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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2017/374

of 3 March 2017

implementing Regulation (EU) No 208/2014 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EU) No 208/2014 of 5 March 2014 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Ukraine [1], and in particular Article 14(1) and (4) thereof,

Having regard to the proposal from the High Representative of Foreign Affairs and Security Policy,

Whereas:

(1) On 5 March 2014, the Council adopted Regulation (EU) No 208/2014.

(2) On the basis of a review by the Council, the entry for one person listed in Annex I to Regulation (EU) No 208/2014 should be deleted.

(3) Annex I to Regulation (EU) No 208/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 208/2014 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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 Brussels, 3 March 2017.

For the Council
The President
M. FARRUGIA

[1] OJ L 66, 6.3.2014, p. 1.

ANNEX

In Annex I to Regulation (EU) No 208/2014, the entry relating to the following person is deleted:

16. Yuriy Volodymyrovych Ivanyushchenko

COMMISSION IMPLEMENTING REGULATION (EU) 2017/375

of 2 March 2017

renewing the approval of the active substance prosulfuron, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 24 in conjunction with Article 20(1) thereof,

Whereas:

(1) The approval of the active substance prosulfuron, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]), expires on 30 June 2017.

(2) An application for the renewal of the inclusion of prosulfuron in Annex I to Council Directive 91/414/EEC ([3]) was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 ([4]) within the time period provided for in that Article.

(3) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.

(4) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 15 July 2013.

(5) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(6) On 25 August 2014 the Authority communicated to the Commission its conclusion ([5]) on whether prosulfuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review report for prosulfuron to the Standing Committee on Plants, Animals, Food and Feed on 29 May 2015.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that the approval criteria provided for in Article 4 are satisfied. Those approval criteria are therefore deemed to be satisfied.

(8) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to restrict the use of plant protection products containing prosulfuron in order to minimise the exposure for groundwater by setting a maximum dose of 20 g of active substance per hectare, every third year on the same field and to require further confirmatory information.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).
([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).
([4]) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).
([5]) EFSA Journal (2014);12(9):3815. Available online: www.efsa.europa.eu

(9) The risk assessment for the renewal of the approval of prosulfuron is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing prosulfuron may be authorised. It is therefore appropriate not to maintain the restriction to uses as an herbicide.

(10) The Commission however considers that prosulfuron is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Prosulfuron is a persistent and toxic substance in accordance with points 3.7.2.1 and 3.7.2.3 respectively, of Annex II to Regulation (EC) No 1107/2009, given that the half-life in fresh water is greater than 40 days and the long-term no-observed effect concentration for freshwater organisms is less than 0,01 mg/L. Prosulfuron therefore fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

(11) It is therefore appropriate to renew the approval of prosulfuron as a candidate for substitution.

(12) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(13) Commission Implementing Regulation (EU) 2016/549 [1] extended the expiry date of prosulfuron in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has been taken ahead of the extended expiry date, this Regulation should apply from 1 May 2017.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance as a candidate for substitution

The approval of the active substance prosulfuron, as a candidate for substitution, is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of 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 1 May 2017.

[1] Commission Implementing Regulation (EU) 2016/549 of 8 April 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bentazone, cyhalofop butyl, diquat, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), metalaxyl-M, picolinafen, prosulfuron, pymetrozine, thiabendazole and thifensulfuron-methyl (OJ L 95, 9.4.2016, p. 4).

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

Done at Brussels, 2 March 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Prosulfuron CAS No 94125-34-5 CIPAC No 579	1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenyl-sulfonyl]-urea	950 g/kg The impurity 2-(3,3,3-trifluoro-propyl)-benzene sulphonamide shall not exceed 10 g/kg in the technical material	1 May 2017	30 April 2024	PART A Use shall be limited to one application every three years on the same field at a maximum dose of 20 g active substance per hectare. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prosulfuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — the risk to non-target terrestrial and aquatic plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (CGA150829) to confirm that this metabolite is not genotoxic and not relevant for risk assessment. The applicant shall submit that information to the Commission, the Member States and the Authority by 31 October 2017.

[1] Further details on identity and specification of active substance are provided in the review report.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 31 on prosulfuron is deleted;

(2) in Part E, the following entry is added:

	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'6	Prosulfuron CAS No 94125-34-5 CIPAC No 579	1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenyl-sulfonyl]-urea	950 g/kg The impurity 2-(3,3,3-tri-fluoro-propyl)-benzene sul-phonamide shall not exceed 10 g/kg in the technical material.	1 May 2017	30 April 2024	PART A Use shall be limited to one application every three years on the same field at a maximum dose of 20 g active substance per hectare. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prosulfuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to non-target terrestrial and aquatic plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (CGA150829) to confirm that this metabolite is not genotoxic and not relevant for risk assessment. The applicant shall submit that information to the Commission, the Member States and the Authority by 31 October 2017.'

(*) Further details on identity and specification of active substance are provided in the review report.

COMMISSION DELEGATED REGULATION (EU) 2017/376

of 3 March 2017

amending Delegated Regulation (EU) 2016/921 as regards reallocation of unused quantities notified pursuant to Article 2(4) of that Regulation

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 219(1) in conjunction with Article 228 thereof,

Whereas:

(1) On 7 August 2014 the government of the Russian Federation ('Russia') introduced a ban on imports of certain products from the Union to Russia, including fruit and vegetables. This import ban created a serious threat of market disturbances caused by significant price falls due to the fact that an important export market was no longer available. This import ban is extended until end of 2017. In such circumstances, threats of market disturbances in the Union remain real for certain specific products such as apples and pears and adequate measures need to be adopted and implemented for as long as the Russian ban remains in force.

(2) The threat of market disturbances is of particular relevance for the fruit and vegetables sector where large quantities of perishable products used to be exported to Russia. It has proved difficult to redirect the entire production to other destinations. Accordingly, a situation continues to exist on the Union market for which the normal measures available under Regulation (EU) No 1308/2013 appear to be insufficient.

(3) In order to prevent a severe and prolonged market disturbance, Commission Delegated Regulations (EU) No 913/2014 ([2]), (EU) No 932/2014 ([3]), (EU) No 1031/2014 ([4]) (EU) 2015/1369 ([5]) and (EU) 2016/921 ([6]) provided for maximum amounts of support for withdrawal, non-harvesting and green harvesting operations, calculated on the basis of traditional exports to Russia.

(4) Delegated Regulation (EU) 2016/921 also recognised that products covered by the scheme established by that Regulation, which were exported to Russia, could be diverted to the markets of other Member States. Producers of the same products within the Member States which did not traditionally export their products to Russia could therefore face significant market disturbance, in particular a price fall. In order to stabilise the market, Union financial assistance was therefore made available for producers in all Member States in respect of one or more of the products covered by that Regulation, but the quantity of the products concerned was not to exceed 3 000 tonnes per Member State.

(5) Member States remained free to decide to what extent they would use the quantity of 3 000 tonnes. Where they chose not to use this quantity, they were to notify the Commission of the unused quantity by 31 October 2016.

(6) By 31 October 2016, Germany, Denmark, Luxembourg, Slovakia, Slovenia, Austria and the United Kingdom formally notified the Commission that they decided not to use their quantities or parts thereof.

([1]) OJ L 347, 20.12.2013, p. 671.

([2]) Commission Delegated Regulation (EU) No 913/2014 of 21 August 2014 laying down temporary exceptional support measures for producers of peaches and nectarines (OJ L 248, 22.8.2014, p. 1).

([3]) Commission Delegated Regulation (EU) No 932/2014 of 29 August 2014 laying down further temporary exceptional support measures for producers of certain fruit and vegetables and amending Regulation (EU) No 913/2014 (OJ L 259, 30.8.2014, p. 2).

([4]) Commission Delegated Regulation (EU) No 1031/2014 of 29 September 2014 laying down further temporary exceptional support measures for producers of certain fruit and vegetables (OJ L 284, 30.9.2014, p. 22).

([5]) Commission Delegated Regulation (EU) 2015/1369 of 7 August 2015 amending Delegated Regulation (EU) No 1031/2014 laying down further temporary exceptional support measures for producers of certain fruit and vegetables (OJ L 211, 8.8.2015, p. 17).

([6]) Commission Delegated Regulation (EU) 2016/921 of 10 June 2016 laying down further temporary exceptional support measures for producers of certain fruit and vegetables (OJ L 154, 11.6.2016, p. 3).

(7) The quantities not used should therefore be reallocated. The reallocation should be based on transparent, objective and fair criteria. This should be best ensured by using as the basis for reallocation the share of each Member State in the total quantity as currently allocated in Annex I to Delegated Regulation (EU) 2016/921. To ensure that the allocation per Member State reaches at least 300 tonnes, for Cyprus, Croatia and Portugal the allocations should be increased from 85 tonnes to 300 tonnes, respectively. This measure is required as reallocation of quantities below 85 tonnes would create an undue administrative burden for national authorities, in particular as regards the checks and at the same time would not significantly affect the situation of the producers and that of the market.

(8) To ensure immediate impact on the market and to help stabilise prices in the Member States concerned, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union* and should apply as from that day until 30 June 2017,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2016/921 is amended as follows:

(1) Article 2 is amended as follows:

(a) In paragraph 1, the first subparagraph is replaced by the following:

'The financial assistance for support measures referred to in Article 1(1) shall be made available to Member States for the quantities of products set out in Annexes I and V.'

(b) The new paragraph 5 is added:

'5. Following the notifications referred to in paragraph 4, the notified unused quantities shall be reallocated among the Member States as set out in Annex V.

These reallocated quantities set out in Annex V shall be in addition to the quantities set out in the second sub-paragraph of paragraph 1.'

(2) In Article 3, the first paragraph is replaced by the following:

'Member States shall allocate the quantities referred to in Article 2(1) and (5) between producer organisations and producers who are not members of producer organisations following the first-come, first-served system.'

(3) Annex V is added, the text of which is set out in the Annex to this Regulation.

Article 2

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

It shall apply as from the day of its publication in the *Official Journal of the European Union* until 30 June 2017.

