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Delegations will find attached document D032106/02.

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COMMISSION REGULATION (EU) No .../..

of **XXX**

amending 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

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of XXX

amending 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

(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 encephalopathies¹, 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 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.
- (2) Annex II to Regulation (EC) No 999/2001 lays down rules governing the determination of the bovine spongiform encephalopathy (BSE) status of Member States or third countries or regions thereof. These rules are based on the international standard established by the World Organisation for Animal Health (OIE) in the Terrestrial Animal Health Code (the Code). In the BSE chapter of the 2013 version of the Code, the expression 'release assessment' has been replaced by 'entry assessment', and the table providing the points targets for a country or region has been significantly amended to better meet the needs of countries with a small or very small cattle population. These amendments should be reflected in Annex II.
- (3) Point 2.2.1 of Chapter B of Annex VII to Regulation (EC) No 999/2001 refers to the methods and protocols set out in Annex X. The wording of this point should be amended to reflect amendments to Annex X brought by this act.
- (4) Chapter A of Annex VIII to Regulation (EC) No 999/2001 lays down rules governing intra-Union trade in live animals, semen and embryos, including the exemption of homozygous ovine ARR embryos from any other classical scrapie related requirement

¹ OJ L 147, 31.5.2001, p. 1.

in intra-Union trade. On 24 January 2013, the European Food Safety Authority (EFSA) adopted a scientific opinion on the risk of transmission of classical scrapie via in vivo derived embryo transfer in ovine animals², where it concluded that the risk of transmitting classical scrapie by the implantation of homozygous or heterozygous ovine ARR embryos could be considered negligible providing that the OIE recommendations and procedures relating to embryo transfer are adhered to. The relevant provisions of Annex VIII should therefore be amended to also exempt intra-Union trade of heterozygous ovine ARR embryos from any other classical scrapie related requirement.

- (5) In certain language versions of Regulation (EC) No 999/2001, there is a terminology incoherence between Points 1.2. and 1.3 of Section A of Chapter A of Annex VIII to that Regulation and the rest of the text. For the sake of coherence, the same term should be used in the language versions concerned.
- (6) Point 2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 lays down the rules governing the approval of the negligible risk status for classical scrapie of a Member State or zone of a Member State. On 4 July 2013, Austria submitted to the Commission the appropriate supporting documentation. Given the favourable outcome of the assessment of this application by the Commission, Austria should be listed as a Member State with a negligible risk of classical scrapie.
- (7) Point 3.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 lists Member States with an approved national control programme for classical scrapie. Considering that Austria should be listed as a Member State with a negligible risk of classical scrapie, it should simultaneously be deleted from the list of Member States with an approved national control programme for classical scrapie, as this status offers guarantees over and above those offered in the control programme.
- (8) Chapter H of Annex IX to Regulation (EC) No 999/2001 lays down rules for the import in the Union of ovine and caprine semen and embryos. These import rules should be updated to reflect amendments to Annex VII brought by this act.
- (9) Annex X to Regulation (EC) No 999/2001 lays down the methods of analysis applicable to TSE testing in bovine, ovine and caprine animals. This Annex should be reviewed to update the information on the designated laboratories, adjust the reference to various guidelines, harmonize some technical terms, and clarify the discriminatory testing process in case of positive TSE cases in ovine and caprine animals, in accordance with the latest scientific knowledge and current practices in the Union.
- (10) Point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001 sets out the lists of rapid tests approved for the monitoring of TSEs in bovine, ovine and caprine animals. On 18 September 2013, IDEXX made an application in order that the name of the test IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA be changed to HerdChek BSE-Scrapie Antigen (IDEXX Laboratories). The new package insert for this test has been approved by the European Union Reference laboratory for TSEs on 2 May 2013. Furthermore, on 6 December 2013, the Enfer Group informed that it has ceased the manufacture of the Enfer Version 3 TSE diagnostic kit and requested the deletion of

² EFSA Journal 2013; 11(2):3080.

this kit from the list of approved BSE rapid tests in bovine animals. The lists in point 4 of Chapter C of Annex X should therefore be adapted accordingly.

- (11) In order to offer sufficient time to Member States to align their scrapie-related certification procedures for ovine embryos, certain amendments introduced by this Regulation should apply from 1 January 2015.
- (12) Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (13) 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

Annexes II, VII, VIII, IX and X to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

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*.

Paragraphs (a), (b) and (e) of point 3 and point 4 of the Annex shall apply from 1 January 2015.

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

Done at Brussels,

For the Commission
The President
José Manuel BARROSO