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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.

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) No 1225/2014

of 17 November 2014

implementing Regulation (EU) No 269/2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of 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 269/2014 of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine [1], and in particular Article 14(1) thereof,

Whereas:

(1) On 17 March 2014, the Council adopted Regulation (EU) No 269/2014.

(2) The information for one person listed under Regulation (EU) No 269/2014 should be amended.

(3) Annex I to Regulation (EU) No 269/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 269/2014 is hereby 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, 17 November 2014.

For the Council
The President
F. MOGHERINI

[1] OJ L 78, 17.3.2014, p. 6.

ANNEX

The entry for the following person set out in Annex I to Regulation (EU) No 269/2014 is replaced by the entry below.

	Name	Identifying information	Statement of reasons	Date of listing
	Vladimir Volfovich ZHIRINOVSKY Владимир Вольфович Жириновский	Born on 25.4.1946 in Almaty (formerly also known as Alma-Ata), Kazakhstan.	Member of the Council of the State Duma; leader of the LDPR party. He actively supported the use of Russian Armed Forces in Ukraine and annexation of Crimea. He has actively called for the split of Ukraine. He signed, on behalf of the LDPR party he chairs, an agreement with the so-called 'Donetsk People's Republic'.	12.9.2014

COMMISSION REGULATION (EU) No 1226/2014

of 17 November 2014

on the authorisation of a health claim made on foods and referring to the reduction of disease risk

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 17(3) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Lactalis B&C, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was asked to deliver an opinion on a health claim related to 'Low fat and low trans spreadable fat rich in unsaturated and omega-3 fatty acids' and reduction of LDL-cholesterol concentrations (Question No EFSA-Q-2009-00458) ([2]). The claim proposed by the applicant was worded as follows: 'Replacing a fat rich in saturated/trans fatty acids by a fat rich in unsaturated fatty acids helps to reduce LDL cholesterol. LDL cholesterol is a cardiovascular risk factor'.

(6) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 25 May 2011 that a cause and effect relationship had been established between the consumption of mixtures of dietary saturated fatty acids (SFAs) and an increase in blood LDL-cholesterol concentrations, and that replacement of a mixture of SFAs with cis-monounsaturated fatty acids and/or cis-polyunsaturated fatty acids in foods or diets on a gram-per-gram basis reduces LDL-cholesterol concentrations. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims. The clinical intervention study claimed by the applicant as proprietary, was not considered necessary by the Authority for reaching its conclusion. It is therefore considered that the requirement laid down in Article 21(1)(c) of Regulation (EC) No 1924/2006 is not fulfilled and accordingly, protection of proprietary data should not be granted.

(7) In its opinion, the Authority concludes that in order to bear the claim, significant amounts of saturated fatty acids should be replaced by monounsaturated and/or polyunsaturated fatty acids in foods or diets on a gram-per-gram basis. Therefore, in order to ensure that a food provides significant amounts of monounsaturated and/or polyunsaturated fatty acids, it is appropriate to limit the use of the claim to fats and oils and to set conditions of use as those referred to in the nutrition claim 'HIGH UNSATURATED FAT' as laid down in the Annex to Regulation (EC) No 1924/2006.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) *EFSA Journal* 2011; 9(5):2168.

(8) Article 16(4) of Regulation (EC) No 1924/2006 provides that an opinion in favour of authorising a health claim is to include certain particulars. Accordingly, those particulars should be set out in the Annex to this Regulation as regards the authorised claim and include, as the case may be, the revised wording of the claim, specific conditions of use of the claim, and, where applicable, conditions or restrictions of use of the food and/or an additional statement or warning, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinions of the Authority.

(9) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that wording and presentation are taken into account in that respect. Therefore where the wording of claims has the same meaning for consumers as that of an authorised health claim, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use indicated in the Annex to this Regulation.

(10) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claim listed in the Annex to this Regulation may be made on foods placed on the Union market in compliance with the conditions laid down in that Annex.

2. The health claim referred to paragraph 1 shall be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

Article 2

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

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

Done at Brussels, 17 November 2014.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Permitted health claim

Application — Relevant provisions of Regulation (EC) No 1924/2006	Applicant — Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(a) health claim referring to reduction of a disease risk	Lactalis B&C, ZA Les Placis, 35230 Bourgbarré, France	Monounsaturated and/or polyunsaturated fatty acids	Replacing saturated fats with unsaturated fats in the diet has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	The claim may be used only for food which is high in unsaturated fatty acids, as referred to in the claim HIGH UNSATURATED FAT as listed in the Annex to Regulation (EC) No 1924/2006	The claim may only be used on fats and oils	Q-2009-00458

COMMISSION IMPLEMENTING REGULATION (EU) No 1227/2014

of 17 November 2014

fixing an adjustment rate for direct payments provided for in Council Regulation (EC) No 73/2009 in respect of calendar year 2014 and repealing Commission Implementing Regulation (EU) No 879/2014

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([1]), and in particular Article 26(4) thereof,

After consulting the Committee on the Agricultural Funds,

Whereas:

(1) On 21 March 2014 the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on fixing an adjustment rate for direct payments provided for in Council Regulation (EC) No 73/2009 in respect of calendar year 2014 ([2]). The European Parliament and the Council had not set that adjustment rate by 30 June 2014. Therefore, in accordance with Article 26(3) of Regulation (EU) No 1306/2013, the Commission has set the adjustment rate in Commission Implementing Regulation (EU) No 879/2014 ([3]).

(2) The forecasts for the direct payments and market related expenditure included in Commission Amending Letter No 1 to the 2015 Draft Budget show the need to adapt the rate of financial discipline which was taken into account in the Draft Budget 2015. That Amending Letter has been established taking into account an amount of financial discipline of EUR 433 million for the reserve for crises in the agricultural sector referred to in Article 25 of Regulation (EU) No 1306/2013. In order to take account of this new information, the Commission should adapt the adjustment rate set in Implementing Regulation (EU) No 879/2014.

(3) As a general rule, farmers submitting an aid application for direct payments for one calendar year (N) are paid within a fixed payment period falling under the financial year (N+1). However, Member States have the possibility to make late payments, within certain limits, to farmers beyond this payment period without any time limits. Such late payments may fall in a later financial year. When financial discipline is applied for a given calendar year, the adjustment rate should not be applied to payments for which aid applications have been submitted in the calendar years other than that for which the financial discipline applies. Therefore, in order to ensure equal treatment of farmers, it is appropriate to provide that the adjustment rate is only applied to payments for which aid applications have been submitted in the calendar year for which the financial discipline is applied, irrespectively of when the payment to farmers is made.

(4) Article 8(1) of Regulation (EU) No 1307/2013 of the European Parliament and of the Council ([4]) lays down that the adjustment rate applied to direct payments determined in accordance with Article 26 of Regulation (EU) No 1306/2013 applies only to direct payments in excess of EUR 2 000 to be granted to farmers in the corresponding calendar year. Furthermore Article 8(2) of Regulation (EU) No 1307/2013 provides that as a result of the gradual introduction of direct payments, the adjustment rate applies only to Bulgaria and Romania from 1 January 2016 and to Croatia from 1 January 2022. The adjustment rate to be determined by the present Regulation should therefore not apply to payments to farmers in those Member States.