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

Done at Brussels, 3 March 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

'ANNEX V

Reallocated quantities of products allocated per Member State as referred to in Article 2

Member States	Reallocated quantities (tonnes)
Poland	7 720
Spain	3 015
Belgium	2 385
Greece	1 150
Italy	1 080
The Netherlands	1 065
France	365
Cyprus	300
Croatia	300
Portugal	300'

COMMISSION IMPLEMENTING REGULATION (EU) 2017/377

of 3 March 2017

concerning the non-approval of the active substance *Pseudozyma flocculosa* strain ATCC 64874 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 13(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ([2]) is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For *Pseudozyma flocculosa* strain ATCC 64874 the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2002/305/EC ([3]).

(2) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands (hereinafter 'the rapporteur Member State') received on 6 March 2001 an application from Maasmond-Westland for the inclusion of the active substance *Pseudozyma flocculosa* strain ATCC 64874 in Annex I to Directive 91/414/EEC. Decision 2002/305/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 11 March 2004.

(4) Artechno SA took over the responsibility of Maasmond-Westland on 4 June 2012 and in accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ([4]) additional information was requested from the applicant.

(5) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance *Pseudozyma flocculosa* strain ATCC 64874 ([5]) on 22 September 2015. The Authority identified several data gaps. In particular, it was not possible to conclude on the risk assessment for human health and aquatic organisms deriving from the use of *Pseudozyma flocculosa* strain ATCC 64874.

(6) Consequently, it was not possible to conclude on the basis of the information available that *Pseudozyma flocculosa* strain ATCC 64874 met the criteria for inclusion in Annex I to Directive 91/414/EEC.

(7) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with Article 9 of Regulation (EU) No 188/2011, the Commission invited the applicant to submit comments on the draft review report. The applicant submitted its comments, which have been carefully examined.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([3]) Commission Decision 2002/305/EC of 19 April 2002 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of clothianidin and *Pseudozyma flocculosa* in Annex I to Council Directive 91/414/EEC concerning the placing of plant-protection products on the market (OJ L 104, 20.4.2002, p. 42).

([4]) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).

([5]) *EFSA Journal* 2015;13(9):4250 [32 pp.]. Available online: www.efsa.europa.eu

(8) However, despite the arguments put forward by the applicant, the concerns referred to in recital 5 could not be eliminated. Consequently, it has not been demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874 satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(9) *Pseudozyma flocculosa* strain ATCC 64874 should therefore not be approved pursuant to Article 13(2) of Regulation (EC) No 1107/2009.

(10) In accordance with Article 8(1)(b) of Directive 91/414/EEC, Member States were given the possibility to grant provisional authorisations, for plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874 for an initial period of three years.

(11) Existing authorisations should consequently be withdrawn.

(12) Member States should be provided with time to withdraw authorisations for plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874.

(13) For plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 24 June 2018.

(14) This Regulation does not prejudice the submission of a further application for *Pseudozyma flocculosa* strain ATCC 64874 in accordance with Article 7 of Regulation (EC) No 1107/2009.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Non-approval of active substance

The active substance *Pseudozyma flocculosa* strain ATCC 64874 is not approved.

Article 2

Transitional measures

Member States shall withdraw existing authorisations for plant protection products containing *Pseudozyma flocculosa* strain ATCC 64874 as active substance by 24 June 2017 at the latest.

Article 3

Grace Period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 24 June 2018 at the latest.

Article 4

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 Brussels, 3 March 2017.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION REGULATION (EU) 2017/378

of 3 March 2017

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC ([1]), and in particular Article 11(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ([2]), and in particular Article 7(5) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved for use in and on foods and their conditions of use.

(2) Commission Implementing Regulation (EU) No 872/2012 ([3]) adopted a list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.

(3) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application submitted by a Member State or by an interested party.

(4) The Union list of flavourings and source materials contains a number of substances for which the European Food Safety Authority ('the Authority') has requested additional scientific data to be provided for completion of the evaluation before the deadlines established in Part A of Annex I to Regulation (EC) No 1334/2008.

(5) In the case of the substances belonging to the Flavouring Group Evaluation ('FGE 203') rev.1: the deadline of 31 December 2012 was established in the Union list for the submission of requested additional scientific data. The substances belonging to this FGE203 rev.1 are: deca-2,4-dien-1-ol (FL No 02.139), hepta-2,4-dien-1-ol (FL No 02.153), hexa-2,4-dien-1-ol (FL No 02.162), nona-2,4-dien-1-ol (FL No 02.188), hexa-2(trans),4(trans)-dienal (FL No 05.057), trideca-2(trans),4(cis),7(cis)-trienal (FL No 05.064), nona-2,4-dienal (FL No 05.071), 2,4-decadienal (FL No 05.081), hepta-2,4-dienal (FL No 05.084), penta-2,4-dienal (FL No 05.101), undeca-2,4-dienal (FL No 05.108), dodeca-2,4-dienal (FL No 05.125), octa-2(trans),4(trans)-dienal (FL No 05.127), deca-2(trans),4(trans)-dienal (FL No 05.140), deca-2,4,7-trienal (FL No 05.141), nona-2,4,6-trienal (FL No 05.173), 2,4-octadienal (FL No 05.186), tr-2,tr-4-nonadienal (FL No 05.194), tr-2,tr-4-undecadienal (FL No 05.196), and hexa-2,4-dienyl acetate (FL No 09.573). Such data has been submitted by the applicant.

(6) That chemical group includes hexa-2(trans),4(trans)-dienal (FL No 05.057) and deca-2(trans),4(trans)-dienal (FL No 05.140) which were used as representative substances for the group and for which toxicity data were submitted.

([1]) OJ L 354, 31.12.2008, p. 34.
([2]) OJ L 354, 31.12.2008, p. 1.
([3]) Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1).

(7) The Authority has evaluated the genotoxicity of these two representative substances in its scientific opinion of 26 March 2014 ([1]).

(8) For hexa-2(trans),4(trans)-dienal (FL No 05.057) it confirmed safety concerns based on the evidence from publications reporting the induction of DNA adducts in different systems *in vitro* and *in vivo*, the IARC classification as possible carcinogen to humans, considering the conclusion drawn by IARC that mechanistic data provide additional support for the relevance of the animal carcinogenicity data to humans and that there is a moderate evidence that tumour induction occurs via a genotoxic mechanism.

(9) For deca-2(trans),4(trans)-dienal (FL No 05.140) it came to the conclusion that a non-threshold mechanism of genotoxicity cannot be excluded on the basis that there is some indication for genotoxicity *in vivo* and considering the evidence from *in vitro* studies for the induction of different types of DNA damage (oxidised DNA bases and bulky adducts).

(10) Overall, the Authority concluded that the safety concern regarding genotoxicity cannot be ruled out for both representative substances of the group and that this conclusion is likewise applicable to the other substances of the FGE group 203.

(11) The parties concerned have indicated that they are undertaking a variety of toxicity studies on the substances in FGE group 203 responding to the concerns expressed by the Authority. In addition, the Commission has requested further information in order to fully evaluate the safety of those substances.

(12) The supporting parties submitted the studies and information on 26 September 2016.

(13) Pending the evaluation by the Authority of the substances in group FGE, the eventual full evaluation of these substances according to the EFSA CEF panel procedure and the completion of the subsequent regulatory process, it is appropriate to limit the conditions of use of those substances to their current use.

(14) Due to technical reasons, transitional periods should be laid down to cover food not complying with the conditions set out in the Annex, which has been placed on the Union market or dispatched from third countries for the Union before the entry into force of this Regulation.

(15) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Part A of Annex I to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

Article 2

1. Foods to which any of the flavouring substances listed in the Annex to this Regulation have been added which do not comply with the conditions set out in that Annex and which have been lawfully placed on the market before the entry into force of this Regulation, may be marketed until their date of minimum durability or use by date.

([1]) Scientific Opinion on Flavouring Group Evaluation 203 Rev 1 (FGE.203 Rev1): alpha,beta-unsaturated aliphatic aldehydes and precursors from chemical subgroup 1.1.4 of FGE.19 with two or more conjugated double-bonds and with or without additional non-conjugated double-bonds. *EFSA Journal* 2014;12(4):3626, 31 pp. doi:10.2903/j.efsa.2014.3626. Available online: www.efsa.europa.eu/efsajournal

2. Foods to which any of the flavouring substances listed in the Annex to this Regulation have been added, and which do not comply with the conditions set out in that Annex and which have been imported into the Union from a third country may be marketed until their date of minimum durability or use by date where the importer of such foods can demonstrate that they were dispatched from the third country concerned and were *en route* to the Union before the entry into force of this Regulation.

3. The transitional periods provided in paragraphs 1 and 2 shall not apply to mixtures of flavourings.

Article 3

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 Brussels, 3 March 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Table 1 of Section 2 of Part A of Annex I to Regulation (EC) No 1334/2008 is amended as follows:

(a) the entry for FL No 02.139 is replaced by the following:

'02.139	Deca-2,4-dien-1-ol	18409-21-7	1189	11748		Restrictions of use as a flavouring substance: In category 2 — not more than 1,5 mg/kg, in category 3 — not more than 5 mg/kg, in category 5 — not more than 9 mg/kg, in category 7 — not more than 15 mg/kg, in category 8 — not more than 5 mg/kg, in category 12 — not more than 3 mg/kg, in category 14.1 — not more than 2 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 16 — not more than 2 mg/kg.	1	EFSA'

(b) the entry for FL No 02.153 is replaced by the following:

'02.153	Hepta-2,4-dien-1-ol	33467-79-7	1784			Restrictions of use as a flavouring substance: In category 1 — not more than 35 mg/kg, in category 2 — not more than 25 mg/kg, in category 3 — not more than 30 mg/kg, in category 4.2 — not more than 50 mg/kg, in category 5 — not more than 50 mg/kg, in category 6 — not more than 25 mg/kg, in category 7 — not more than 50 mg/kg, in category 8 — not more than 10 mg/kg, in category 9 — not more than 10 mg/kg, in category 12 — not more than 100 mg/kg, in category 14.1 — not more than 25 mg/kg, in category 15 — not more than 50 mg/kg, in category 16 — not more than 25 mg/kg.	1	EFSA'

(c) the entry for FL No 02.162 is replaced by the following:

'02.162	Hexa-2,4-dien-1-ol	111-28-4	1174			Restrictions of use as a flavouring substance: In category 3 — not more than 4 mg/kg, in category 4.2 — not more than 2 mg/kg, in category 5 — not more than 2 mg/kg, in category 12 — not more than 4 mg/kg, in category 14.1 — not more than 4 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 1 mg/kg, in category 16 — not more than 2 mg/kg.	1	EFSA'

