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Delegations will find attached document D036076/10.

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex V 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

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex V 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

(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 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in 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.

(2) Point 1 of Annex V to Regulation (EC) No 999/2001 designates as specified risk material ('SRM') certain bovine, ovine and caprine tissues if they come from animals whose origin is in a Member State or third country, or in one of their regions, with a controlled or undetermined Bovine Spongiform Encephalopathy ('BSE') risk status. Point 2 of that Annex extends the list of tissues designated as SRM to Member States with a negligible BSE risk status, but not to third countries with the same status. As a consequence, Member States with a negligible BSE risk status are to remove and dispose of SRM, while imports into the Union of such tissues from third countries with a negligible BSE risk status are allowed.

(3) The World Organization for Animal Health ('OIE') only recommends the exclusion from international trade of SRM derived from bovine animals originating in countries with a controlled or undetermined BSE risk, while no such exclusion is recommended for bovine animals originating from countries with a negligible BSE risk status[2].

(4) The Commission Strategy Paper on Transmissible Spongiform Encephalopathies for 2010-2015[3] envisages the possibility to review the current obligation for Member States with a

[1] OJ L 147, 31.5.2001, p. 1.

[2] Article 11.4.14 of the OIE Terrestrial Animal Health Code, Edition 2014 (OIE - Terrestrial Animal Health Code - V 8 - 15/07/2014).

[3] Communication from the Commission to the European Parliament and the Council - The TSE Road map 2 - A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015; COM(2010)384 final.

negligible risk status to remove SRM from the food and feed chain if an increasing number of Member States reach such status. With the adoption on 20 October 2014 of Commission Implementing Decision 2014/732/EU[4], which is based on the World Animal Health Organisation (OIE) Resolution No 18 of May 2014[5], seventeen Union Member States have been recognised as having a negligible BSE risk status.

(5) Authorising all bovine tissues currently classified as SRM to be used in the food chain in Member States with a negligible BSE risk status is considered premature at this stage due to certain remaining scientific uncertainties linked to Atypical BSE.

(6) On 19 January 2011, the European Food Safety Authority (EFSA) published a joint opinion prepared with the European Centre for Disease Prevention and Control (ECDC) on any possible epidemiological or molecular association between Transmissible Spongiform Encephalopathies (TSEs) in animals and humans ('the joint EFSA and ECDC Opinion')[6]. In this joint opinion, the EFSA and ECDC confirmed the identification of atypical forms of BSE in cattle and made the distinction between classical BSE, L-type atypical BSE and H-type atypical BSE.

(7) According to this joint opinion, several elements indicate that the L-type atypical BSE agent has the potential to be a zoonotic agent. By contrast, such elements are absent for the H-type atypical BSE agent. This joint opinion also stated that the unusually old age of all H-type atypical BSE and L-type atypical BSE identified cases and their apparent low prevalence in the population suggest that these Atypical BSE forms are arising spontaneously, independently of the animal feeding practices. The BSE surveillance system in the Union showed a very low prevalence and relative constant level of atypical BSE cases in recent years.

(8) On 11 January 2011, EFSA published a Scientific Opinion on the revision of the quantitative risk assessment of the BSE risk posed by processed animal proteins[7] ('EFSA's 2011 opinion'). This scientific opinion indicates that 90% of the total infectivity amount in a BSE clinical case is associated with central and peripheral nervous system tissues. More precisely, this opinion estimated that 65% of the total amount of infectivity in a clinical case of BSE is associated with the brain and 26% is associated with the spinal cord.

(9) On 11 July 2014, EFSA published a scientific report on a Protocol for further laboratory investigations into the distribution of infectivity of Atypical BSE[8]. According to that scientific report, collective data indicate that Classical BSE shares the same tissue distribution as the Atypical BSE cases, with the higher titres of infectious prion proteins and/or infectivity detected in the central and peripheral nervous systems.

(10) For all those reasons, the brain and the spinal cord of cattle over 12 months whose origin is in a Member State with negligible BSE risk status should remain in the list of SRM, pending further knowledge is gained on the risk linked to Atypical-BSE.

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4 Commission Implementing Decision 2014/732/EU of 20 October 2014 amending Decision 2007/453/EC as regards the BSE status of Bulgaria, Estonia, Croatia, Latvia, Luxembourg, Hungary, Malta, Portugal and Slovakia (OJ L 302, 22.10.2014, p. 58–61).

5 Resolution No. 18, 'Recognition of the Bovine Spongiform Encephalopathy Risk Status of Member Countries', adopted by the World Assembly of Delegates of the OIE on 27 May 2014 (82 GS/FR – Paris, May 2014).

6 EFSA Journal 2011; 9(1):1945.

7 *EFSA Journal 2011*; 9(1):1947.

8 *EFSA Journal 2014*;12(7):3798.

(11) Given the practical difficulties to ensure the absence of contamination of the bones of the skull with brain tissues, the skull of cattle over 12 months whose origin is in a Member State with negligible BSE risk status should also be maintained as SRM.

(12) The data examined by EFSA mainly refer to Europe, due to the very robust surveillance system in the EU. Discussions at OIE level are ongoing to review the BSE chapter of the OIE Terrestrial Animal Health Code in the light of recently acquired knowledge concerning Atypical-BSE. The Union rules as regards SRM in Member States and third countries with negligible BSE risk status should be reviewed in the light of the outcome of these discussions.

(13) The skull, the brain, the spinal cord and the eyes of bovine animals over 12 months are not known to be imported into the Union.

(14) In order to ensure more similar conditions for putting on the market commodities from the Member States compared to imports of commodities from third countries, while taking into account the possible remaining risk linked to the use in the food and/or feed chain of certain tissues, the additional requirement extending the prohibition of SRM of bovines to Member States with a negligible BSE risk should therefore be repealed except for the skull, the brain and spinal cord of bovine animals over 12 months.

(15) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(16) Should future scientific evidence point out public health risks that are currently unknown, the Union rules as regards SRM in Member States and third countries with negligible BSE risk should be reviewed.

(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

In Annex V to Regulation (EC) No 999/2001, point 2 is replaced by the following:

'2. **Specific requirements for Member States with negligible BSE risk status**

Tissues listed in point 1.(a)(i) and 1.(b), which are derived from animals whose origin is in Member States with a negligible BSE risk, shall be considered as specified risk material.'.

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,

For the Commission
The President
Jean-Claude JUNCKER