([1]) OJ L 347, 20.12.2013, p. 549.
([2]) COM(2014)175.
([3]) Commission Implementing Regulation (EU) No 879/2014 of 12 August 2014 fixing an adjustment rate for direct payments provided for in Council Regulation (EC) No 73/2009 in respect of calendar year 2014 (OJ L 240, 13.8.2014, p. 20).
([4]) Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

(5) In order to ensure that the adapted adjustment rate is applicable as from the date on which the payments to farmers are to start in accordance with Regulation (EU) No 1306/2013, this Regulation should apply from 1 December 2014.

(6) The adapted adjustment rate should be taken into account for the calculation of all payments to be granted to a farmer for an aid application submitted in respect of calendar year 2014. For the sake of clarity, Implementing Regulation (EU) No 879/2014 should therefore be repealed,

HAS ADOPTED THIS REGULATION:

Article 1

1. For the purpose of applying the adjustment provided for in Articles 25 and 26 of Regulation (EU) No 1306/2013 and in accordance with Article 8(1) of Regulation (EU) No 1307/2013, the amounts of the payments within the meaning of Article 2(d) of Council Regulation (EC) No 73/2009 [1] to be granted to a farmer in excess of EUR 2 000 for an aid application submitted in respect of calendar year 2014 shall be reduced by 1,302214 %.

2. The reduction provided for in paragraph 1 shall not apply in Bulgaria, Croatia and Romania.

Article 2

Implementing Regulation (EU) No 879/2014 is repealed.

Article 3

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

It shall apply from 1 December 2014.

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

Done at Brussels, 17 November 2014.

For the Commission
The President
Jean-Claude JUNCKER

[1] Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003 (OJ L 30, 31.1.2009, p. 16).

COMMISSION REGULATION (EU) No 1228/2014

of 17 November 2014

authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 17(3) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Abtei Pharma Vertriebs GmbH, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Calcium and vitamin D3 chewing tablets and bone loss (Question No EFSA-Q-2008-721) ([2]). The claim proposed by the applicant was worded as follows: 'Chewing tablets with calcium and vitamin D improve bone density in women 50 years and older. Thus chewing tablets may reduce the risk of osteoporotic fractures'.

(6) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 7 August 2009 that a cause and effect relationship had been established between the intake of calcium, either alone or in combination with vitamin D, and reducing the loss of bone mineral density (BMD) in postmenopausal women. Reducing the loss of BMD may contribute to a reduction in the risk of bone fractures. Accordingly, two health claims reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims. However, the Authority concluded that the information provided was insufficient to establish conditions of use for the claims. Subsequently, the Commission went back to the Authority to seek further advice to enable the risk managers to set appropriate conditions of use for the relevant health claims. The Authority concluded in its opinion received by the Commission and the Member States on 17 May 2010 (Question No EFSA-Q-2009-00940) ([3]) that at least 1 200 mg of calcium from all sources or at least 1 200 mg of calcium and 800 I.U. (20 µg) of vitamin D from all sources should be consumed daily in order to obtain the claimed effect.

(7) When the health claim is made only on calcium, in order to ensure that a food provides a significant quantity of calcium, it is appropriate to set conditions of use which allow the claim to be made only on foods which provide at least 400 mg of calcium per quantified portion.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) EFSA Journal (2009) 1180, 1-13.
([3]) EFSA Journal (2010);8(5):1609.

(8) Taking into account the high level of vitamin D intake required to achieve the claimed effect (20 µg), when the health claim is made on the combination of calcium and vitamin D, it is appropriate to limit the use of the claim to food supplements. In order to ensure that a food supplement would provide a significant quantity of calcium and vitamin D in the context of this claim, it is appropriate to set conditions of use which allow the claim to be made only on food supplements which provide at least 400 mg of calcium and 15 µg of vitamin D per daily portion.

(9) Following an application from DSM Nutritional Products Europe AG, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of vitamin D and risk of falling for men and women 60 years of age and older (Question No EFSA-Q-2010-01233) ([1]). The claim proposed by the applicant was worded as follows: 'Vitamin D reduces the risk of falling. Falling is a risk factor for fractures'.

(10) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 30 September 2011 that a cause and effect relationship had been established between the intake of vitamin D and a reduction in the risk of falling, which is positively associated with postural instability and muscle weakness. A reduction in the risk of falling among men and women 60 years of age and older is beneficial to human health by reducing the risk of bone fractures. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(11) In its opinion, the Authority also concluded that 800 I.U. (20 µg) of vitamin D, from all sources, should be consumed daily in order to obtain the claimed effect. Taking into account the high level of vitamin D intake required to achieve the claimed effect (20 µg), it is appropriate to limit the use of the claim to food supplements. In order to ensure that a food supplement would provide a significant quantity of vitamin D in the context of this claim, it is appropriate to set conditions of use which allow the claim to be made only on food supplements which provide at least 15 µg of vitamin D per daily portion.

(12) Article 16(4) of Regulation (EC) No 1924/2006 provides that an opinion in favour of authorising a health claim should include certain particulars. Accordingly, those particulars should be set out in Annex I to this Regulation as regards the authorised claims and include, as the case may be, the revised wording of the claim, specific conditions of use of the claim, and, where applicable, conditions or restrictions of use of the food and/or an additional statement or warning, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinions of the Authority.

(13) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that wording and presentation are taken into account in that respect. Therefore where the wording of claims has the same meaning for consumers as that of an authorised health claim, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use indicated in Annex I to this Regulation.

(14) Following an application from GP International Holding B.V., submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to glucosamine hydrochloride and reduced rate of cartilage degeneration (Question No EFSA-Q-2009-00412) ([2]). The claim proposed by the applicant was worded as follows: 'Slowing down/reduce the destruction process of cartilage of the musculoskeletal system and consequently reduce the risk of osteoarthritis'.

(15) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 29 October 2009 that a cause and effect relationship had not been established between the consumption of glucosamine hydrochloride and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(16) Following an application from the European Natural Soyfood Manufacturers Association (ENSA), the European Vegetable Protein Federation (EUVEPRO) and the Soya Protein Association (SPA), submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of isolated soy protein on reduction of blood LDL-cholesterol concentrations (Question No EFSA-Q-2011-00784) ([3]). The claim proposed by the applicant was worded as follows: 'Protein-rich soybean component has been shown to lower/reduce blood cholesterol; blood cholesterol lowering may reduce the risk of (coronary) heart disease'.

([1]) EFSA Journal (2011);9(9):2382.
([2]) EFSA Journal 2009;7(10):1358.
([3]) EFSA Journal 2012;10(2):2555.

(17) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 2 February 2012 that a cause and effect relationship had not been established between the consumption of isolated soy protein, as defined by the applicant, and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(18) Following an application from Health Concern B.V., submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations (Question No EFSA-Q-2009-00237, EFSA-Q-2011-01114) ([1]). The claim proposed by the applicant was worded as follows: 'Actively lowers cholesterol'.