(d) the entry for FL No 02.188 is replaced by the following:

'02.188	Nona-2,4-dien-1-ol	62488-56-6	1183	11802	At least 92 %; secondary component 3-4 % 2-nonen-1-ol	Restrictions of use as a flavouring substance: In category 1 — not more than 2 mg/kg, in category 2 — not more than 5 mg/kg, in category 3 — not more than 5 mg/kg, in category 4.2 — not more than 5 mg/kg, in category 5 — not more than 10 mg/kg, in category 6 — not more than 1 mg/kg, in category 7 — not more than 14,5 mg/kg, in category 8 — not more than 5 mg/kg, in category 12 — not more than 10 mg/kg, in category 14.1 — not more than 2 mg/kg, in category 14.2 — not more than 5 mg/kg, in category 15 — not more than 5 mg/kg, in category 16 — not more than 2,5 mg/kg.	1	EFSA'

(e) the entry for FL No 05.057 is replaced by the following:

'05.057	Hexa-2(trans),4 (trans)-dienal	142-83-6	1175	640		Restrictions of use as a flavouring substance: In category 1 — not more than 10 mg/kg, in category 3 — not more than 10 mg/kg,	1	EFSA'

						in category 4.2 — not more than 15 mg/kg, in category 5 — not more than 20 mg/kg, in category 6 — not more than 0,05 mg/kg, in category 7 — not more than 15 mg/kg, in category 8 — not more than 15 mg/kg, in category 9 — not more than 20 mg/kg, in category 11 — not more than 50 mg/kg, in category 12 — not more than 4 mg/kg, in category 14.1 — not more than 15 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 16 — not more than 10 mg/kg.		

(f) the entry for FL No 05.064 is replaced by the following:

‘05.064	Trideca-2(trans),4 (cis),7(cis)-trienal	13552-96-0	1198	685	At least 71 %; secondary components 14 % 4-cis-7-cis-tridecadienol; 6 % 3-cis-7-cis-tridecadienol; 5 % 2-trans-7-cis-tridecadienal; 3 % 2-trans-4-trans-7-cis-tridecatrienal	Restrictions of use as a flavouring substance: In category 2 — not more than 1 mg/kg, in category 8 — not more than 2 mg/kg, in category 9 — not more than 1 mg/kg, in category 12 — not more than 1 mg/kg, in category 15 — not more than 1 mg/kg.	1	EFSA’

(g) the entry for FL No 05.071 is replaced by the following:

‘05.071	Nona-2,4-dienal	6750-03-4	1185	732	At least 89 %; secondary components 5-6 % 2,4-nonadien-1-ol and 1-2 % 2-nonen-1-ol	Restrictions of use as a flavouring substance: In category 1 — not more than 1,5 mg/kg, in category 2 — not more than 5 mg/kg, in category 3 — not more than 1 mg/kg, in category 4.2 — not more than 1 mg/kg, in category 5 — not more than 5 mg/kg, in category 6 — not more than 1 mg/kg, in category 7 — not more than 5 mg/kg, in category 8 — not more than 5 mg/kg, in category 9 — not more than 5 mg/kg, in category 10 — not more than 1 mg/kg,	1	EFSA’

						in category 11 — not more than 1 mg/kg, in category 12 — not more than 10 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 5 mg/kg, in category 16 — not more than 1 mg/kg.		

(h) the entry for FL No 05.081 is replaced by the following:

‘05.081	2,4-Decadienal	2363-88-4	3135	2120	At least 89 %; secondary components mixture of the (cis, cis)-; (cis, trans)- and (trans, cis)- 2,4-decadienals (sum of all isomers 95 %); acetone and isopropanol	Restrictions of use as a flavouring substance: In category 1 — not more than 1,5 mg/kg, in category 2 — not more than 5 mg/kg, in category 3 — not more than 1,5 mg/kg, in category 4.2 — not more than 5 mg/kg, in category 5 — not more than 5 mg/kg (except in category 5.3 — not more than 10 mg/kg), in category 6 — not more than 5 mg/kg, in category 7 — not more than 5 mg/kg, in category 8 — not more than 10 mg/kg, in category 9 — not more than 3 mg/kg, in category 10 — not more than 1 mg/kg, in category 11 — not more than 7,5 mg/kg, in category 12 — not more than 10 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 20 mg/kg, in category 16 — not more than 1,5 mg/kg.	1	EFSA’

(i) the entry for FL No 05.084 is replaced by the following:

‘05.084	Hepta-2,4-dienal	4313-03-5	1179	729	At least 92 %; secondary components 2-4 % (E,Z)-2,4-heptadienal and 2-4 % 2,4-heptadienoic acid	Restrictions of use as a flavouring substance: In category 1 — not more than 5 mg/kg, in category 2 — not more than 10 mg/kg,	1	EFSA’

						in category 3 — not more than 1 mg/kg, in category 4.2 — not more than 1 mg/kg, in category 5 — not more than 5 mg/kg, in category 6 — not more than 0,5 mg/kg, in category 7 — not more than 10 mg/kg, in category 8 — not more than 6 mg/kg, in category 9 — not more than 6 mg/kg, in category 10 — not more than 1 mg/kg, in category 11 — not more than 1 mg/kg, in category 12 — not more than 2 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 3 mg/kg, in category 16 — not more than 1 mg/kg		

(j) the entry for FL No 05.101 is replaced by the following:

‘05.101	Penta-2,4-dienal	764-40-9	1173	11695		Restrictions of use as a flavouring substance: In category 1 — not more than 1 mg/kg, in category 3 — not more than 1 mg/kg, in category 5 — not more than 1 mg/kg, in category 6 — not more than 1 mg/kg, in category 7 — not more than 1 mg/kg, in category 8 — not more than 1 mg/kg, in category 12 — not more than 1 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 16 — not more than 1 mg/kg.	1	EFSA’

(k) the entry for FL No 05.108 is replaced by the following:

‘05.108	Undeca-2,4-dienal	13162-46-4	1195	10385		Restrictions of use as a flavouring substance: In category 1 — not more than 1 mg/kg, in category 2 — not more than 5 mg/kg. In category 3 — not more than 1 mg/kg.	1	EFSA’

						In category 4.2 — not more than 1 mg/kg, in category 5 — not more than 1 mg/kg (except in category 5.3 — not more than 10 mg/kg), in category 6 — not more than 1 mg/kg, in category 7 — not more than 5 mg/kg, in category 8 — not more than 3 mg/kg, in category 9 — not more than 3 mg/kg, in category 10 — not more than 1 mg/kg, in category 11 — not more than 1 mg/kg, in category 12 — not more than 1 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 3 mg/kg, in category 16 — not more than 1 mg/kg.		

(l) the entry for FL No 05.125 is replaced by the following:

‘05.125	Dodeca-2,4-dienal	21662-16-8	1196	11758	At least 85 %; secondary component 11-12 % 2-trans-4-cis isomer	Restrictions of use as a flavouring substance: In category 1 — not more than 1 mg/kg, in category 2 — not more than 5 mg/kg, in category 3 — not more than 1 mg/kg, in category 4.2 — not more than 1 mg/kg, in category 5 — not more than 1 mg/kg (except in category 5.3 — not more than 10 mg/kg), in category 6 — not more than 1 mg/kg, in category 7 — not more than 3 mg/kg, in category 8 — not more than 3 mg/kg, in category 9 — not more than 3 mg/kg, in category 10 — not more than 1 mg/kg, in category 11 — not more than 1 mg/kg, in category 12 — not more than 1 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 3 mg/kg, in category 16 — not more than 1 mg/kg.	1	EFSA’

(m) the entry for FL No 05.127 is replaced by the following:

'05.127	Octa-2(trans),4 (trans)-dienal	30361-28-5	1181	11805		Restrictions of use as a flavouring substance: In category 1 — not more than 1 mg/kg, in category 3 — not more than 1 mg/kg, in category 5 — not more than 10 mg/kg, in category 6 — not more than 5 mg/kg, in category 7 — not more than 2 mg/kg, in category 8 — not more than 2 mg/kg, in category 12 — not more than 2 mg/kg, in category 14.1 — not more than 3 mg/kg, in category 15 — not more than 1 mg/kg, in category 16 — not more than 2 mg/kg.	1	EFSA'

(n) the entry for FL No 05.140 is replaced by the following:

'05.140	Deca-2(trans),4 (trans)-dienal	25152-84-5	1190	2120	At least 89 %; secondary components 3-4 % mixture of (cis-cis)-; (cis-trans)- and (trans-cis)- 2,4-decadienals; 3-4 % acetone and trace of isopropanol	Restrictions of use as a flavouring substance: In category 1 — not more than 1,5 mg/kg, in category 2 — not more than 5 mg/kg, in category 3 — not more than 1,5 mg/kg, in category 4.2 — not more than 5 mg/kg, in category 5 — not more than 5 mg/kg, (except in category 5.3 — not more than 10 mg/kg), in category 6 — not more than 5 mg/kg, in category 7 — not more than 5 mg/kg In category 8 — not more than 10 mg/kg, in category 9 — not more than 3 mg/kg, in category 10 — not more than 1 mg/kg, in category 11 — not more than 7,5 mg/kg, in category 12 — not more than 10 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 20 mg/kg, in category 16 — not more than 1,5 mg/kg.	1	EFSA'

(o) the entry for FL No 05.141 is replaced by the following:

'05.141	Deca-2,4,7-trienal	51325-37-2	1786			Restrictions of use as a flavouring substance: In category 1 — not more than 1 mg/kg, in category 2 — not more than 1 mg/kg, in category 3 — not more than 1 mg/kg, in category 4.2 — not more than 1 mg/kg, in category 5 — not more than 1 mg/kg, in category 6 — not more than 1 mg/kg, in category 7 — not more than 1 mg/kg, in category 8 — not more than 1 mg/kg, in category 9 — not more than 1 mg/kg, in category 10 — not more than 1 mg/kg, in category 11 — not more than 1 mg/kg, in category 12 — not more than 1 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 1 mg/kg, in category 16 — not more than 1 mg/kg.	1	EFSA'

(p) the entry for FL No 05.173 is replaced by the following:

