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Delegations will find attached document D052851/03.

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annex XV to Commission Regulation (EU) No 142/2011 as regards health certification at import into the Union concerning transmissible spongiform encephalopathies

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annex XV to Commission Regulation (EU) No 142/2011 as regards health certification at import into the Union concerning transmissible spongiform encephalopathies

(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 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[1], and in particular the first paragraph of Article 23 and the introductory phrase and point (m) of Article 23a thereof,

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)[2], and in particular the introductory phrase and point (d) and the final paragraph of Article 42(2) thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies ('TSEs') in bovine, ovine and caprine animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof. That Regulation also provides a legal basis for the classification, as laid down in Commission Decision 2007/453/EC,[3] of Member States and third countries or regions thereof according to their disease status for bovine spongiform encephalopathy (BSE) into those with a negligible BSE risk, a controlled BSE risk and an undermined BSE risk.

(2) Annex IX to Regulation (EC) No 999/2001 set outs the requirements for the importation into the Union of live animals, embryos, ova and products of animal origin. More particularly, Chapter B of that Annex sets out the requirements for imports of bovine animals, which takes into account the BSE status of the third countries or regions. In addition, Chapter D of that Annex lays down requirements for the provision of an attestation concerning the TSE related risk in the health certificate required for the importation into the Union of certain animal by-products and derived products, including, inter alia, processed animal protein.

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1 OJ L 147, 31.5.2001, p. 1.

2 OJ L 300, 14.11.2009, p. 1.

3 Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84).

(3) Chapter B of Annex IX to Regulation (EC) No 999/2001, as amended by Commission Regulation (EU) 2016/1396[4], requires that live bovine animals imported into the Union must not have been exposed to BSE cases or their cohort. Taking into account the fact that the main transmission route of BSE is through feed contaminated with the BSE prion, that requirement should be amended to provide that live bovine animals imported into the Union may not be BSE cases or their cohort. Chapter B of Annex IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.

(4) Regulation (EC) No 1069/2009 lays down public health and animal health rules for animal by-products and derived products in order to prevent and minimise risks to public and animal health arising from those products. Commission Regulation (EU) No 142/2011[5] lays down implementing measures for the public and animal health rules for animal by-products and derived products laid down in Regulation (EC) No 1069/2009, including certain requirements for the importation of animal by-products and derived products from third countries.

(5) Annex I to Regulation (EU) No 142/2011 lists certain definitions to be used for the purposes of that Regulation. Article 31 of Regulation (EU) No 412/2011 provides that consignments of animal by-products and derived products for importation into or transit through the Union are to be accompanied by health certificates and declarations, in accordance with the models set out in Annex XV thereto.

(6) Point 1 of Article 11.4.13 of the Terrestrial Animal Health Code of the World Organisation for Animal Health ('OIE Code')[6] recommends that meat-and-bone meal and greaves derived from ruminants, as defined in the OIE Code, and commodities containing such products, which originate from countries or zones with a negligible BSE risk status in which there has been an indigenous BSE case, may enter international trade only if the products were derived from cattle born after the date of the effective implementation, in the country, of the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the OIE Code. Point 2 of that Article recommends that meat-and-bone meal and greaves derived from ruminants, as defined in the OIE Code, and commodities containing such products, may not enter international trade if they originate from countries or zones with a controlled or undetermined BSE risk status.

(7) The OIE Code defines meat-and-bone meal as the solid protein products obtained when animal tissues are rendered, including any intermediate protein product other than peptides of a molecular weight less than 10 000 daltons and amino-acids. Thus, meat-and-bone meal as defined in the OIE Code covers both the definition of meat-and-bone meal set out in point 27 of Annex I to Regulation (EU) No 142/2011 and the definition of processed animal protein set out in point 5 of that Annex.

(8) In accordance with Article 41(2)(c) of Regulation (EC) No 1069/2009, imports into the Union of meat-and-bone meal, as defined in Union legislation, may only take place

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4 Commission Regulation (EU) 2016/1396 of 18 August 2016 amending certain 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 225, 19.8.2016, p. 76).

5 Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

6 http://www.oie.int/international-standard-setting/terrestrial-code/access-online/

if implementing rules have been adopted setting out the conditions for such importation. Since no such implementing rules have been adopted, the importation into the Union of meat-and-bone meal, derived from Category 1 or Category 2 material, is currently not allowed. However, imports into the Union of processed animal protein, as defined in Union legislation, may take place, subject to compliance with the TSE related import conditions laid down in Section B of Chapter D of Annex IX to Regulation (EC) No 999/2001, as well as with the conditions on the import of processed animal protein laid down in Regulation (EU) No 142/2011.

(9) In order to align the TSE conditions for imports into the Union, laid down in Regulation (EC) No 999/2001, with the recommendations included in the BSE Chapter of the OIE Code, it is appropriate to amend Section B of Chapter D of Annex IX to Regulation (EC) No 999/2001 so that the requirement laid down in that Section take account of the recommendations of Article 11.4.13 of the OIE Code. However, since the use of processed animal protein derived from ruminants in the manufacturing of petfood is authorised in the Union, in order not to apply a discriminatory treatment towards imports compared to European Union production, the recommendations of Article 11.4.13 of the OIE Code should not be followed for the importation of petfood containing processed animal protein derived from ruminants, provided that such petfood is processed and labelled in accordance with Union legislation.