(19) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 17 July 2012 that a cause and effect relationship had not been established between the consumption of a combination of plant sterols and Cholesternorm®mix and the claimed effect at the proposed conditions of use. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(20) Following an application from Minami Nutrition Health BVBA, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of eicosapentaenoic acid (EPA) on a reduction of the Arachidonic Acid (AA)/EPA ratio in blood in children with attention deficit hyperactivity disorder (ADHD) (Question No EFSA-Q-2012-00573) ([2]). The claim proposed by the applicant was worded as follows: 'EPA has been shown to reduce the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour'.

(21) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 8 April 2013 that the target population for the claim is a diseased population (i.e. children with ADHD) and that the claimed effect relates to the treatment of a disease.

(22) Regulation (EC) No 1924/2006 complements the general principles of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([3]). Article 2(1)(b) of Directive 2000/13/EC provides that the labelling shall not attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties. Accordingly, as the attribution of medicinal properties to foods is prohibited, the claim related to the effects of eicosapentaenoic acid (EPA) on a reduction of the AA/EPA ratio in blood in children with ADHD should not be authorised.

(23) Following an application from McNeil Nutritionals and Raisio Nutrition Ltd, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the consumption of 2 g/day of plant stanols (as plant stanol esters) as part of a diet low in saturated fat and a two-fold greater reduction in blood LDL-cholesterol concentrations compared to the consumption of a diet low in saturated fat alone (Question No EFSA-Q-2012-00915) ([4]). The claim proposed by the applicant was worded as follows: 'Consuming 2 g/day plant stanols (as plant stanol esters) as part of a diet low in saturated fat results in a 2-fold greater reduction in LDL-cholesterol than consuming a low saturated fat diet alone. High cholesterol is a risk factor in the development of coronary heart disease'.

(24) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 8 April 2013 that the evidence provided by the applicant does not establish that the consumption of 2 g/day plant stanols (as plant stanol esters) as part of a diet low in saturated fat results in a two-fold greater reduction in LDL-cholesterol concentrations compared with consuming a diet low in saturated fat alone. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(25) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

([1]) EFSA Journal 2012;10(7):2810.
([2]) EFSA Journal 2013;11(4):3161.
([3]) OJ L 109, 6.5.2000, p. 29.
([4]) EFSA Journal 2013;11(4):3160.

(26) The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 14(1) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff.

(27) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claims listed in Annex I to this Regulation may be made on foods placed on the Union market in compliance with the conditions laid down in that Annex.

2. The health claims referred to in paragraph 1 shall be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

Article 2

The health claims listed in Annex II to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

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, 17 November 2014.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Permitted health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Applicant — Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	Abtei Pharma Vertriebs GmbH, Abtei 1, 37696, Marienműnster, Germany.	Calcium	Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food which provides at least 400 mg of calcium per quantified portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1 200 mg of calcium from all sources.	For foods with added calcium the claim may be used only for those targeting women 50 years and older	Q-2008-721 Q- 2009-00940
Article 14(1)(a) health claim referring to a reduction of a disease risk	Abtei Pharma Vertriebs GmbH, Abtei 1, 37696, Marienműnster, Germany.	Calcium and vitamin D	Calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food supplements which provide at least 400 mg of calcium and 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1 200 mg of calcium and 20 µg of vitamin D from all sources.	For food supplements with added calcium and vitamin D the claim may be used only for those targeting women 50 years and older	Q-2008-721 Q- 2009-00940
Article 14(1)(a) health claim referring to a reduction of a disease risk	DSM Nutritional Products Europe AG, P.O. Box 2676, 4002 Basel, Switzerland.	Vitamin D	Vitamin D helps to reduce the risk of falling associated with postural instability and muscle weakness. Falling is a risk factor for bone fractures among men and women 60 years of age and older.	The claim may be used only for food supplements which provide at least 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 20 µg of vitamin D from all sources.	For food supplements with added vitamin D the claim may be used only for those targeting men and women 60 years and older	Q-2010-01233

ANNEX II

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	Glucosamine hydrocloride	Slowing down/reduce the destruction process of cartilage of the musculoskeletal system and consequently reduce the risk of osteoarthritis.	Q-2009-00412
Article 14(1)(a) health claim referring to a reduction of a disease risk	Isolated soy protein	Protein-rich soybean component has been shown to lower/reduce blood cholesterol; blood cholesterol lowering may reduce the risk of (coronary) heart disease.	Q-2011-00784
Article 14(1)(a) health claim referring to a reduction of a disease risk	Plant sterols in combination with Cholesternorm®mix	Actively lowers cholesterol.	Q-2009-00237 Q-2011-01114
Article 14(1)(a) health claim referring to a reduction of a disease risk	Eicosapentanoic acid (EPA)	EPA has been shown to reduce the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour.	Q-2012-00573
Article 14(1)(a) health claim referring to a reduction of a disease risk	Plant stanols (as plant stanol esters)	Consuming 2 g/day plant stanols (as plant stanol esters) as part of a diet low in saturated fat results in a 2-fold greater reduction in LDL-cholesterol than consuming a low saturated fat diet alone. High cholesterol is a risk factor in the development of coronary heart disease.	Q-2012-00915

COMMISSION REGULATION (EU) No 1229/2014

of 17 November 2014

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 18(5) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(3) The Authority is to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Italsur S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of Tuscan black cabbage, 'tri-coloured' Swiss chard, 'bi-coloured' spinach and 'blu savoy' cabbage and protection of blood lipids from oxidative damage (Question No EFSA-Q-2013-00574) ([2]). The claim proposed by the applicant was worded as follows: 'contributes to the protection of blood lipids from oxidative damage'.

(6) On 30 October 2013, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of Tuscan black cabbage, 'tri-coloured' Swiss chard, 'bi-coloured' spinach and 'blu savoy' cabbage and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from Italsur S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard and protection of blood lipids from oxidative damage (Question No EFSA-Q-2013-00575) ([3]). The claim proposed by the applicant was worded as follows: 'contributes to the protection of blood lipids from oxidative damage'.

(8) On 30 October 2013, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) The EFSA Journal 2013;11(10):3413.
([3]) The EFSA Journal 2013;11(10):3414.

(9) Following an application from Italsur S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of Tuscan black cabbage, 'tri-coloured' Swiss chard, 'bi-coloured' spinach and 'blu savoy' cabbage and maintenance of normal blood LDL-cholesterol concentration (Question No EFSA-Q-2013-00576) ([1]). The claim proposed by the applicant was worded as follows: 'maintains normal blood cholesterol concentration'.

(10) On 30 October 2013, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of Tuscan black cabbage, 'tri-coloured' Swiss chard, 'bi-coloured' spinach and 'blu savoy' cabbage and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) Following an application from Italsur S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard and maintenance of normal blood LDL-cholesterol concentration (Question No EFSA-Q-2013-00579) ([2]). The claim proposed by the applicant was worded as follows: 'maintain normal blood cholesterol concentrations'.

(12) On 30 October 2013, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(13) Following an application from Omikron Italia S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of diosmin, troxerutin and hesperidin and maintenance of normal venous-capillary permeability (Question No EFSA-Q-2013-00353) ([3]). The claim proposed by the applicant was worded as follows: 'the flavonoid mixture containing 300 mg of diosmin, 300 mg of troxerutin and 100 mg of hesperidin is a useful co adjuvant in maintaining physiological venous-capillary permeability'.