'05.173	Nona-2,4,6-trienal	57018-53-8	1785			Restrictions of use as a flavouring substance: In category 1 — not more than 15 mg/kg, in category 2 — not more than 10 mg/kg, in category 3 — not more than 15 mg/kg, in category 4.2 — not more than 15 mg/kg, in category 5 — not more than 20 mg/kg, in category 6 — not more than 10 mg/kg, in category 7 — not more than 25 mg/kg, in category 8 — not more than 5 mg/kg, in category 9 — not more than 5 mg/kg, in category 12 — not more than 25 mg/kg, in category 14.1 — not more than 10 mg/kg, in category 15 — not more than 15 mg/kg, in category 16 — not more than 15 mg/kg.	1	EFSA'

(q) the entry for FL No 05.186 is replaced by the following:

'05.186	2,4-Octadienal	5577-44-6		11805		Restrictions of use as a flavouring substance: In category 1 — not more than 1 mg/kg, in category 3 — not more than 1 mg/kg, in category 5 — not more than 10 mg/kg, in category 6 — not more than 5 mg/kg, in category 7 — not more than 2 mg/kg, in category 8 — not more than 2 mg/kg, in category 12 — not more than 2 mg/kg, in category 14.1 — not more than 3 mg/kg, in category 15 — not more than 1 mg/kg, in category 16 — not more than 2 mg/kg.	1	EFSA'

(r) the entry for FL No 05.194 is replaced by the following:

'05.194	tr-2, tr-4-Nonadienal	5910-87-2		732	At least 89 %; secondary components at least 5 % 2,4-nonadien-1-ol and 2-nonen-1-ol and other isomers of 2,4-nonadienal	Restrictions of use as a flavouring substance: In category 1 — not more than 1,5 mg/kg, in category 2 — not more than 5 mg/kg, in category 3 — not more than 1 mg/kg, in category 4.2 — not more than 1 mg/kg, in category 5 — not more than 5 mg/kg, in category 6 — not more than 1 mg/kg, in category 7 — not more than 5 mg/kg, in category 8 — not more than 5 mg/kg, in category 9 — not more than 5 mg/kg, in category 10 — not more than 1 mg/kg, in category 11 — not more than 1 mg/kg, in category 12 — not more than 10 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 5 mg/kg, in category 16 — not more than 1 mg/kg.	1	EFSA'

(s) the entry for FL No 05.196 is replaced by the following:

'05.196	tr-2, tr-4-Undecadienal	30361-29-6		10385		Restrictions of use as a flavouring substance: In category 1 — not more than 1 mg/kg, in category 2 — not more than 5 mg/kg, in category 3 — not more than 1 mg/kg, in category 4.2 — not more than 1 mg/kg, in category 5 — not more than 1 mg/kg (except in category 5.3 — not more than 10 mg/kg), in category 6 — not more than 1 mg/kg, in category 7 — not more than 5 mg/kg, in category 8 — not more than 3 mg/kg, in category 9 — not more than 3 mg/kg, in category 10 — not more than 1 mg/kg, in category 11 — not more than 1 mg/kg, in category 12 — not more than 1 mg/kg, in category 14.1 — not more than 1 mg/kg, in category 14.2 — not more than 1 mg/kg, in category 15 — not more than 3 mg/kg, in category 16 — not more than 1 mg/kg.	1	EFSA'

(t) the entry for FL No 09.573 is replaced by the following:

'09.573	Hexa-2,4-dienyl acetate	1516-17-2	1780	10675		Restrictions of use as a flavouring substance: In category 1 — not more than 25 mg/kg, in category 3 — not more than 20 mg/kg, in category 4.2 — not more than 25 mg/kg, in category 5 — not more than 25 mg/kg, in category 6 — not more than 10 mg/kg, in category 7 — not more than 25 mg/kg, in category 12 — not more than 10 mg/kg, in category 14.1 — not more than 20 mg/kg, in category 14.2 — not more than 20 mg/kg, in category 15 — not more than 25 mg/kg, in category 16 — not more than 25 mg/kg.	1	EFSA'

COMMISSION IMPLEMENTING REGULATION (EU) 2017/379

of 3 March 2017

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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 Brussels, 3 March 2017.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General
Directorate-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	EG	235,2
	IL	243,7
	MA	92,8
	TR	90,4
	ZZ	165,5
0707 00 05	MA	64,3
	TR	181,6
	ZZ	123,0
0709 91 00	EG	97,7
	ZZ	97,7
0709 93 10	MA	54,0
	TR	151,7
	ZZ	102,9
0805 10 22, 0805 10 24, 0805 10 28	EG	45,1
	IL	64,7
	MA	48,6
	TN	56,4
	TR	73,1
	ZZ	57,6
0805 50 10	EG	74,7
	TR	71,3
	ZZ	73,0
0808 10 80	CN	135,3
	US	128,5
	ZZ	131,9
0808 30 90	CL	202,2
	CN	107,3
	ZA	122,4
	ZZ	144,0

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COUNCIL DECISION (CFSP) 2017/380

of 3 March 2017

extending the mandate of the European Union Special Representative for the Middle East Peace Process (MEPP)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 33 and Article 31(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 15 April 2015, the Council adopted Decision (CFSP) 2015/599 ([1]) appointing Mr Fernando GENTILINI as the European Union Special Representative (EUSR) for the Middle East Peace Process (MEPP). The EUSR's mandate is to expire on 28 February 2017.

(2) The EUSR's mandate should be extended for a further period of 16 months.

(3) The EUSR will implement the mandate in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

European Union Special Representative

The mandate of Mr Fernando GENTILINI as the EUSR for the Middle East Peace Process (MEPP) is extended until 30 June 2018. The Council may decide that the mandate of the EUSR be terminated earlier, based on an assessment by the Political and Security Committee (PSC) and a proposal from the High Representative of the Union for Foreign Affairs and Security Policy (HR).

Article 2

Policy objectives

1. The EUSR's mandate shall be based on the Union's policy objectives regarding the MEPP.

2. The overall objective is a comprehensive peace that should be achieved on the basis of a two-State solution, with Israel and a democratic, contiguous, viable, peaceful and sovereign Palestinian State living side by side within secure and recognised borders enjoying normal relations with their neighbours in accordance with United Nations (UN) Security Council Resolutions 242(1967) and 338(1973) and recalling other relevant Resolutions, including 2334(2016), the Madrid principles, including land for peace, the Roadmap, the agreements previously reached by the parties, the Arab Peace Initiative and the recommendations of the Middle East Quartet ('the Quartet') of 1 July 2016. In light of the different strands of the Israeli-Arab relations, the regional dimension constitutes an essential element for a comprehensive peace.

([1]) Council Decision (CFSP) 2015/599 of 15 April 2015 appointing the European Union Special Representative for the Middle East Peace Process (MEPP) (OJ L 99, 16.4.2015, p. 29).

3. In achieving this objective, policy priorities are the preservation of the two-State solution and relaunching and supporting the peace process. Clear parameters defining the basis for negotiations are key elements for a successful outcome and the Union has set out its position with regard to such parameters in the Council conclusions of December 2009, December 2010 and July 2014, which it will continue to actively promote.

4. The Union is committed to working with the parties and with partners in the international community, including through participating in the Quartet and actively pursuing appropriate international initiatives to create a new dynamic for the negotiations.

Article 3

Mandate

1. In order to achieve the policy objectives, the EUSR's mandate shall be to:

(a) provide an active and efficient Union contribution to actions and initiatives leading to a final settlement of the Israeli/Palestinian conflict based on the two-State solution and in line with the Union parameters and relevant UN Security Council Resolutions including UNSCR 2334(2016) and put forward proposals for EU action in this regard;

(b) facilitate and maintain close contacts with all the parties to the peace process, relevant political actors, other countries of the region, members of the Quartet and other relevant countries, as well as the UN and other relevant international organisations, like the League of Arab States, in order to work with them in strengthening the peace process;

(c) work as appropriate to promote and contribute to a possible new framework of negotiations in consultation with all the key stakeholders and the Member States, in particular through advancing the objectives of the Joint Declaration adopted by the participants of the conference held in Paris on 15 January 2017 ([1]);

(d) actively support and contribute to peace negotiations between the parties, including by putting forward proposals on behalf of the Union and in line with its consolidated longstanding policy in the context of those negotiations;

(e) ensure continued presence of the Union in relevant international fora;

(f) contribute to crisis management and prevention, including with regard to Gaza;

(g) contribute, where requested, to the implementation of international agreements reached between the parties and engage with them diplomatically in the event of non-compliance with the terms of those agreements;

(h) contribute to political efforts to bring about a fundamental change leading to a sustainable solution for the Gaza Strip which is an integral part of a future Palestinian State and should be addressed in the negotiations;

(i) pay particular attention to factors affecting the regional dimension of the peace process, to the engagement with Arab partners and to the implementation of the Arab Peace Initiative;

(j) engage constructively with signatories to agreements within the framework of the peace process in order to promote compliance with the basic norms of democracy, including respect for international humanitarian law, human rights and the rule of law;

(k) make proposals for Union intervention in the peace process and on the best way of pursuing Union initiatives and ongoing peace process related Union efforts, such as the Union's contribution to Palestinian reforms and including the political aspects of relevant Union development projects;

(l) engage the parties in refraining from unilateral actions threatening the viability of the two-State solution, notably in Jerusalem and in Area C of the occupied West Bank;

(m) report regularly, as Envoy to the Quartet, on progress and evolution in the negotiations, as well as on the Quartet activities, and contribute to the preparation of Quartet Envoys meetings on the basis of Union positions and through coordination with other Quartet members;

([1]) One Member State (United Kingdom) only attended as observer and did not sign up to the Joint Declaration adopted at the conference.

(n) contribute to the implementation of the Union's human rights policy in cooperation with the EUSR for Human Rights, including the Union Guidelines on human rights, in particular the Union Guidelines on Children and Armed Conflict as well as on violence against women and girls and combating all forms of discrimination against them, and Union policy regarding UN Security Council Resolution 1325 (2000) on Women, Peace and Security, including by monitoring and reporting on developments as well as formulating recommendations in this regard;

(o) contribute to a better understanding of the role of the Union among opinion leaders in the region.

2. The EUSR shall support the work of the HR, while maintaining an overview of all MEPP related activities of the Union in the region.

Article 4

Implementation of the mandate

1. The EUSR shall be responsible for the implementation of the mandate, acting under the authority of the HR.

2. The PSC shall maintain a privileged link with the EUSR and shall be the EUSR's primary point of contact with the Council. The PSC shall provide the EUSR with strategic guidance and political direction within the framework of the mandate, without prejudice to the powers of the HR.

