of 16 June 1997 adopted by the Council on the basis of Article K.3 of the Treaty on European Union concerning the information exchange, risk assessment and the control of new synthetic drugs (OJ L 167, 25.6.1997, p. 1).

⁽⁴⁾ Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

⁽⁵⁾ Regulation (EU) No .../... of the European Parliament and of the Council of ... [on new psychoactive substances] (OJ L ...).

Thursday 17 April 2014

- (5) ~~The New psychoactive substances subjected to permanent market restriction pursuant to Regulation (EU) No .../... should, **once they have been added to the Annex to Framework Decision 2004/757/JHA**, therefore, be covered by Union criminal law provisions on illicit drug trafficking. This would also help streamline and clarify the Union legal framework, as the same criminal law provisions would apply to substances covered by the UN Conventions and to the most harmful new psychoactive substances. **In order to add such substances to the Annex, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the Annex and thereby the definition of 'drug' in Framework Decision 2004/757/JHA should, therefore, be amended. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.**~~ [Am. 4]
- (6) In order to swiftly address the emergence and spread of harmful new psychoactive substances in the Union, Member States should apply the provisions of Framework Decision 2004/757/JHA to new psychoactive substances ~~posing severe health, social and safety risks within twelve months from their submission~~ **which have been subject to permanent market restriction under restrictions on account of the severe health, social and safety risks which they pose, pursuant to Regulation (EU) No .../... within 12 months of those new psychoactive substances being added to the Annex to that Framework Decision.** [Am. 5]
- (6a) **This Directive, in accordance with the provisions of Framework Decision 2004/757/JHA which it amends, does not make provision for the criminalisation of the possession of new psychoactive substances for personal use, without prejudice to the right of Member States to criminalise the possession of drugs for personal use at national level.** [Am. 6]
- (6b) **The Commission should assess the impact of Framework Decision 2004/757/JHA on drug supply, including on the basis of information provided by Member States. For that purpose, Member States should provide detailed information on the distribution channels for psychoactive substances in their territory used for the supply of psychoactive substances intended for distribution in other Member States, such as specialised shops and online retailers, as well as on other characteristics of their respective drug markets. The European Monitoring Centre for Drugs and Drug Addiction should support the Member States in collecting and sharing accurate, comparable and reliable information and data on drug supply.** [Am. 7]
- (6c) **Member States should provide the Commission with data on various indicators of national law enforcement interventions within their territory, including dismantled drug production facilities, drug supply offences, national retail drug prices and forensic analyses of drug seizures.** [Am. 8]
- (7) Since the objective of this Directive, namely to extend the application of the Union criminal law provisions that apply to illicit drug trafficking to new psychoactive substances posing severe health, social and safety risks, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (8) This Directive respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, and notably the right to an effective remedy and to a fair trial, the presumption of innocence and the right of defence, the right not to be tried or punished twice in criminal proceedings for the same criminal offence ~~and~~, the principles of legality and proportionality of criminal offences, **the right of access to preventive healthcare and the right to benefit from medical treatment.** [Am. 9]
- (8a) **The Union and its Member States should further develop the Union approach based on fundamental rights, prevention, medical care and harm reduction, with the aim of helping drug users to overcome their addiction and at reducing the negative social, economic and public health impact of drugs.** [Am. 10]

Thursday 17 April 2014

- (9) [In accordance with Article 3 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the Area of Freedom, Security and Justice, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, the United Kingdom and Ireland have notified their wish to take part in the adoption and application of this Directive.]

AND/OR

- (10) [In accordance with Articles 1 and 2 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the Area of Freedom, Security and Justice, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, and without prejudice to Article 4 of that Protocol, the United Kingdom and Ireland are not taking part in the adoption of this Directive and are not bound by it or subject to its application.]
- (11) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Directive and is not bound by it or subject to its application.
- (12) Framework Decision 2004/757/JHA should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Framework Decision 2004/757/JHA is amended as follows:

- (1) In Article 1, point 1 is replaced by the following:

‘1. “drug” means: shall mean any of the following substances:

- (a) any of the substances covered by the 1961 United Nations Single Convention on Narcotic Drugs (as amended by the 1972 Protocol) and the 1971 United Nations Convention on Psychotropic Substances;
- (b) any of the substances listed in the Annex;
- (c) any ~~new psychoactive substance posing severe health, social and safety risks, subjected to permanent market restriction on the basis of [Article 13(1) of Regulation (EU) No .../... on new psychoactive substances]~~ **mixture or solution containing one or more substances listed under points (a) and (b);** [Am. 11]

- (1a) Article 2 is amended as follows:**

- (a) the introductory part of paragraph 1 is replaced by the following:**

‘1. Each Member State shall take the necessary measures to ensure that the following intentional conduct when committed without right as defined in national law is punishable;’ [Am. 12]

- (b) paragraph 2 is replaced by the following:**

‘2. The conduct described in paragraph 1 shall not be included within the scope of this Framework Decision when committed for personal use as defined by national law;’[Am. 13]