(14) On 13 January 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of diosmin, troxerutin and hesperidin and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) Following an application from Omikron Italia S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of diosmin, troxerutin and hesperidin and maintenance of normal venous tone (Question No EFSA-Q-2013-00354) ([4]). The claim proposed by the applicant was worded as follows: 'the flavonoid mixture containing 300 mg of diosmin, 300 mg of troxerutin and 100 mg of hesperidin is a useful co adjuvant in maintaining physiological venous tone'.

(16) On 13 January 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of diosmin, troxerutin and hesperidin and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(17) Following an application from Italsur S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of the barley soup 'Orzotto' and protection of blood lipids from oxidative damage (Question No EFSA-Q-2013-00578) ([5]). The claim proposed by the applicant was worded as follows: 'contributes to the protection of blood lipids from oxidative damage'.

([1]) The EFSA Journal 2013;11(10):3415.
([2]) The EFSA Journal 2013;11(10):3416.
([3]) The EFSA Journal 2014;12(1):3511.
([4]) The EFSA Journal 2014;12(1):3512.
([5]) The EFSA Journal 2014;12(1):3519.

(18) On 10 January 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of the barley soup 'Orzotto' and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

Article 2

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

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

Done at Brussels, 17 November 2014.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of Tuscan black cabbage, 'tri-coloured' Swiss chard, 'bi-coloured' spinach and 'blu savoy' cabbage	Contributes to the protection of blood lipids from oxidative damage	Q-2013-00574
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard	Contributes to the protection of blood lipids from oxidative damage	Q-2013-00575
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of Tuscan black cabbage, 'tri-coloured' Swiss chard, 'bi-coloured' spinach and 'blu savoy' cabbage	Maintains normal blood cholesterol concentration	Q-2013-00576
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard	Maintain normal blood cholesterol concentrations	Q-2013-00579
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of diosmin, troxerutin and hesperidin	The flavonoid mixture containing 300 mg of diosmin, 300 mg of troxerutin and 100 mg of hesperidin is a useful co adjuvant in maintaining physiological venous-capillary permeability	Q-2013-00353
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of diosmin, troxerutin and hesperidin	The flavonoid mixture containing 300 mg of diosmin, 300 mg of troxerutin and 100 mg of hesperidin is a useful co adjuvant in maintaining physiological venous tone	Q-2013-00354
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Barley soup 'Orzotto'	Contributes to the protection of blood lipids from oxidative damage	Q-2013-00578

COMMISSION IMPLEMENTING REGULATION (EU) No 1230/2014

of 17 November 2014

concerning the authorisation of copper bilysinate as a feed additive for all animal species

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of copper bilysinate. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of copper bilysinate as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 July 2014 ([2]) that, under the proposed conditions of use, copper bilysinate does not have an adverse effect on animal health, human health or the environment and that it may be considered as an efficacious source of copper for all animal species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of copper bilysinate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.

(6) 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

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2014; 12(7):3796.

Article 2

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

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

Done at Brussels, 17 November 2014.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Cu) in mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b411	—	Copper bilysinate	*Characterisation of the additive* Powder or granulate with a content of copper ≥ 14,5 % and lysine ≥ 84,0 %. *Characterisation of the active substance* Copper chelate of L-lysinate-HCl Chemical formula: $Cu(C_6H_{13}N_2O_2)_2 \times 2HCl$ CAS number: 53383-24-7 *Analytical methods* (1)*:* For the quantification of Lysine content in the feed additive: — Ion-exchange chromatography combined with post-column derivatisation and colorimetric or fluorescence detection — EN ISO 17180. For the quantification of total copper content in the feed additive and premixtures: — Inductively coupled plasma atomic emission spectrometry (ICP-AES) — EN 15510,	All animal species	—	—	Bovines: — bovines before the start of rumination: 15 (total), — other bovines: 35 (total). Ovines: 15 (total). Piglets up to 12 weeks: 170 (total). Crustaceans: 50 (total). Other animals: 25 (total).	1. The additive shall be incorporated into feed in the form of a premixture. 2. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 3. The following words shall be included in the labelling: — For feed for sheep if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.' — For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.' — 'The lysine content of the additive should be considered when formulating feed.'	8 December 2024.

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Cu) in mg/kg of complete feedingstuff with a moisture content of 12 %			
			or — Inductively coupled plasma atomic emission spectrometry after pressure digestion, (ICP-AES) — EN 15621. For the quantification of total copper in the feed materials and compound feed: — Atomic absorption spectrometry (AAS) — Commission Regulation (EC) No 152/2009, or — Inductively coupled plasma atomic emission spectrometry (ICP-AES) — EN 15510, or — Inductively coupled plasma atomic emission spectrometry after pressure digestion (ICP-AES) — EN 15621.						

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

COMMISSION IMPLEMENTING REGULATION (EU) No 1231/2014

of 17 November 2014

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, 17 November 2014.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-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	AL	94,9
	MA	77,1
	MK	78,8
	ZZ	83,6
0707 00 05	AL	67,4
	JO	194,1
	TR	128,5
	ZZ	130,0
0709 93 10	AL	65,0
	MA	52,3
	TR	125,4
	ZZ	80,9
0805 20 10	MA	130,6
	ZZ	130,6
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	TR	74,4
	ZZ	74,4
0805 50 10	TR	78,7
	ZZ	78,7
0806 10 10	BR	293,5
	LB	337,2
	PE	282,9
	TR	149,1
	US	303,0
	ZZ	273,1
0808 10 80	BR	54,0
	CA	135,3
	CL	80,6
	MD	29,7
	NZ	144,2
	US	102,4
	ZA	108,6
	ZZ	93,5
0808 30 90	CN	75,6
	ZZ	75,6

(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 2014/800/CFSP

of 17 November 2014

launching the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine) and amending Decision 2014/486/CFSP

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 28 and Articles 42(4) and 43(2) thereof,

Having regard to Council Decision 2014/486/CFSP of 22 July 2014 on the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine) ([1]), and in particular Article 4 thereof,

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

Whereas:

(1) On 22 July 2014, the Council adopted Decision 2014/486/CFSP.

(2) On 20 October 2014, the Council approved the operation plan for EUAM Ukraine.

(3) Following the recommendation of the Civilian Operation Commander and after EUAM Ukraine having reached the initial operational capability, EUAM Ukraine should be launched on 1 December 2014.

(4) Decision 2014/486/CFSP foresaw the financial reference amount of EUR 2 680 000 for the period until 30 November 2014. A new financial reference amount for the period of 12 months starting on 1 December 2014 should be provided. Decision 2014/486/CFSP should therefore be amended.

(5) EUAM Ukraine will be conducted 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

The European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine) shall be launched on 1 December 2014.

Article 2

The Civilian Operation Commander for EUAM Ukraine is hereby authorised with immediate effect to start execution of the operation.