3. The EUSR shall work in close coordination with the European External Action Service (EEAS) and its relevant departments.

4. The EUSR shall work in close coordination with the Union Representative Office in Jerusalem, the Union delegation in Tel Aviv, as well as with all other relevant Union delegations in the region.

5. The EUSR shall be primarily based in the region while ensuring a regular presence at EEAS headquarters.

Article 5

Financing

1. The financial reference amount intended to cover the expenditure related to the EUSR's mandate for the period from 1 March 2017 to 30 June 2018 shall be EUR 1 825 000.

2. The expenditure shall be managed in accordance with the procedures and rules applicable to the general budget of the Union.

3. The management of the expenditure shall be subject to a contract between the EUSR and the Commission. The EUSR shall be accountable to the Commission for all expenditure.

Article 6

Constitution and composition of the team

1. Within the limits of the EUSR's mandate and the corresponding financial means made available, the EUSR shall be responsible for constituting a team. The team shall include the expertise on specific policy issues as required by the mandate. The EUSR shall keep the Council and the Commission promptly informed of the composition of the team.

2. Member States, the institutions of the Union and the EEAS may propose the secondment of staff to work with the EUSR. The salary of such seconded personnel shall be covered by the sending Member State, the sending institution of the Union or the EEAS, respectively. Experts seconded by Member States to the institutions of the Union or the EEAS may also be posted to work with the EUSR. International contracted staff shall have the nationality of a Member State.

3. All seconded personnel shall remain under the administrative authority of the sending Member State, the sending institution of the Union or the EEAS, respectively, and shall carry out their duties and act in the interest of the EUSR's mandate.

4. The EUSR staff shall be co-located within the relevant EEAS departments or Union delegations in order to ensure coherence and consistency of their respective activities.

Article 7

Privileges and immunities of the EUSR and the EUSR's staff

The privileges, immunities and further guarantees necessary for the completion and smooth functioning of the EUSR's mission and the members of the EUSR's staff shall be agreed with the host countries, as appropriate. Member States and the EEAS shall grant all necessary support to such effect.

Article 8

Security of EU classified information

The EUSR and the members of the EUSR's team shall respect the security principles and minimum standards established by Council Decision 2013/488/EU ([1]).

Article 9

Access to information and logistical support

1. Member States, the Commission, the EEAS and the General Secretariat of the Council shall ensure that the EUSR is given access to any relevant information.

2. The Union delegations in the region and/or the Member States, as appropriate, shall provide logistical support in the region.

Article 10

Security

In accordance with the Union's policy on the security of personnel deployed outside the Union in an operational capacity under Title V of the Treaty, the EUSR shall take all reasonably practicable measures, in accordance with the EUSR's mandate and on the basis of the security situation in the area of responsibility, for the security of all personnel under the EUSR's direct authority, in particular by:

(a) establishing a specific security plan based on guidance from the EEAS, including specific physical, organisational and procedural security measures, governing the management of the secure movement of personnel to, and within, the area of responsibility, as well as management of security incidents and including a contingency and evacuation plan;

(b) ensuring that all personnel deployed outside the Union are covered by high risk insurance, as required by the conditions in the area of responsibility;

([1]) Council Decision 2013/488/EU of 23 September 2013 on the security rules for protecting EU classified information (OJ L 274, 15.10.2013, p. 1).

(c) ensuring that all members of the EUSR's team to be deployed outside the Union, including locally contracted personnel, have received appropriate security training before or upon arriving in the area of responsibility, based on the risk ratings assigned to that area by the EEAS;

(d) ensuring that all agreed recommendations made following regular security assessments are implemented and providing the Council, the HR and the Commission with written reports on their implementation and on other security issues within the framework of the progress report and the report on the implementation of the mandate.

Article 11

Reporting

The EUSR shall regularly provide the HR and the EEAS with oral and written reports. The EUSR shall report regularly to the PSC in addition to the minimum requirements for reporting and objective setting as set out in the Guidelines on appointments, mandate and financing of Union Special Representatives. The EUSR shall also report to Council working parties, as necessary. Regular reports shall be circulated through the COREU network. The EUSR may provide the Foreign Affairs Council with reports. In accordance with Article 36 of the Treaty, the EUSR may be involved in briefing the European Parliament.

Article 12

Coordination

1. The EUSR shall contribute to the unity, consistency and effectiveness of the Union's action and shall help ensure that all Union instruments and Member States' actions are engaged consistently, to attain the Union's policy objectives. The activities of the EUSR shall be coordinated with those of the Commission. The EUSR shall provide regular briefings to the Union delegations and the Member States' missions in Tel Aviv and Jerusalem.

2. In the field, close liaison shall be maintained with the relevant Heads of Member States' Missions, Heads of the Union delegations and Heads of CSDP Missions. They shall make every effort to assist the EUSR in the implementation of the mandate. The EUSR, in close coordination with the Head of Union delegation in Tel Aviv and the Union Representative Office in Jerusalem, shall provide the Heads of the European Union Police Mission in the Palestinian Territory (EUPOL COPPS) and of the European Union Border Assistance Mission for the Rafah Crossing Point (EU BAM Rafah) with local political guidance. The EUSR shall also liaise with other international and regional actors in the field.

Article 13

Review

The implementation of this Decision and its consistency with other contributions from the Union to the region shall be kept under regular review. The EUSR shall present the Council, the HR and the Commission with a progress report by 30 September 2017 and a comprehensive mandate implementation report by 31 March 2018.

Article 14

Entry into force

This Decision shall enter into force on the date of its adoption.

It shall apply from 1 March 2017.

Done at Brussels, 3 March 2017.

For the Council
The President
M. FARRUGIA

COUNCIL DECISION (CFSP) 2017/381

of 3 March 2017

amending Decision 2014/119/CFSP concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 5 March 2014, the Council adopted Decision 2014/119/CFSP ([1]).

(2) On 4 March 2016 the Council extended the restrictive measures against 16 persons until 6 March 2017 ([2]).

(3) On the basis of a review of the restrictive measures set out in Decision 2014/119/CFSP, the application of those restrictive measures should be extended until 6 March 2018. The entry for one person listed in the Annex to Decision 2014/119/CFSP should be deleted.

(4) Decision 2014/119/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2014/119/CFSP is amended as follows:

(1) in Article 5, the second paragraph is replaced by the following:

'This Decision shall apply until 6 March 2018.';

(2) the Annex is amended as set out in in the Annex to this Decision.

Article 2

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

Done at Brussels, 3 March 2017.

For the Council
The President
M. FARRUGIA

([1]) Council Decision 2014/119/CFSP of 5 March 2014 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Ukraine (OJ L 66, 6.3.2014, p. 26).

([2]) Council Decision (CFSP) 2016/318 of 4 March 2016 amending Decision 2014/119/CFSP concerning restrictive measures against certain persons, entities and bodies in view of the situation in Ukraine (OJ L 60, 5.3.2016 p. 76).

ANNEX

In the Annex to Decision 2014/119/CFSP the entry relating to the following person is deleted:

16. Yuriy Volodymyrovych Ivanyushchenko

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2017

of 1 March 2017

of the Joint Committee established under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs) [2017/382]

THE JOINT COMMITTEE,

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America (the 'Agreement') done in 1998, and in particular its Articles 14 and 21, and

Whereas the Joint Committee is to take a decision to amend the Sectoral Annex on GMPs pursuant to Article 21(2) of the Agreement;

HAS DECIDED AS FOLLOWS:

1. Attachment A to this Decision is the United States — European Union Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices ('Amended Sectoral Annex') which amends the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs) done in 1998 and replaces it with a consolidated version.
2. Attachment A has been agreed by the Parties.

This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who, pursuant to Article 21(2) of the Agreement are authorized to act on behalf of the Parties for purposes of amending the Annexes. This Decision shall be effective from the date of the later of these signatures.

Signed in Washington DC, 19 January 2017.

On behalf of the United States of America

Michael B. G. FROMAN

Signed in Brussels, 1 March 2017.

On behalf of the European Union

Cecilia MALMSTRÖM

ATTACHMENT A

United States — European Union amended sectoral annex for pharmaceutical good manufacturing practices (GMPs)

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition between the United States and the European Union, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices done in 1998.

CHAPTER 1

DEFINITIONS, PURPOSE, SCOPE AND PRODUCT COVERAGE

Article 1

Definitions

For purposes of this Annex:

1. 'Assessment pursuant to this Annex' means:

   for the European Union (EU), an equivalence assessment; and

   for the United States, a capability assessment.

   An assessment pursuant to this Annex includes a reassessment.

2. 'Recognized authority' means:

   for the EU, an equivalent authority; and

   for the United States, a capable authority.

3. 'Capable authority' means an authority that the Food and Drug Administration (FDA) FDA has determined is capable according to the criteria and procedures specified in Appendix 4 and referred to in the U.S. laws, regulations and administrative provisions listed in Appendix 1. For greater certainty, a finding that a regulatory authority is 'capable' does not require that the authority maintain procedures for conducting inspections and overseeing manufacturing facilities that are identical to FDA's procedures.

4. 'Equivalent authority' means an authority in respect of which the EU has made a positive equivalence determination according the criteria and procedures specified in Appendix 4 and as referred to in the EU laws, regulations and administrative provisions listed in Appendix 1.

5. 'Equivalence' means that the regulatory system under which an authority operates is sufficiently comparable to assure that the process of inspection and the ensuing official GMP documents will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. For greater certainty, 'equivalence' does not require that the respective regulatory systems have identical procedures.

6. 'Enforcement' means an action taken by an authority to protect the public from products of suspect quality, safety and efficacy or to assure that products are manufactured in compliance with appropriate laws, regulations, standards and commitments made as part of the approval to market a product.

7. 'Good Manufacturing Practices' (GMPs) means systems that assure proper design, monitoring, and control of manufacturing processes and facilities, the adherence to which assures the identity, strength, quality, and purity of pharmaceuticals. GMPs include strong quality management systems, obtaining appropriate quality raw materials (including starting materials) and packaging materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories.

8. 'Inspection' means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with Good Manufacturing Practices and/or commitments made as part of the approval to market a product.

9. 'Inspection Report' means a report written by an investigator or inspector of an authority listed in Appendix 2 concerning an inspection of a manufacturing facility that the investigator or inspector conducted that describes the purpose and scope of an inspection and includes written observations and findings bearing on the manufacturing facilities conformance to applicable GMP requirements set out in the laws, regulations and administrative procedures listed in Appendix 1 and any commitments made as part of the approval to market a product.

