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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending Section E of Chapter V of Annex IV 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**

# COMMISSION REGULATION (EU) .../...

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## **amending Section E of Chapter V of Annex IV 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**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 999/2001<sup>1</sup>, 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) Annex IV to Regulation (EC) No 999/2001 prohibits the feeding to certain farmed animals of processed animal proteins (PAP) derived from non-ruminants.
- (3) Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 provides that the export of PAP derived from non-ruminants, and of products containing such protein, is to be authorised only if they are destined for uses not prohibited by Regulation (EC) No 999/2001 and if a written agreement is concluded, prior to the export, between the competent authority of the exporting Member State, or the Commission, and the competent authority of the importing third country, which contains an undertaking from the importing third country to respect the intended use and not to re-export the PAP, or the products containing such protein, for uses prohibited by Regulation (EC) No 999/2001.
- (4) This requirement is exceptional in the Union legislation as it implies an element of extraterritoriality. This has caused the reluctance of certain third countries to conclude such prior written agreements.
- (5) This requirement was originally intended to control the spread of Bovine Spongiform Encephalopathy (BSE) in the world at a time when BSE was in its epidemic phase in the Union and when the European continent was the main part of the world affected by the epidemic.
- (6) With a number of BSE cases reported in the EU of 7 in 2013 and 8 in 2014, compared to 2,166 in 2001 and 2,124 in 2002, BSE is no longer in its epidemic phase and the BSE situation in the Union is now the same as that of most countries in the world.
- (7) Furthermore, since the adoption on 20 October 2014 of Commission Implementing Decision 2014/732/EU<sup>2</sup>, which is based on the World Animal Health Organisation

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<sup>1</sup> 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).

(OIE) Resolution No 18 of May 2014<sup>3</sup>, seventeen Union Member States have been recognised as having a negligible BSE risk status. This reflects the very favourable BSE situation in the Union.

- (8) The requirement that exports of non-ruminant PAP, and of products containing such protein, are authorised only if they are destined for uses not prohibited by Regulation (EC) No 999/2001 and if a written agreement is concluded prior to the export, to ensure that this intended use is respected, should therefore be withdrawn.
- (9) According to the definitions laid down in Annex I to Commission Regulation (EU) No 142/2011<sup>4</sup>, PAP are proteins derived entirely from Category 3 material, as defined in article 10 of Regulation (EC) No 1069/2009<sup>5</sup>, while proteins derived from the processing of Category 1 or Category 2 materials are defined as meat-and-bone meal (MBM). Export of MBM from the EU to third countries is prohibited by Regulation (EC) No 1069/2009, except for the export of scientific and trade samples.
- (10) Point 1 of Section E of Chapter V of Annex IV to Regulation (EC) No 999/2001 prohibits the export of PAP derived from ruminants and products containing such PAP, except for processed petfood containing ruminant PAP.
- (11) It is not possible to identify visually whether PAP contain ruminant materials or are derived from Category 1 of Category 2 material. For control purposes, it is therefore appropriate to carry out tests in order to ensure that PAP exported from the EU to third countries, and products containing PAP, do not contain proteins of ruminant origin and are derived exclusively from Category 3 material.
- (12) The test to ensure the absence of proteins derived from ruminants should be carried out based on the Polymerase Chain Reaction (PCR) method laid down in point 2.2 of Annex VI of Regulation (EC) No 152/2009<sup>6</sup>.
- (13) According to Chapter V of Annex VIII to Regulation (EU) No 142/2011, products derived from Category 1 and Category 2 material are to be permanently marked with glyceroltriheptanoate (GTH). The test to ensure the absence of MBM should therefore aim at confirming the absence of GTH in the concerned product, and should be based on the gas chromatographic method as validated by the Joint Research Centre (JRC).
- (14) Points 2 of Section E of Chapter V of Regulation (EC) No 999/2001 should therefore be amended accordingly and points 3 and 4 of the same Section should be repealed.

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<sup>2</sup> 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).

<sup>3</sup> 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 2017 (82 GS/FR – Paris, May 2014).

<sup>4</sup> 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 054, 26.2.2011, p.1).

<sup>5</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

<sup>6</sup> Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

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

HAS ADOPTED THIS REGULATION:

#### *Article 1*

In Annex IV to Regulation (EC) No 999/2001, Section E of Chapter V is amended as follows:

#### *'SECTION E*

##### *Export of processed animal protein and products containing such protein*

1. The export of processed animal protein derived from ruminants, and of products containing such protein, shall be prohibited.

By way of derogation, that prohibition shall not apply to processed petfood which contains processed animal protein derived from ruminants and which has undergone treatment and which is labelled in accordance with Union legislation.

2. The export of processed animal protein derived from non-ruminants, or products containing such protein, is subjected to the following conditions:

Before issuing the export certificate for a specific consignment, the competent authority responsible for the export must ensure that the processed animal protein derived from non-ruminants, or product containing such protein, was sampled and:

- (a) based on the PCR method as laid down in point 2.2 of Annex VI to Regulation (EC) No 152/2009, did not reveal the presence of unauthorised ruminant material; and,
- (b) based on the gas chromatographic method coupled to mass spectrometry detection, as validated by the Joint Research Centre<sup>7</sup>, did not reveal the presence of GTH.

If a sample reveals the presence of GTH or of unauthorised ruminant material, the consignment from which the sample with unfavourable results was derived shall be disposed of or used in accordance with Articles 12, 13 or 14 of Regulation (EC) No 1069/2009, within the territory of the EU.

#### *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*

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<sup>7</sup> C. von Holst et al. (2012) Determination of glyceroltriheptanoate (GTH) in processed animal by-products by gas chromatography, JRC 68602 (2012), available at: [https://ec.europa.eu/jrc/sites/default/files/JRC\\_68602\\_GTH\\_protocol\\_JRC\\_technical\\_note\\_6th\\_edition.pdf](https://ec.europa.eu/jrc/sites/default/files/JRC_68602_GTH_protocol_JRC_technical_note_6th_edition.pdf)

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