Article 3

Article 14(1) of Decision 2014/486/CFSP is replaced by the following:

'1. The financial reference amount intended to cover the expenditure related to EUAM Ukraine until 30 November 2014 shall be EUR 2 680 000. The financial reference amount intended to cover the expenditure related to EUAM Ukraine for the period from 1 December 2014 to 30 November 2015 shall be EUR 13 100 000. The financial reference amount for the subsequent periods shall be decided by the Council.'.

([1]) OJ L 217, 23.7.2014, p. 42.

Article 4

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

Done at Brussels, 17 November 2014.

For the Council
The President
F. MOGHERINI

COUNCIL DECISION 2014/801/CFSP

of 17 November 2014

amending Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

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

Whereas:

(1) On 17 March 2014, the Council adopted Decision 2014/145/CFSP ([1]).

(2) The information for one person listed under Decision 2014/145/CFSP should be amended.

(3) The Annex to Decision 2014/145/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2014/145/CFSP is hereby amended as set out 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, 17 November 2014.

For the Council
The President
F. MOGHERINI

([1]) Council Decision 2014/145/CFSP of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (OJ L 78, 17.3.2014, p. 16).

ANNEX

The entry for the following person set out in the Annex to Decision 2014/145/CFSP is replaced by the entry below.

	Name	Identifying information	Statement of reasons	Date of listing
	Vladimir Volfovich ZHIRINOVSKY Владимир Вольфович Жириновский	Born on 25.4.1946 in Almaty (formerly also known as Alma-Ata), Kazakhstan.	Member of the Council of the State Duma; leader of the LDPR party. He actively supported the use of Russian Armed Forces in Ukraine and annexation of Crimea. He has actively called for the split of Ukraine. He signed, on behalf of the LDPR party he chairs, an agreement with the so-called 'Donetsk People's Republic'.	12.9.2014

COMMISSION IMPLEMENTING DECISION

of 14 November 2014

amending Decisions 2010/470/EU and 2010/472/EU as regards the animal health requirements relating to scrapie for trade in and imports into the Union of embryos of animals of the ovine and caprine species

(notified under document C(2014) 8339)

(Text with EEA relevance)

(2014/802/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC ([1]), and in particular the third indent of Article 11(3), Article 17(2)(b), the first indent of Article 18(1), and the introductory phrase and point (b) of Article 19 thereof,

Whereas:

(1) Part A of Annex IV to Commission Decision 2010/470/EU ([2]) sets out the model health certificate for intra-Union trade in consignments of ova and embryos of animals of the ovine and caprine species collected or produced after 31 August 2010.

(2) Part 2 of Annex IV to Commission Decision 2010/472/EU ([3]) sets out the model health certificate for the importation into the Union of consignments of ova and embryos of animals of the ovine and caprine species.

(3) Regulation (EC) No 999/2001 of the European Parliament and of the Council ([4]) lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals. Chapter A of Annex VIII to that Regulation sets out the conditions for intra-Union trade in live animals, semen and embryos. In addition, Annex IX to that Regulation sets out the conditions for the importation into the Union of live animals, embryos, ova and products of animal origin from third countries.

(4) In the light of new scientific evidence, Regulation (EC) No 999/2001 was amended by Commission Regulation (EU) No 630/2013 ([5]). Those amendments, relating to scrapie, were reflected by Commission Implementing Decision 2013/470/EU ([6]) in the model health certificate for intra-Union trade in consignments of ova and embryos of animals of the ovine and caprine species set out in Part A of Annex IV to Decision 2010/470/EU and the model health certificate for imports into the Union of consignments of ova and embryos of animals of the ovine and caprine species set out in Part 2 of Annex IV to Decision 2010/472/EU, with a transitional period until 31 December 2014.

([1]) OJ L 268, 14.9.1992, p. 54.
([2]) Commission Decision 2010/470/EU of 26 August 2010 laying down model health certificates for trade within the Union in semen, ova and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species (OJ L 228, 31.8.2010, p. 15).
([3]) Commission Decision 2010/472/EU of 26 August 2010 on imports of semen, ova and embryos of animals of the ovine and caprine species into the Union (OJ L 228, 31.8.2010, p. 74).
([4]) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).
([5]) Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 179, 29.6.2013, p. 60).
([6]) Commission Implementing Decision 2013/470/EU of 20 September 2013 amending Decisions 2010/470/EU and 2010/472/EU as regards the animal health requirements relating to scrapie for trade in and imports into the Union of semen, ova and embryos of animals of the ovine and caprine species (OJ L 252, 24.9.2013, p. 32).

(5) In accordance with a scientific opinion on the risk of transmission of classical scrapie via *in vivo* derived embryo transfer in ovine animals of the European Food Safety Authority (EFSA) adopted on 24 January 2013, where it was concluded that the risk of transmitting classical scrapie by the implantation of homozygous or heterozygous ovine ARR embryos could be considered negligible, provided that the OIE recommendations and procedures relating to embryo transfer are followed, the relevant provisions of Regulation (EC) No 999/2001 were amended by Commission Regulation (EU) No 1148/2014 ([1]).

(6) The model health certificate for intra-Union trade in consignments of ova and embryos of animals of the ovine and caprine species set out in Part A of Annex IV to Decision 2010/470/EU and the model health certificate for imports into the Union of consignments of ova and embryos of animals of the ovine and caprine species set out in Part 2 of Annex IV to Decision 2010/472/EU should therefore be amended in order to reflect the requirements laid down in Regulation (EC) No 999/2001, as amended by Regulation (EU) No 1148/2014.

(7) In addition, in the model health certificate for intra-Union trade in consignments of ova and embryos of animals of the ovine and caprine species set out in Part A of Annex IV to Decision 2010/470/EU, certain references to Regulation (EC) No 999/2001 need to be amended in order to remove any ambiguity.

(8) Furthermore, in the model health certificate for imports into the Union of consignments of ova and embryos of animals of the ovine and caprine species set out in Part 2 of Annex IV to Decision 2010/472/EU, a more precise wording is required in order to ensure a clear understanding that testing regimes referring to epizootic haemorrhagic disease (EHD) apply to the donor females of ovine or caprine species.

(9) Decisions 2010/470/EU and 2010/472/EU should therefore be amended accordingly.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Annex IV to Decision 2010/470/EU is amended in accordance with Annex I to this Decision.

Article 2

Annex IV to Decision 2010/472/EU is amended in accordance with Annex II to this Decision.

Article 3

This Decision shall apply from 1 January 2015.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 14 November 2014.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

([1]) Commission Regulation (EU) No 1148/2014 of 28 October 2014 amending the Annexes II, VII, VIII, IX and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 308, 29.10.2014, p. 66).