10. 'Official GMPs document' means a document issued by an authority listed in Appendix 2 following an inspection of a manufacturing facility. Examples of official GMPs documents include inspection reports, certificates issued by an authority attesting the compliance of a manufacturing facility with GMPs, GMPs non-compliance statement issued by authorities of the EU, and notice of observations, untitled letters, warning letters, and import alerts issued by the FDA.

11. 'Pharmaceuticals' includes drugs and medicinal products as defined in the laws and regulations listed in Appendix 1.

12. 'Post-approval inspections' means GMP surveillance inspections during the marketing of products.

13. 'Pre-approval inspections' means pharmaceutical inspections of manufacturing facilities carried out in the territory of a Party as part of the review of an application before marketing approval is granted.

14. 'Regulatory System' means the body of legal requirements for Good Manufacturing Practices, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

Article 2

Purpose

This Annex facilitates the exchange of official GMPs documents between the Parties and reliance on the factual findings in such documents. This Annex seeks to facilitate trade and benefit public health by allowing each Party to leverage and to reallocate its inspection resources, including by avoiding duplication of inspections, so as to improve oversight of manufacturing facilities and better address quality risk and prevent adverse health consequences.

Article 3

Scope

1. The provisions of this Annex apply to pharmaceutical inspections of manufacturing facilities carried out in the territory of a Party during the marketing of products (hereafter referred to as 'post-approval inspections') and, to the extent provided for in Article 11, before products are marketed (hereafter referred to as 'pre-approval inspections'), as well as, to the extent provided for in Article 8(3), to pharmaceutical inspections of manufacturing facilities carried out outside the territory of either Party.

2. Appendix 1 names the laws, regulations and administrative provisions governing these inspections and the GMPs requirements.

3. Appendix 2 lists all the authorities responsible for the oversight of facilities that manufacture products within the product coverage of this Annex.

4. Articles 6, 7, 8, 9, 10 and 11 of the Agreement do not apply to this Annex.

Article 4

Product coverage

1. These provisions apply to marketed finished pharmaceuticals for human or animal use, intermediates (for the EU as defined in EU legislation) and in-process materials (for the United States as defined under U.S. law), certain marketed biological products for human use, and active pharmaceutical ingredients, only to the extent they are regulated by the authorities of both Parties as listed in Appendix 2 and subject to Article 20.

2. Human blood, human plasma, human tissues and organs, and veterinary immunologicals are excluded from the scope of this Annex.

3. Appendix 3 contains the list of products covered by this Annex.

CHAPTER 2

DETERMINATION OF RECOGNITION

Article 5

Assessments

1. Each Party shall conduct assessments of authorities listed in Appendix 2 pursuant to this Annex on the request of the other Party as expeditiously as possible, including for authorities added to Appendix 2 after the effective date of this Annex and as regards products listed in Appendix 3 (including those that are included in the scope of this Annex pursuant to Article 20 after the effective date of this Annex).

2. Each Party shall use the criteria and procedure specified in Appendix 4 to conduct assessments pursuant to this Annex.

Article 6

Participation in and completion of assessments

Each Party with respect to the authorities listed in Appendix 2 shall participate in the procedure as described in Appendix 4. Each Party shall exercise good faith efforts to complete assessments pursuant to this Annex as expeditiously as possible. To this end:

(a) The EU shall complete an assessment of the FDA for human pharmaceuticals under this Annex no later than by 1 July 2017.

(b) The FDA shall complete an assessment under this Annex of each EU Member State authority for human pharmaceuticals listed in Appendix 2 as set out in Appendix 5.

Article 7

Recognition of authorities

1. Each Party shall determine whether to recognize an authority according to the criteria specified in Appendix 4. Each Party shall promptly notify the Joint Sectoral Committee of any determination to recognize an authority of the other Party. The Joint Sectoral Committee shall maintain a list of recognized authorities and shall keep the list up-to-date. The list shall be made publicly available by each Party.

2. The assessing Party shall promptly notify the other Party and the relevant authority of any deficiencies identified in the course of the assessment. In the event of a negative determination, the assessing Party shall notify the other Party and the relevant authority of the reasons for the negative determination and provide sufficient detail to allow the authority to understand corrective measures that must be taken to attain a positive determination. A Party may request the other Party to conduct a reassessment of any authority for which the other Party has made a negative determination once the authority has taken necessary corrective measures in accordance with Article 5.

3. An assessing Party shall, upon request of the other Party, promptly discuss with the other Party in the Joint Sectoral Committee the reasons for a negative determination. In case of a negative determination, efforts shall be made by the Joint Sectoral Committee to discuss within 3 months the appropriate timeframe and exact steps to be taken to reassess the relevant authority.

CHAPTER 3

OPERATIONAL ASPECTS

Article 8

Recognition of inspections

1. A Party shall recognize pharmaceutical inspections and accept official GMPs documents issued by a recognized authority of the other Party for manufacturing facilities located in the territory of the issuing authority, except as provided in paragraph 2.

2. A Party may in specific circumstances opt not to accept an official GMPs document issued by a recognized authority of the other Party for manufacturing facilities located in the territory of the issuing authority. Examples of such circumstances include the indication of material inconsistencies or inadequacies in an inspection report, quality defects identified in the post-market surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. A Party opting not to accept an official GMPs document issued by a recognized authority of the other Party shall notify the other Party and the relevant authority of the reasons for not accepting the document and may request clarification from that authority. The authority shall endeavour to respond to the request for clarification in a timely manner and shall normally provide the clarification based on input from one or more members of the inspection team.

3. A Party may accept official GMPs documents issued by a recognized authority of the other Party for manufacturing facilities located outside the territory of the issuing authority.

4. Each Party may determine the terms and conditions under which it accepts official GMPs documents issued under paragraph 3.

5. For purposes of this Annex, to accept an official GMPs document means to rely on the factual findings in such document.

Article 9

Batch testing

In the EU, as provided in Article 51 paragraph 2 of Directive 2001/83/EC of the European Parliament and of the Council ([1]) and in Article 55 paragraph 2 of Directive 2001/82/EC of the European Parliament and of the Council ([2]), the qualified person will be relieved of responsibility for carrying out the controls laid down in Article 51 paragraph 1 of Directive 2001/83/EC and in Article 55 paragraph 1 of Directive 2001/82/EC provided that these controls have been carried out in the United States, the product was manufactured in the United States and that each batch/lot is accompanied by a batch certificate (in alignment with the WHO certification scheme on the quality of medicinal products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

([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).

([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).

Article 10

Transmission of official GMPs documents

If an importing Party requests a recognized authority of the other Party for a post-approval official GMPs document, the recognized authority shall transmit the document to the Party within 30 calendar days of the date of the request. If, based on that document, the importing Party determines that a new inspection of the manufacturing facility is needed, the importing Party shall notify the relevant recognized authority of the other Party and request, in accordance with Article 11, the recognized authority of the other Party to conduct a new inspection.

Article 11

Requests for pre-approval and post-approval inspections

1. A Party or a recognized authority of a Party may request in writing that a recognized authority of the other Party conduct a pre-approval or post-approval inspection of a manufacturing facility. The request shall include the reason for the request and identify the precise issues to be addressed in the inspection and the requested timeline for completing the inspection and transmitting the official GMPs documents.

2. In the EU, requests shall be sent directly to the relevant recognized authority, with a copy to the European Medicines Agency (EMA).

3. Within 15 calendar days of receipt of the request, the recognized authority shall acknowledge receipt and confirm whether it will conduct the inspection in accordance with the requested timelines. Where the authority receiving the request is of the opinion that official GMPs documents relevant to the request are already available or are pending, it should inform the requesting authority accordingly and share these documents upon request.

4. For greater certainty, if the recognized authority indicates that it will not conduct the inspection, the requesting authority has the right to conduct its own inspection of the manufacturing facility and the requested authority has the right to join the inspection.

Article 12

Maintenance

Each Party shall maintain ongoing activities to monitor that recognized authorities in its territory maintain the criteria for recognition. For the purpose of such monitoring activities, each Party shall rely on established programmes that include regular audits or assessments of authorities based on the criteria specified in Appendix 4. The frequency and nature of such activities shall be consistent with international best practices. A Party may invite the other Party to participate in these monitoring activities at the other Party's expense. Each Party shall notify the other Party of any significant changes to its monitoring programmes.

Article 13

Suspension of a recognized authority

1. Each Party has the right to suspend recognition of a recognized authority of the other Party. This right shall be exercised in an objective and reasoned manner and communicated in writing to the other Party and the recognized authority.

2. A Party suspending recognition of a recognized authority of the other Party shall, upon request of the other Party or the authority whose recognition was suspended, promptly discuss in the Joint Sectoral Committee the suspension, the reason therefore, and corrective actions that would need to be taken for the suspension to be lifted.

3. Upon the suspension of an authority previously listed as a recognized authority, a Party is no longer obligated to accept official GMPs documents of the suspended authority. A Party shall continue to accept official GMPs documents of that authority prior to suspension, unless the Party decides otherwise based on health or safety considerations. The suspension shall remain in effect until the Parties decide to lift the suspension or until a positive determination of recognition has been made in accordance with Article 7 pursuant to a reassessment.

CHAPTER 4

JOINT SECTORAL COMMITTEE

Article 14

Role and composition of the Joint Sectoral Committee

1. A Joint Sectoral Committee is set up to monitor the activities performed under this Annex.

2. The Committee shall be co-chaired by a representative of the FDA for the United States and a representative of the EU who each shall have one vote in the Joint Sectoral Committee. The Joint Sectoral Committee shall make its decision by unanimous consent. The Joint Sectoral Committee shall determine its own rules and procedures.

3. The Joint Sectoral Committee's functions include in particular:

(a) developing and keeping up to date the list of recognized authorities, including any limitation in terms of inspection type or products, and the list of authorities in Appendix 2 and communicating the lists to all authorities listed in Appendix 2 and the Joint Committee,

(b) providing a forum to discuss issues relating to this Annex, including relating to disagreements as regards determinations of recognition or suspension and timelines for completing assessments under this Annex of authorities listed in Appendix 2;

(c) in accordance with Article 20 and Appendix 3, considering the status, and taking decisions on the inclusion, of the products referred to in Article 20; and

(d) adopting, where necessary, appropriate complementary technical and administrative arrangements for the effective implementation of this Annex.