(10) Section B of Chapter D of Annex IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.

(11) Products of animal origin may be required to be declared for use as animal by-products by Union law, or by the decision of the responsible operator. When an operator decides that products of animal origin are to be declared as animal by-products, that decision is irreversible. Such animal by-products are excluded from use for human consumption. Certain animal by-products have the same Combined Nomenclature (CN) customs codes as animal products intended for human consumption which are laid down in Annex I to Council Regulation (EEC) No 2658/87[7]. For the classification in the CN customs codes the customs authorities in Member States need to be able to clearly differentiate between products which are fit for human consumption and those which are unfit for human consumption. In order to avoid any confusion for the purpose of that classification, the health guarantees referred to in the import certificates of unprocessed animal by-products should clarify that, although the animal by-products originate from animal products which were fit for human consumption at a former stage, they are now classified and treated as animal by-products which are permanently excluded from the food chain. The model health certificates set out in Chapters 3(D), 3(F) and 8 of Annex XV to Regulation (EU) NO 142/2011 should therefore be amended accordingly.

(12) In addition, the TSE attestation in the model certificates for imports of and transit through the Union of certain animal by-products set out in Chapters 1, 1a, 2(A), 2(B), 3(A), 3(B), 3(C), 3(D), 3(E), 3(F), 4(B), 4(C), 4(D), 6(B), 8, 10(A), 10(B), 11, 12 and 18 of Annex XV to Regulation (EU) No 142/2011 should be amended to take account of the requirements of Chapter D of Annex IX to Regulation (EC) No 999/2001, as

[7] Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

amended by Commission Regulation (EU) No 630/2013[8], by Commission Regulation (EU) 2016/1396 and by this Regulation.

(13) The import conditions for processed animal protein referred to in the model health certificate set out in Chapter 1 of Annex XV to Regulation (EU) No 142/2011 require the absence of blood from ruminants in processed animal proteins imported from third countries. However, the new TSE attestation set out in point II.7. of that model health certificate, as amended by this Regulation, provides for adequate guarantees to mitigate the TSE risk in such products. Therefore, the wording "other than ruminants" should be deleted in all the model health certificates set out in Annex XV to Regulation (EU) No 142/2011 that are to be amended by this Regulation.

(14) Chapters 1, 1a, 2(A), 2(B), 3(A), 3(B), 3(C), 3(D), 3(E), 3(F), 4(B), 4(C), 4(D), 6(B), 8, 10(A), 10(B), 11, 12 and 18 of Annex XV to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(15) In addition, consignments of intermediate products intended for the manufacturing of cosmetic and pharmaceutical products are required to be accompanied by a declaration completed in accordance with the model set out in Chapter 20 of Annex XV to Regulation (EU) No 142/2011 when presented at a border inspection post ('BIP') for the purpose of veterinary checks. Intermediate products may consist of or may contain animal by-products. The existing model declaration indicates only a limited number of appropriate CN codes which are to be used by the operator to notify the product to the customs authorities in the Member States. It is not possible to set out an exhaustive list of CN codes in advance in the model declaration which would cover all combinations of animal by-products in the intermediate products. Therefore, it is appropriate to replace the existing CN codes in order that the person responsible for the consignment may declare intermediate products to the BIP by an appropriate CN code in accordance with Commission Decision 2007/275/EC[9]. Chapter 20 of Annex XV to Regulation (EU) No 142/2011 should be amended accordingly.

(16) In order to avoid any disruption of trade, this Regulation should provide for a transitional period during which time the commodities concerned by the amendments made to Regulation (EU) No 142/2011 should continue to be accepted for importation into and transit through the Union, provided that those commodities comply with the requirements of those acts before they were amended by this Regulation.

(17) 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

Annex IX to Regulation (EC) No 999/2001 is amended in accordance with Annex I to this Regulation.

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8 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).

9 Commission Decision 2007/275/EC of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC (OJ L 116, 4.5.2007, p. 9).

Article 2

Annex XV to Regulation (EU) No 142/211 is amended in accordance with Annex II to this Regulation.

Article 3

For a transitional period until 30 September 2019, consignments of animal by-products and of derived products accompanied by a health certificate duly completed and signed in accordance with the appropriate model health certificate set out in Chapters 1, 1a, 2(A), 2(B), 3(A), 3(B), 3(C), 3(D), 3(E), 3(F), 4(B), 4(C), 4(D), 6(B), 8, 10(A), 10(B), 11, 12 and 18 of Annex XV to Regulation (EU) No 142/2011 in the version applicable before the amendments provided for by Article 2 of this Regulation, and, where applicable, by a declaration, which has been duly completed and signed in accordance with the model declaration set out in Chapter 20 of that Annex in its version applicable before the amendments provided for by Article 2 of this Regulation, shall continue to be accepted for importation into and transit though the Union, provided that such health certificates or declarations were duly completed and signed no later than 31 July 2019.

Article 4

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,

For the Commission
The President
Jean-Claude JUNCKER