ANNEX I

In Annex IV to Decision 2010/470/EU, Part A is replaced by the following:

'PART A

Model health certificate IVA for trade within the Union in consignments of ova and embryos of animals of the ovine and caprine species collected or produced in accordance with Council Directive 92/65/EEC after 31 August 2010 and dispatched by an approved embryo collection or production team of origin of the ova or embryos

EUROPEAN UNION **Intra trade certificate**

Part I: Details of consignment presented

I.1. Consignor Name Address Postal code		I.2. Certificate reference No	I.2.a. Local reference No
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postal code		I.6.	
		I.7.	
I.8. Country of origin ISO code	I.9. Region of origin Code	I.10. Country of destination ISO code	I.11. Region of destination Code
I.12. Place of origin Embryo team ☐ Name Approval number Address Postal code		I.13. Place of destination Holding ☐ Embryo team ☐ Name Approval number Address Postal code	
I.14.		I.15.	
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification		I.17.	
I.18. Description of commodity		I.19. Commodity code (CN code) **05 11 99 85**	
			I.20. Quantity
I.21. Temperature of products Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages
I.23. Seal/Container No			I.24. Type of packaging
I.25. Commodities certified for: Artificial reproduction ☐			
I.26. Transit through third country ☐ Third country ISO code Exit point Code Entry point BIP No		I.27. Transit through Member States ☐ Member State ISO code Member State ISO code Member State ISO code	
I.28. Export ☐ Third country ISO code Exit point Code		I.29.	
I.30.			
I.31. Identification of the commodities Species (Scientific name) Category Donor identity Date of collection Approval number of the team Quantity			

EUROPEAN UNION **Ovine and caprine ova/embryos — Part A**

II. Health information	II.a. Certificate reference number	II.b.

Part II: Certification

I, the undersigned official veterinarian, hereby certify that:

([1]) *either* [II.1. the *in vivo* derived embryos ([1])/*in vivo* derived ova ([1]) described above were collected, processed and stored by an embryo collection team ([2]) approved and supervised in accordance with Chapter I(III)(1) of Annex D to Directive 92/65/EEC;]

([1]) *or* [II.1. the *in vitro* produced embryos ([1])/micromanipulated embryos ([1]) described above were produced, processed and stored by an embryo production team ([2]) approved and supervised in accordance with Chapter I(III)(1) and (2) of Annex D to Directive 92/65/EEC;]

([1]) *either* [II.2. the *in vivo* derived embryos described above meet the requirements of Chapter III(II)(1) of Annex D to Directive 92/65/EEC;]

([1]) *or* [II.2. the *in vivo* derived ova described above meet the requirements of Chapter III(II)(2) of Annex D to Directive 92/65/EEC;]

([1]) *or* [II.2. the *in vitro* produced embryos described above meet the requirements of Chapter III(II)(3) of Annex D to Directive 92/65/EEC;]

([1]) *or* [II.2. the micromanipulated embryos described above meet the requirements of Chapter III(II)(4) of Annex D to Directive 92/65/EEC;]

([1]) [II.3. the consignment consists of embryos of the ovine or caprine species which:

([1]) *either* [were collected from animals which have been kept continuously since birth on a holding or holdings recognised as having a negligible or a controlled risk of classical scrapie in accordance with point 1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]]

([1]) *or* [were collected from animals which have been kept continuously for the last three years before the collection on a holding or holdings which have complied for the last three years before collection with the requirements laid down in points (a) to (f) of point 1.3. of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]]

([1]) *or* [were collected from animals which have been kept continuously since birth in a Member State or zone of a Member State with a negligible risk status for classical scrapie approved in accordance with the first subparagraph of point 2.2. of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]]

([1]) *or* [were collected from ovine animals and

([1]) *either* [are of the ARR/ARR prion protein genotype;]]

([1]) *or* [carry at least one ARR allele and were collected after the date of 1 January 2015;]]

II.4. the ova or embryos described above come from female donors of the ovine ([1])/caprine species ([1]) which meet the requirements of Chapter IV(3) of Annex D to Directive 92/65/EEC;

([1]) *either* [II.5. the embryos described above were conceived as a result of artificial insemination of the donor females with semen which was collected, processed, stored and transported under conditions which comply with the requirements of Chapters I(I), II(I) and III(I) of Annex D to Directive 92/65/EEC;]

([1]) *or* [II.5. the embryos described above were conceived as a result of *in vitro* fertilisation of ova complying with the conditions in Chapter III(II)(2) of Annex D to Directive 92/65/EEC with semen which was collected, processed, stored and transported under conditions which comply with the requirements of Chapters I(I), II(I) and III(I) of Annex D to Directive 92/65/EEC;]

([1]) *or* [II.5. the ova have not been in contact with semen of the ovine and caprine species;]

II.6. the ova or embryos described above were sent to the place of loading in a sealed container in accordance with point 6 of Chapter III(II) of Annex D to Directive 92/65/EEC and bearing the number detailed in Box I.23.

Notes

Part I:

Box I.12: *Place of origin* shall correspond to the embryo collection team or embryo production team of embryos collection/production.

Box I.13: *Place of destination* shall correspond to the embryo collection team, embryo production team or to the holding of ova/embryos destination.

EUROPEAN UNION **Ovine and caprine ova/embryos — Part A**

II. Health information	II.a. Certificate reference number	II.b.

Box I.23: Identification of container and seal number shall be indicated.

Box I.31: *Category*: specify if: *in vivo* derived embryos, *in vivo* derived ova, *in vitro* produced embryos or micromanipulated embryos.

Donor identity shall correspond to the official identification of the animal.

Date of collection shall be indicated in the following format: dd/mm/yyyy.

Approval number of the team shall correspond to the embryo collection team or embryo production team of ova/embryos collection/production.

Part II:

([1]) Delete as appropriate.

([2]) Only approved embryo collection or production teams listed in accordance with Article 11(4) of Directive 92/65/EEC on the Commission website:

http://ec.europa.eu/food/animal/approved_establishments/establishments_vet_field_en.htm.

— The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian or official inspector

Name (in capital letters): Qualification and title:

Local veterinary unit: LVU No:

Date: Signature:

Stamp:'

ANNEX II

In Annex IV to Decision 2010/472/EU, Part 2 is replaced by the following:

'PART 2

Model health certificate for imports of consignments of ova and embryos of animals of the ovine and caprine species

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postal code Tel.		I.6. Person responsible for the load in EU Name Address Postal code Tel.	
I.7. Country of origin / ISO code	I.8. Region of origin / Code	I.9. Country of destination / ISO code	I.10. Region of destination / Code
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Name Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code) **05 11 99 85**	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Seal/Container No		I.24.	
I.25. Commodities certified for: Artificial reproduction ☐			
I.26. For transit through EU to third country ☐ Third country ISO code		I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species (Scientific name) Category Donor identity Date of collection Date of freezing Approval number of the team Quantity			

COUNTRY **Ovine and caprine ova/embryos**

II. Health information	II.a. Certificate reference number	II.b.

Part II: Certification

I, the undersigned, official veterinarian, hereby certify that:

II.1. The exporting country .....