4. The Joint Sectoral Committee shall meet at the request of either Party with respect to issues relating to disagreements as regards to determinations of recognition or suspension and otherwise at such times as the Parties may agree. The Joint Sectoral Committee may meet in person or by other means.

CHAPTER 5

REGULATORY COOPERATION AND INFORMATION EXCHANGE

Article 15

Regulatory cooperation

The Parties shall inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or significant changes to pharmaceutical inspection procedures and to provide the opportunity to comment on such proposals.

Article 16

Exchange of information

The Parties shall establish appropriate arrangements, including access to relevant databases, for the exchange of official GMPs documents and other appropriate information related to the inspection of a manufacturing facility and the exchange of information concerning any confirmed problem reports, corrective actions, recalls, rejected import consignments and other regulatory and enforcement problems for products subject to this Annex.

Article 17

Alert System

Each Party shall maintain an Alert System that permits authorities of the other Party when relevant to be made aware proactively and with the appropriate speed in case of quality defect, recalls, counterfeit or falsified products, or potential serious shortages and other problems concerning quality or non-compliance with GMP, which could necessitate additional controls or suspension of the distribution of the affected products.

CHAPTER 6

SAFEGUARD CLAUSE

Article 18

Safeguard clause

1. Each Party recognizes that the importing country has a right to fulfil its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. An authority of a Party has the right to conduct its own inspection of a manufacturing facility in the territory of the other Party.

2. An authority of a Party conducting its own inspection of a manufacturing facility in the territory of the other Party should be an exception from the normal practice of a Party as of the date on which the Articles referred to in Article 19(2) become applicable.

3. An authority of a Party, prior to conducting an inspection under paragraph 1, shall notify the other Party in writing and the authority of the other Party has the right to join the inspection conducted by the Party.

CHAPTER 7

FINAL PROVISIONS

Article 19

Entry Into Force

1. This Annex shall enter into force on the date on which the Parties have completed an Exchange of Letters confirming completion of any respective procedures for the entry into force of this Annex.

2. Notwithstanding paragraph 1, Articles 8, 10, 11 and 12 of this Annex shall not apply until 1 November 2017, except as provided in paragraph 4.

3. Notwithstanding paragraph 1, Article 9 of this Annex shall not apply until the date on which all the EU Member State authorities for human pharmaceuticals listed in Appendix 2 have been recognized by the FDA.

4. If, by 1 November 2017, the FDA has not completed assessments under this Annex of at least eight Member State authorities for human pharmaceuticals listed in Appendix 2, despite having received complete capability assessment packages from those authorities as specified in paragraph II.A.1 of Appendix 4 in accordance with the schedule set out in Appendix 5, application of the Articles referred to in paragraph 2 shall be postponed to the date on which the FDA has completed assessments of at least eight such authorities.

Article 20

Transitory Provisions

1. No later than by 15 July 2019, the Joint Sectoral Committee shall consider whether to include veterinary products within the product coverage of this Annex. The Joint Sectoral Committee shall exchange views on the organisation of the assessment of respective authorities by 15 December 2017.

2. No later than 15 July 2022, the Joint Sectoral Committee shall consider whether to include vaccines for human use and plasma derived pharmaceuticals within the product coverage of this Annex. Without prejudice to this consideration, as of the effective date of this Annex, a Party shall notify the relevant authority of the other Party in advance of conducting a post-approval inspection of a manufacturing facility of such products located in the territory of the Party and give the authority the option of joining the inspection. In order to support the inclusion of vaccines for human use and plasma derived pharmaceuticals within the product coverage of this Annex, the Joint Sectoral Committee shall take into account, in particular, the experience gained through such joint inspections.

3. No later than 15 July 2019, the Joint Sectoral Committee shall review experience gained in order to decide whether the provisions on pre-approval inspections provided in Article 11 shall be reviewed.

4. Products referred to in paragraphs 1 and 2 shall be included within the product coverage of this Annex only once the Joint Sectoral Committee so decides pursuant to paragraphs 1 and 2.

5. Where the FDA identifies the need for a post-approval inspection of a manufacturing facility in a territory of a Member State authority of which an assessment under this Annex is pending or that the FDA has otherwise not recognized, the FDA shall notify that authority and the EMA in writing.

(a) No later than 30 calendar days of the date it receives a notification pursuant to paragraph 5, the authority in whose territory the manufacturing facility is located or EMA on behalf of this authority shall inform the FDA whether it has opted to request a recognized authority of the EU to conduct the inspection and, if so, whether such recognized authority of the EU will conduct the inspection by the date specified in the notification. The authority in whose territory the manufacturing facility is located shall be allowed to join the inspection.

(b) In the case that a recognized authority of the EU will conduct the inspection, the recognized authority or EMA on behalf of this authority shall inform the FDA of the date(s) on which it will conduct the inspection and submit the official GMPs documents relevant to the inspection to the FDA and the authority of the territory in which the inspection has been conducted by the date specified in the notification in accordance with the applicable laws, regulations and administrative provisions listed in Appendix 1. The FDA shall have the option to participate in the inspection.

(c) In the case that a recognized authority of the EU will not conduct the inspection and the FDA conducts the inspection, the authority of the territory in which the inspection has been conducted has the right to participate in the inspection and the FDA shall submit the official GMPs documents relevant to the inspection to this authority.

Article 21

Termination

1. The Annex shall terminate on 15 July 2019 in the event that the FDA, by that date, has not completed an assessment under this Annex of each EU Member State authority for human pharmaceuticals listed in Appendix 2, provided that the FDA has received complete capability assessment packages as specified in paragraph II.A.1 of Appendix 4 from each Member State authority in accordance with the schedule set out in Appendix 5.

2. The date specified in paragraph 1 shall be extended by 90 calendar days for each authority that provides a complete capability assessment package as specified in paragraph II.A.1 of Appendix 4 after the applicable deadline set out in Appendix 5 but before 15 July 2019.

3. The FDA shall, on request, discuss any disagreement raised by the EU regarding an assessment in the Joint Sectoral Committee. If the Joint Sectoral Committee cannot agree on resolution of the disagreement, the EU may notify in writing to the FDA its formal disagreement and the Annex shall terminate three months from the date of such notification or on such other date as the Joint Sectoral Committee may agree.

Appendix 1

List of Applicable Laws, Regulations and Administrative Provisions

FOR THE UNITED STATES

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. Of particular relevance: 21 USC 351(a)(2)(B) (drug adulterated if not manufactured in conformance with current good manufacturing practice); 21 U.S.C. 355(d)(3); 21 U.S.C. 355(j)(4)(A) (approval of human drug contingent on adequacy of methods, facilities, and controls for manufacturing, processing, and packing to preserve the identity, strength, quality, and purity of drug); 21 U.S.C. 360b(c)(2)(A)(i); 360b(d)(1)(C) (approval of animal drug contingent on contingent on adequacy of methods, facilities, and controls for manufacturing, processing, and packing to preserve the identity, strength, quality, and purity of drug); 21 U.S.C. 374 (inspection authority); 21 U.S.C. 384(e) (recognition of foreign government inspections)

Public Health Service Act Section 351, 42 U.S.C. 262. Of particular relevance: 42 U.S.C. 262(a)(2)(C)(i)(II) (licensing of biologic contingent on demonstration that the facility in which it is manufactured, processed, packed, or held meets standards designed to assure that the product continues to be safe, pure, and potent); 42 U.S.C. 262(j) (Federal Food, Drug, and Cosmetic Act applies to biologic products)

21 CFR Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding Drugs; General)

21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)

21 CFR Part 600, Subpart B (Establishment Standards); Subpart C (Establishment Inspection)

FOR THE EUROPEAN UNION

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;

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;

Directive 2001/20/EC of European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;

Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;

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;

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products;

Commission delegated Regulation (EU) No 1252/2014 of 28 May 2014 of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use;

Current version of the Guide to good manufacturing practices contained in volume IV of Rules governing medicinal products in the European Union and compilation of the community procedures on inspections and exchange of information.

Appendix 2

LIST OF AUTHORITIES

UNITED STATES

The Food and Drug Administration

EUROPEAN UNION

Country	For medicinal products for human use	For medicinal products for veterinary use
Austria	Austrian Agency for Health and Food Safety/Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	See responsible authority for human medicinal products
Belgium	Federal agency for medicines and health products/Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/Agence fédérale des médicaments et produits de santé	See responsible authority for human medicinal products
Bulgaria	Bulgarian Drug Agency/ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА	Bulgarian Food Safety Agency/Българска агенция по безопасност на храните
Cyprus	Ministry of Health — Pharmaceutical Services/Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	Ministry of Agriculture, Rural Development and Environment-Veterinary Services/Κτηνιατρικές Υπηρεσίες- Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος
Czech Republic	State Institute for Drug Control/Státní ústav pro kontrolu léčiv (SÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments/Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)
Croatia	Agency for Medicinal Products and Medical Devices/Agencija za lijekove i medicinske proizvode (HALMED)	Ministry of Agriculture, Veterinary and Food Safety Directorate/Ministarstvo Poljoprivrede, Uprava za veterinarstvo i sigurnost hrane
Denmark	Danish Medicines Agency/Laegemiddelstyrelsen	See responsible authority for human medicinal products
Germany	Federal Institute for Drugs and Medical Devices/Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines/Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel Federal Ministry of Health/Bundesministerium für Gesundheit (BMG)/Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) [1]	Federal Office for Consumer Protection and Food Safety/Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Federal Ministry of Food and Agriculture, Bundesministerium für Ernährung und Landwirtschaft