- (1b) The following Articles are inserted:**

‘Article 8a

Delegation of power

The Commission shall be empowered to adopt delegated acts to amend the Annex to this Framework Decision, in particular to add to the Annex new psychoactive substances subjected to permanent market restriction on the basis of Article 13(1) of Regulation (EU) No .../... of the European Parliament and of the Council (*). [Am. 15]

Thursday 17 April 2014

Article 8b**Exercise of delegation**

1. *The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.*

2. *The power to adopt delegated acts referred to in Article 8a shall be conferred on the Commission for a period of ten years from ... (+). The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the ten year period. The delegation of power shall be tacitly extended for a further period of ten years, unless the European Parliament or the Council opposes such extension not later than three months before the end of that period.*

3. *The delegation of powers referred to in Article 8a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.*

4. *As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.*

5. *A delegated act adopted pursuant to Article 8a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council. [Am. 16]*

(*) *Regulation (EU) No .../... of the European Parliament and of the Council of ... [on new psychoactive substances] (OJ L ...);*

(2) In Article 9, the following paragraphs are added:

'3. In respect of new psychoactive substances ~~subjected to permanent market restriction on the basis of [Article 13 (1) of Regulation (EU) No .../... on new psychoactive substances]~~ **added to the Annex to this Framework Decision**, Member States shall bring into force the laws, regulations and administrative provisions necessary to apply the provisions of this Framework Decision to these new psychoactive substances within twelve months after ~~the~~ entry into force of the ~~permanent market restriction~~ **amendment to the Annex**. They shall forthwith communicate to the Commission the text of those provisions. [Am. 14]

When Member States adopt those provisions, they shall contain a reference to this Framework Decision or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

4. By ... (+) and every five years thereafter, the Commission shall assess the extent to which the Member States have taken the necessary measures to comply with this Framework Decision and publish a report.;

(3) An Annex, as set out in the Annex to this Directive, is added.

(+) Date of the entry into force of this Directive.

(+) Five years after the entry into force of this Directive.

Thursday 17 April 2014

Article 2

Transposition

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ... (+) at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

Entry into force

This Directive shall enter into force on ... (+).

Article 4

Addressees

This Directive is addressed to the Member States in accordance with the Treaties.

Done at ...,

For the European Parliament

The President

For the Council

The President

(+) 12 months after the entry into force of this Directive.

(+) The day of entry into force of Regulation (EU) No .../... [on new psychoactive substances].

Thursday 17 April 2014

ANNEX

ANNEX

List of substances referred to in point (1)(b) of Article 1

- (a) P-Methylthioamphetamine or 4-Methylthioamphetamine, as referred to in Council Decision 1999/615/JHA ⁽¹⁾.
- (b) Paramethoxymethylamphetamine or N-methyl-1-(4-methoxyphenyl)-2-aminopropane, as referred to in Council Decision 2002/188/JHA ⁽²⁾.
- (c) 2,5-dimethoxy-4-iodophenethylamine, 2,5-dimethoxy-4-ethylthiophenethylamine, 2,5-dimethoxy-4-(n)-propylthiophenethylamine and 2,4,5-trimethoxyamphetamine, as referred to in Council Decision 2003/847/JHA ⁽³⁾.
- (d) 1-benzylpiperazine or 1-benzyl-1,4-diazacyclohexane or N-benzylpiperazine or benzylpiperazine as referred to in Council Decision 2008/206/JHA ⁽⁴⁾.
- (e) 4-methylmethcathinone, as referred to in Council Decision 2010/759/EU ⁽⁵⁾.
- (f) 4-methylamphetamine, as referred to in Council Decision 2013/129/EU ⁽⁶⁾.
- (g) 5-(2-aminopropyl)indole, as referred to in Council Implementing Decision 2013/496/EU ⁽⁷⁾.

⁽¹⁾ Council Decision 1999/615/JHA of 13 September 1999 defining 4-MTA as a new synthetic drug which is to be made subject to control measures and criminal penalties (OJ L 244, 16.9.1999, p. 1).

⁽²⁾ Council Decision 2002/188/JHA of 28 February 2002 concerning control measures and criminal sanctions in respect of the new synthetic drug PMMA (OJ L 63, 6.3.2002, p. 14).

⁽³⁾ Council Decision 2003/847/JHA of 27 November 2003 concerning control measures and criminal sanctions in respect of the new synthetic drugs 2C-I, 2C-T-2, 2C-T-7 and TMA-2 (OJ L 321, 6.12.2003, p. 64).

⁽⁴⁾ Council Decision 2008/206/JHA of 3 March 2008 on defining 1-benzylpiperazine (BZP) as a new psychoactive substance which is to be made subject to control measures and criminal provisions (OJ L 63, 7.3.2008, p. 45).

⁽⁵⁾ Council Decision 2010/759/EU of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures (OJ L 322, 8.12.2010, p. 44).

⁽⁶⁾ Council Decision 2013/129/EU of 7 March 2013 on subjecting 4-methylamphetamine to control measures (OJ L 72, 15.3.2013, p. 11).

⁽⁷⁾ Council Implementing Decision 2013/496/EU of 7 October 2013 on subjecting 5-(2-aminopropyl)indole to control measures (OJ L 272, 12.10.2013, p. 44).

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