(*name of exporting country*) ([2])

II.1.1. has been free from rinderpest, peste des petits ruminants, sheep and goat pox, contagious caprine pleuropneumonia, and Rift Valley fever during the 12 months immediately prior to collection of the ova ([1])/embryos ([1]) to be exported and until their date of dispatch to the Union and no vaccination against these diseases took place during that period;

([1]) *either* [II.1.2. has been free from foot-and-mouth disease during the 12 months immediately prior to collection of the ova ([1])/embryos ([1]) and did not carry out vaccination against foot-and-mouth disease during that period;]

([1]) *or* [II.1.2. has not been free from foot-and-mouth disease during the 12 months immediately prior to collection of the ova ([1])/embryos ([1]) and/or carried out vaccination against foot-and-mouth disease during that period and the donor females come from holdings on which no animal was vaccinated against foot-and-mouth disease during 30 days prior to collection and no animal of susceptible species showed clinical signs of foot-and-mouth disease during the 30 days prior to, and at least 30 days after, the ova ([1])/embryos ([1]) were collected and the ova ([1])/embryos ([1]) were not subjected to penetration of *zona pellucida*;]

II.2. The ova ([1])/embryos ([1]) to be exported:

II.2.1. were collected ([1])/produced ([1]) and processed on premises within a 10-km radius of which there was no incidence of foot-and-mouth disease, vesicular stomatitis, Rift Valley fever in the 30 days immediately prior to their collection;

II.2.2. were stored at all times on approved premises within a 10-km radius of which there was no incidence of foot-and-mouth disease, vesicular stomatitis or Rift Valley fever from the time of their collection until 30 days thereafter;

II.2.3. were collected ([1])/produced ([1]) by the team described in Box I.11., which has been approved and supervised in accordance with the conditions for the approval and supervision of embryo collection teams and embryo production teams laid down in Chapter I(III) of Annex D to Directive 92/65/EEC;

II.2.4. meet the conditions for ova and embryos laid down in Chapter III(II) of Annex D to Directive 92/65/EEC;

II.2.5. come from the donor females of ovine ([1])/caprine ([1]) species which:

([1]) *either* [II.2.5.1. were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during collection of the ova ([1])/embryos ([1]);]

([1]) *or* [II.2.5.1. were kept during a bluetongue virus seasonally free period in a seasonally free zone;]

([1]) *or* [II.2.5.1. were kept protected from the vector for at least 60 days prior to, and during the collection of the ova ([1])/embryos ([1]);]

([1]) *or* [II.2.5.1. underwent a serological test for the detection of antibody to the bluetongue virus serogroup, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals between 21 and 60 days after collection of the ova ([1])/embryos ([1]) and giving negative results;]

([1]) *or* [II.2.5.1. underwent an agent identification test for bluetongue virus, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on a blood sample taken on the day of the ova ([1])/embryos ([1]) collection or the day of slaughtering and giving negative results;]

II.2.5.2. to the best of my knowledge do not come from holdings and have not been in contact with animals of a holding, in which, based on the official notification system and according to the written declaration made by the owner, any of the following diseases has been clinically detected within the periods referred to in points (a) to (d) prior to collection of the ova ([1])/embryos ([1]) to be exported:

(a) contagious agalactia of sheep or goats (*Mycoplasma agalactiae, Mycoplasma capricolum, Mycoplasma mycoides var. mycoides* 'large colony'), within the last six months;

(b) paratuberculosis and caseous lymphadenitis, within the last 12 months;

COUNTRY **Ovine and caprine ova/embryos**

II. Health information		II.a. Certificate reference number	II.b.

	(c)	pulmonary adenomatosis, within the last three years;
([1]) *either*	[(d)	Maedi/Visna for sheep or caprine viral arthritis/encephalitis for goats, within the last three years;]
([1]) *or*	[(d)	Maedi/Visna for sheep or caprine viral arthritis/encephalitis for goats, within the last 12 months, and all the infected animals were slaughtered and remaining animals subsequently reacted negatively to two tests carried out at least six months apart;]
	II.2.5.3.	showed no clinical signs of disease on the day of the ova ([1])/embryos ([1]) collection;
([1])([4]) *either*	[II.2.5.4.	originate from the region described in Box I.8., which has been recognised as officially brucellosis *(B. melitensis)*-free, and]
([1]) *or*	[II.2.5.4.	have belonged to a holding which has obtained and maintained its officially brucellosis *(B. melitensis)*-free status in accordance with Directive 91/68/EEC, and]
([1]) *or*	[II.2.5.4.	originate from a holding, where in respect of brucellosis (*B. melitensis*) all susceptible animals have been free from any clinical or any signs of this disease for the last 12 months, none of the ovine and caprine animals have been vaccinated against this disease, save those vaccinated with Rev. 1 vaccine more than two years ago, and all ovine and caprine animals over six months of age have been subjected to at least two tests ([3]), carried out with negative results on samples taken on ..... (*date*) and on ..... (*date*) at least six months apart, the latter being within 30 days prior to collection of the ova ([1])/embryos ([1]),]
and		have not been kept previously in a holding of a lower status;
([1]) *either*	[II.2.5.5.	have remained in the exporting country for at least the past six months prior to collection of the ova ([1])/embryos ([1]) to be exported;]
([1]) *or*	[II.2.5.5.	during the past six months prior to collection of the ova ([1])/embryos ([1]) they complied with the animal health conditions applying to donors of the ova/embryos[(1)] which are intended for export to the Union and they have been imported into the exporting country at least 30 days prior to collection of the ova ([1])/embryos ([1]) from ..... ([2]);]
	II.2.5.6.	have been kept continuously since birth in a country where the following conditions are fulfilled:
	II.2.5.6.1.	classical scrapie is compulsorily notifiable;
	II.2.5.6.2.	an awareness, surveillance and monitoring system is in place;
	II.2.5.6.3.	ovine and caprine animals affected with classical scrapie are killed and completely destroyed;
	II.2.5.6.4.	the feeding to ovine and caprine animals of meat-and-bone meal, or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period of at least the last seven years;
([1]) *either*	[II.2.5.7.	have been kept continuously for the last three years before the collection of the embryos to be exported in a holding or holdings which has/have been complying for the last three years before the collection of the embryos to be exported with the requirements laid down in points (a) to (f) of point 1.3. of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]
([1]) *or*	[II.2.5.7.	are ovine animals and the embryos
	([1]) *either*	[are of the ARR/ARR prion protein genotype;]]
	([1]) *or*	[carry at least one ARR allele and were collected after the date of 1 January 2015;]]
	[II.2.6.	were collected ([1])/produced ([1]) in the exporting country,
([1]) *either*	[II.2.6.1.	which according to official findings is free from epizootic haemorrhagic disease (EHD);]]
([1])([5]) *or*	[II.2.6.1.	in which according to official findings the following serotypes of epizootic haemorrhagic disease (EHD) exist: ..... and the donor females of ovine ([1])/caprine ([1]) species were subjected with negative results in each case to the following tests carried out in an approved laboratory:
	([1]) *either*	[a serological test ([6]) for the detection of antibody to the EHD virus serogroup, carried out on samples of blood taken on two occasions not more than 12 months apart prior to and not less than 21 days following collection for this consignment of ova ([1])/embryos ([1]);]]
	([1]) *or*	[a serological test ([6]) for the detection of antibody to the EHD virus serogroup, carried out on samples of blood taken at intervals of not more than 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment of ova ([1])/embryos ([1]);]]

COUNTRY **Ovine and caprine ova/embryos**

II. Health information	II.a. Certificate reference number	II.b.

([1]) *or* [an agent identification test ([6]), carried out on samples of blood collected at commencement and conclusion of, and at least every 7 days, if carried out as virus isolation test, or at least every 28 days, if carried out as polymerase chain reaction, during collection for this consignment of ova ([1])/embryos ([1]);]]

II.2.7. were collected ([1])/produced ([1]) after the date on which the embryo collection team was approved by the competent authority of the exporting country;

II.2.8. were processed and stored under approved conditions for at least 30 days immediately after their collection ([1])/production ([1]) and transported under conditions for ova and embryos laid down in Chapter III(II) of Annex D to Directive 92/65/EEC;

II.2.9. were sent to the place of loading in a sealed container in accordance with the requirements for the transport of embryos laid down in point 6 of Chapter III(II) of Annex D to Directive 92/65/EEC and bearing the number detailed in Box I.23.