Country	For medicinal products for human use	For medicinal products for veterinary use
Estonia	State Agency of Medicines/Ravimiamet	See responsible authority for human medicinal products
Greece	National Organisation for Medicines/Ethnikos Organismos Farmakon (EOF) — (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ))	See responsible authority for human medicinal products
Spain	Spanish Agency of Medicines and Medical Devices/Agencia Española de Medicamentos y Productos Sanitarios (2)	See responsible authority for human medicinal products
Finland	Finnish Medicines Agency/Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)	See responsible authority for human medicinal products
France	French National Agency for Medicines and Health Products Safety Agence nationale de sécurité du médicament et des produits de santé (ANSM)	French agency for food, environmental and occupational health safety — *National Agency for Veterinary Medicinal Products*/Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail-Agence Nationale du Médicament Vétérinaire (Anses-ANMV)
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet/National Institute of Pharmacy and Nutrition	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products/Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)
Ireland	Health Products Regulatory Authority (HPRA)	See responsible authority for human medicinal products
Italy	*Italian Medicines Agency*/Agenzia Italiana del Farmaco	Direction General for Animal Health and Veterinary Medicinal Products Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari
Latvia	State Agency of Medicines/Zāļu valsts aģentūra	Assessment and Registration Department of the Food and Veterinary Service/Pārtikas un veterinārā dienesta Novērtēšanas un reģistrācijas departaments
Lithuania	State Medicines Control Agency/Valstybinė vaistų kontrolės tarnyba	State Food and Veterinary Service/Valstybinės maisto ir veterinarijos tarnyba
Luxembourg	Minìstere de la Santé, Division de la Pharmacie et des Médicaments	See responsible authority for human medicinal products
Malta	Medicines Regulatory Authority	Veterinary Medicines and Animal Nutrition section VMANS) (Veterinary Regulation Directorate (VRD) within The Veterinary and Phytosanitary Regulation Department (VPRD)

Country	For medicinal products for human use	For medicinal products for veterinary use
Netherlands	Healthcare Inspectorate/Inspectie voor de Gezondheidszorg (IGZ)	Medicines Evaluation Board/Bureau Diergeneesmiddelen, College ter Beoordeling van Geneesmiddelen (CBG)
Poland	The Main Pharmaceutical Inspectorate/ Główny Inspektorat Farmaceutyczny (GIF)	See responsible authority for human medicinal products
Portugal	National Authority of Medicines and Health Products/INFARMED, I.P Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	General Directorate of Food and Veterinary/ DGAV — Direção Geral de Alimentação e Veterinária (PT)
Romania	National Agency for Medicines and Medical Devices/Agenția Națională a Medicamentului și a Dispozitivelor Medicale	National Sanitary Veterinary and Food Safety Authority/Autoritatea Națională Sanitară Veterinară și pentru Siguranța Alimentelor
Sweden	Medical Products Agency/Läkemedelsverket	See responsible authority for human medicinal products
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia/Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	See responsible authority for human medicinal products
Slovak Republic (Slovakia)	State Institute for Drug Control/Štátny ústav pre kontrolu liečiv (ŠÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments/Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (USKVBL)
United Kingdom	Medicines and Healthcare products Regulatory Agency	Veterinary Medicines Directorate

(1) For the purpose of this Annex, and without prejudice to the internal division of competence in Germany on matters falling within the scope of this Annex, ZLG shall be understood as covering all the competent Laender authorities issuing GMP documents and conducting pharmaceutical inspections.

(2) For the purpose of this Annex, and without prejudice to the internal division of competence in Spain on matters falling within the scope of this Annex, Agencia Española de Medicamentos y Productos Sanitarios shall be understood as covering all the competent regional authorities issuing GMP documents and conducting pharmaceutical inspections.

Appendix 3

LIST OF PRODUCTS COVERED BY THE ANNEX

Recognizing that precise definition of medicinal products and drugs are to be found in the laws, regulations and administrative provisions referred to in Appendix 1, an indicative list of products covered by the Annex is given below. This applies to processing, packaging, testing and sterilizing facilities, including contract facilities performing these functions.

1. Marketed finished pharmaceuticals for human use in various pharmaceutical dosage forms such as tablets, capsules, ointments, and injectables, including:

   (a) Medical gases;

   (b) Radiopharmaceuticals or radioactive biological products;

   (c) Herbal (botanical) products (*); and

   (d) Homeopathic products;

2. Marketed biological products:

   (a) Vaccines for human use (**);

   (b) Plasma derived pharmaceuticals (**);

   (c) Therapeutic biotechnology-derived biological products; and

   (d) Allergenic products.

3. In process materials (for the United States as defined under U.S. law) and intermediates (for the European Union as defined in EU legislation);

4. Active pharmaceutical ingredients or bulk drug substance;

5. Investigational products (clinical trial material) (***); and

6. Veterinary products (**):

   (a) veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals;

   (b) pre-mixes for the preparation of veterinary medicated feeds (EU), Type A medicated articles for the preparation of veterinary medicated feeds (US);

(*) These are included to the extent that they are regulated as drugs by the FDA and medicinal products by the EU.

(**) These products are only included within the product coverage of this Annex to the extent the Joint Sectoral Committee decides to include them pursuant to Article 20.

(***) The FDA does not routinely conduct GMP inspections for investigational medicinal products. Inspection information on these products will be provided to the extent that they are available and resources allow. These products are only included within the product coverage of this Annex to the extent the Joint Sectoral Committee decides to include them.

Appendix 4

CRITERIA AND PROCEDURE FOR ASSESSMENTS UNDER THIS ANNEX

I. CRITERIA FOR ASSESSMENTS UNDER THIS ANNEX

Each Party will apply the following criteria to determine whether to recognize an authority listed in Appendix 2:

(i) The authority has the legal and regulatory authority to conduct inspections against a standard for GMP (as defined in Article 1).

(ii) The authority manages conflict of interest in an ethical manner.

(iii) The authority has the ability to evaluate risks and mitigate them.

(iv) The authority maintains appropriate oversight of manufacturing facilities within its jurisdiction.

(v) The authority has and uses sufficient resources.

(vi) The authority employs trained and qualified inspectors with the skills and knowledge to identify manufacturing practices that may lead to patient harm.

(vii) The authority has the tools necessary to take action to protect the public from harm due to poor quality drugs or medicinal products.

II. PROCEDURES FOR ASSESSMENTS UNDER THIS ANNEX

A. **Assessment of EU authorities by FDA**

1. To receive a capability assessment for an authority listed in Appendix 2, each Member State authority shall submit capability assessment packages containing the following materials before the FDA will initiate an assessment:

   (i) a finalized Joint Audit Programme audit report of an audit, where the FDA has been given three months advance notice to be an observer, that includes the full report of the observed inspection, any associated corrective measures, and all documents cited by the auditors in the report for the indicators as identified by FDA in the Joint Audit Programme audit checklist as essential for the assessment and for any indicators that required the authority to propose a corrective and preventative action;

   (ii) a completed conflicts of interest questionnaire established by the FDA signed by a principal of the authority;

   (iii) a total of four inspection reports including the report from the inspections observed during the Joint Audit Program audit;

   (iv) standard operating procedures or a description on how the authority finalizes inspection reports;

   (v) standard operating procedures related to training and inspector qualification, including training files for all inspectors who conducted the inspections in the reports provided to the FDA (pursuant to subparagraph (iii)); and

   (vi) its most recent inventory of manufacturing facilities within its territory and under the authority's jurisdiction, including type of manufacturing facility of products falling within the product coverage of this Annex, and upon request, completion of a table provided by the FDA detailing types of manufacturing facilities.

2. During a capability assessment, the FDA may require additional information or further clarification from the Member State authority.

3. The FDA may waive the requirement to submit certain information listed under II.A.1 and may request alternative information from the Member State authority. The decision to waive any assessment materials will be made by the FDA on a case by case basis.

4. Upon receipt of all requisite information specified in paragraph II.A from a Member State authority, the FDA intends to submit such information for official translation into English within a reasonable timeframe. The FDA will complete assessments and determine capability of the Member State authority no later than 70 calendar days from the date the FDA receives a translation of all requisite information specified in paragraph II.A for the Member State authority. The FDA will dedicate two capability assessment teams; therefore, the FDA shall conduct assessments of two Member State authorities at any given time.

B. **Assessment of FDA by the EU**

The EU will carry out its assessment of FDA based on:

(i) The performance of an audit in line with the elements of the Joint Audit Programme taking into account audits performed in the framework of the Pharmaceutical Inspection Convention/Scheme (PIC/S) and audits performed in the context of Article 111(b)(1) of Directive 2001/83/EC.

(ii) An assessment of the equivalence of legislative and regulatory GMP requirements.

C. **Reassessment of authorities**

In the event an assessing Party issues a negative determination or suspension of an authority of the other Party, it may reassess the authority. The scope of the reassessment shall relate to the reasons for the negative determination or suspension.

III. MAINTAINING RECOGNITION

To maintain recognition, it is required that the authority continue to meet the criteria set out in paragraph I.A and remain subject to the monitoring activities described in Article 12 which for Member State authorities the FDA requires monitoring through an audit program that includes an audit (that the FDA has the option to observe) of each recognized Member State authority every five to six years. In case an authority has not been subject to an audit for a period of 6 years, the other Party shall have the right to audit such authority.

Appendix 5

SCHEDULE FOR INITIAL ASSESSMENT OF MEMBER STATE AUTHORITIES

1. Member State authorities for human pharmaceuticals listed in Appendix 2 shall submit complete capability assessment packages containing the information specified in paragraph II.A.1 of Appendix 4 according to the following schedule:

   — No later than January 1, 2017: capability assessment packages from four Member State authorities

   — No later than February 15, 2017: capability assessment packages from three additional Member State authorities

   — No later than April 1, 2017: capability assessment packages from two additional Member State authorities.

   — No later than May 15, 2017: capability assessment packages from two additional Member State authorities

   — No later than September 15, 2017: capability assessment packages from two additional Member State authorities

   — No later than December 15, 2017: capability assessment packages from four additional Member State authorities

   — No later than March 15, 2018: capability assessment packages from four additional Member State authorities

   — No later than June 15, 2018: capability assessment packages from seven additional Member State authorities

2. The FDA shall complete assessments under this Annex of Member State authorities for human pharmaceuticals listed in Appendix 2 as set out in paragraph II.A.4 and according to the following schedule, provided that the FDA receives complete capability assessment packages for such authorities containing the information specified in paragraph II.A.1 of Appendix 4 according to the schedule set out in paragraph 1:

   — November 1, 2017: eight assessments

   — March 1, 2018: four additional assessments

   — June 1, 2018: two additional assessments

   — December 1, 2018: six additional assessments

   — July 15, 2019: eight additional assessments

3. For each Member State authority:

   (a) The EU shall submit a final audit report to the FDA no later than 60 days before the due date of the capability assessment package for the authority.

   (b) The FDA shall provide a finalized capability assessment package checklist to the authority no later than 20 days after the FDA receives the audit report.

   (c) The authority shall submit the capability assessment package to FDA no later than 40 days after the authority receives the capability assessment package checklist.

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