([1]) [II.2.10. the consignment consists of embryos of the ovine or caprine species which were conceived by artificial insemination ([1])/as a result of *in vitro* fertilisation ([1]) using semen coming from semen collection centres approved ([7]) in accordance with:

([1]) *either* [II.2.10.1. Article 11(2) of Directive 92/65/EEC and located in a Member State of the European Union; and the semen complies with the requirements of Directive 92/65/EEC.]]

([1]) *or* [II.2.10.1. Article 17(3)(b) of Directive 92/65/EEC and located in a third country or part thereof listed in Annex I to Decision 2010/472/EU, and the semen complies with the requirements set out in Part 2 of Annex II to that Decision.]]

Notes

Part I:

Box I.6: *Person responsible for the load in EU*: this box is to be filled in only if it is a certificate for transit commodity.

Box I.11: *Place of origin* shall correspond to the approved embryo collection team or embryo production team by which the ova/embryos were collected/produced, processed and stored; and listed in accordance with Article 17(3)(b) of Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm.

Box I.22: Number of packages shall correspond to the number of containers.

Box I.23: Identification of container and seal number shall be indicated.

Box I.26: Fill in according to whether it is a transit or an import certificate.

Box I.27: Fill in according to whether it is a transit or an import certificate.

Box I.28: S*pecies*: select amongst '*Ovis aries*' or '*Capra hircus*' as appropriate.

Category: specify if *in vivo* derived embryos, *in vivo* derived ova, *in vitro* produced embryos or micromanipulated embryos.

Donor identity shall correspond to the official identification of the animal.

Date of collection shall be indicated for *in vivo* derived embryos and in the following format: dd.mm.yyyy.

Date of freezing shall be indicated in the following format: dd.mm.yyyy.

Approval number of the team: shall correspond to the approved embryo collection team or embryo production team by which the ova/embryos were collected/produced, processed and stored; and listed in accordance with Article 17(3)(b) of Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm.

Part II:

([1]) Delete as appropriate.

([2]) Only third countries or parts thereof listed in Annex I to Decision 2010/472/EU.

COUNTRY **Ovine and caprine ova/embryos**

II. Health information	II.a. Certificate reference number	II.b.

([3]) Tests shall be carried out in accordance with Annex C to Directive 91/68/EEC.

([4]) Only for the territory appearing with the entry 'V' in column 6 of Part 1 of Annex I to Commission Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010, p. 1).

([5]) See remarks for exporting country or part thereof concerned in Annex III to Decision 2010/472/EU.

([6]) Standards for EHD virus diagnostic tests are described in Chapter 2.1.3. of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

([7]) Only approved semen collection centres listed in accordance with Article 11(4) and Article 17(3)(b) of Directive 92/65/EEC on the Commission websites:

http://ec.europa.eu/food/animal/approved_establishments/establishments_vet_field_en.htm;
http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm.

— The signature and the stamp must be in a different colour to that of the printing.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:'

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2014 OF THE EU-SWITZERLAND JOINT COMMITTEE

of 10 October 2014

determining the cases of exemption from transmitting the data referred to in the first subparagraph of Article 3(3) of Annex I to the Agreement of 25 June 2009 between the European Community and the Swiss Confederation on the simplification of inspections and formalities in respect of the carriage of goods and on customs security measures

(2014/803/EU)

THE JOINT COMMITTEE,

Having regard to the Agreement of 25 June 2009 between the European Community and the Swiss Confederation on the simplification of inspections and formalities in respect of the carriage of goods and on customs security measures ('the Agreement'), and in particular Article 21(3) thereof, in conjunction with the second subparagraph of Article 3(3) of Annex I thereto,

Whereas:

(1) The Agreement is intended to maintain the simplification of inspections and formalities in respect of the passage of goods at frontiers and the smooth flow of trade between the two Contracting Parties, whilst ensuring a high level of security in the supply chain.

(2) The Contracting Parties have undertaken to guarantee in their respective territories an equivalent level of security through measures based on legislation in force in the European Union.

(3) When goods destined for a third country leave the customs territory of a Contracting Party through the customs territory of the other Contracting Party, the security data contained in the exit summary declaration lodged with the competent authority of the former Contracting Party shall be transmitted by it to the competent authority of the latter.

(4) The Joint Committee may determine cases in which this transmission of information is not necessary as long as the level of security assured by the Agreement is not affected.

(5) The Member States of the European Union and the Swiss Confederation are Contracting Parties to the Chicago Convention on International Civil Aviation; under Annex 17 to the Convention, in order to protect international aviation from acts of unlawful interference, air carriers subject the whole of an aircraft's cargo to security checks prior to loading.

(6) The European Community and the Swiss Confederation are bound by the Air Transport Agreement of 21 June 1999, which governs aviation safety and security in particular,

HAS DECIDED:

Article 1

Where exports of goods under the first subparagraph of Article 3(3) of Annex I to the Agreement are concerned, the transmission of data shall not be required provided:

(a) the goods are accepted by an airline for transport out of the customs territories of the Contracting Parties;

(b) the exit of goods through the customs office of the second Contracting Party takes place by air;

(c) an exit summary declaration or an export customs declaration which meets the requirements for a summary declaration has been submitted to the customs office responsible for the place from which the goods are exported;

(d) when the goods arrive at the customs office at the point of exit of the second Contracting Party's customs territory, the carrier provides that customs office, on request, with a copy of the Union export accompanying document or any similar document issued by the Swiss customs authorities and containing the security data for the exported goods.

Article 2

The Decision shall enter into force on the day following its adoption.

Done at Vacallo, 10 October 2014.

For the EU–Switzerland Joint Committee

The President

Michaela SCHÄRER-RICKENBACHER

CORRIGENDA

Corrigendum to Council Decision 2014/252/EU of 14 April 2014 on the conclusion of the Agreement between the European Union and the Republic of Turkey on the readmission of persons residing without authorisation

(Official Journal of the European Union L 134 of 7 May 2014)

On page 1, recital 3:

for: 'In accordance with Articles 1 and 2 of the Protocol (No 21) on the position of the United Kingdom and Ireland in respect of the Area of Freedom, Security and Justice, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, and without prejudice to Article 4 of the said Protocol, the United Kingdom is not taking part in the adoption of this Decision and is not bound by it or subject to its application.',

read: 'In accordance with Article 3 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the Area of Freedom, Security and Justice, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, the United Kingdom has notified, by letter of 21 September 2012, its wish to take part in the adoption and application of this Decision.'.

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