Commission Regulation (EU) 2016/1396 of 18 August 2016 amending certain Annexes to Regulation (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) 2016/1396

of 18 August 2016

amending certain Annexes to Regulation (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 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 the criteria based on which the BSE status of countries or regions shall be determined in accordance with Article 5(2) of that Regulation. Those criteria are based on the conditions set out in the chapter on bovine spongiform encephalopathy (BSE) of the Terrestrial Animal Health Code of the World Animal Health Organisation (OIE).

(3) In May 2015, the OIE World Assembly of Delegates amended the BSE Chapter of the OIE Terrestrial Animal Health Code, by adding the following sentence in Article 11.4.1 of the Code: ‘For the purpose of official BSE risk status recognition, BSE excludes “atypical BSE” as a condition believed to occur spontaneously in all cattle populations at a very low rate’[(2)]. Atypical BSE should therefore be excluded from the definition of ‘BSE’ for the purpose of Annex II to Regulation (EC) No 999/2001.

(4) Annexes III, V and VII to Regulation (EC) No 999/2001 contain a number of references to Council Directive 64/433/EEC[(3)], Regulation (EC) No 1774/2002 of the European Parliament and of the Council[(4)] and Commission Regulation (EC) No 1974/2006[(5)]. As those three acts have been repealed, references in the Annexes to Regulation (EC) No 999/2001 should be updated.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1396. (See end of Document for details)*

(5) The specific requirements set out in Annex V to Regulation (EC) No 999/2001, concerning to the removal of specified risk material for bovine animals whose origin is in Member States with a negligible BSE risk, was amended by Commission Regulation (EU) 2015/1162[(6)]. As a consequence of this amendment, certain provisions relating to the removal of specified risk material set out in Annex V and in Annex IX to Regulation (EC) No 999/2001 should also be amended, as developed below.

(6) First, in accordance with the amendment made to the specific requirements for Member States with a negligible BSE risk status set out in Annex V to Regulation (EC) No 999/2001, by Regulation (EU) 2015/1162, tonsils are no longer defined as specified risk material for bovine animals whose origin is in Member States with negligible BSE risk. The transverse cut rostral to the lingual process of the basihyoid bone for tongues of bovine animals, required in accordance with point 7 of Annex V to Regulation (EC) No 999/2001, should therefore only apply to bovine animals whose origin is in Member States with controlled or undetermined BSE risk. Point 7 of that Annex V should therefore be amended accordingly.

(7) Second, in accordance with the amendment made to Annex V to Regulation (EC) No 999/2001, by Regulation (EU) 2015/1162, the vertebral column is defined as specified risk material only for a minority of bovine animals in the Union. Taking into account the evolution of the epidemiological situation in the Union and the need to reduce administrative burden on operators, the requirement set out in point 11.3.(a) of Annex V to Regulation (EC) No 999/2001, to provide information on the label of the carcasses as regards the removal of the vertebral column, should be modified as follows: while so far a blue stripe must be indicated on the label of the carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column when the removal of the vertebral column is not required, after a transitional period, a red stripe should be indicated on the label of the carcases or wholesale cuts of carcasses of bovine animals containing vertebral column when the removal of the vertebral column is required.

(8) The same modification from a requirement to indicate a blue stripe when the removal of the vertebral column is not required to a requirement to indicate a red stripe when the removal of the vertebral column is required, should apply for products of bovine origin imported into the Union. Point 3 of Section C and point 3 of Section D of Chapter C of Annex IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.

(9) In order to give economic operators and competent authorities inside and outside the Union the necessary time to adjust to this new regime of red stripe required when the removal of the vertebral column is required, this provision should enter into force after a transitional period until 30 June 2017.

(10) Article 8(3) of Regulation (EC) No 999/2001 prohibits the practice, in Member States or regions thereof, with a controlled or undetermined BSE risk, of lacerating, after stunning, central nervous tissues by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injection into the cranial cavity, of bovine, ovine and caprine animals whose meat is intended for human or animal consumption. Point 6 of Annex V to Regulation (EC) No 999/2001 extends that prohibition to Member States with a negligible BSE risk, until all Member States are

classified as countries with negligible BSE risk. Since atypical BSE is considered a spontaneous disease which occurs at a low prevalence also in countries with a negligible BSE risk, that prohibition should remain applicable after all Member States have been classified as countries with a negligible BSE risk. Point 6 of Annex V to Regulation (EC) No 999/2001 should therefore be amended to remove this time limitation.

(11) Point 2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 sets out the rules relating to the approval of the negligible risk status for classical scrapie of Member States or zones of a Member State. On 25 June 2014 and 24 August 2014, Finland and Sweden respectively submitted an application to the Commission to be recognised as having a negligible risk status for classical scrapie.

(12) On 13 January 2015, the Commission requested the scientific and technical assistance of the European Food Safety Authority (EFSA) to evaluate whether Finland and Sweden, in their respective applications, demonstrated compliance with point 2.1.(c) and point 2.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(13) On 19 November 2015, the EFSA published two scientific reports in response to the Commission's request[7] ('the EFSA reports'). The EFSA reports conclude that, based on the testing sensitivity provided by the past evaluations of screening diagnostic tests by the EFSA and the Joint Research Centre Institute for Reference Materials and Measurement (IRMM), Sweden demonstrated compliance with point 2.1.(c) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 for each of the preceding seven years, and Finland demonstrated such compliance for each of the preceding seven years, except for 2010, a year during which the level of confidence of detecting classical scrapie at a prevalence rate exceeding 0,1 per cent was 94,73 per cent. As the difference between a level of confidence of 94,73 per cent and of 95 per cent is negligible when it comes to the risk of missing a case of classical scrapie, and as the criterion of point 2.1.(c) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 was fulfilled in all six other years, the criterion can be considered as fulfilled for the past 7 years.

(14) The EFSA reports also conclude that, based on the testing sensitivity provided by the past evaluations of screening diagnostic tests by the EFSA and the IRMM, Sweden and Finland's intentions concerning surveillance of classical scrapie in the future would comply with point 2.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(15) Taking into account the EFSA reports and the favourable outcome of the Commission assessment of those applications with the other criteria set out in point 2.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001, Finland and Sweden should be listed as Member States with a negligible risk of classical scrapie.

(16) Point 3.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 lists the Member States with an approved national control programme for classical scrapie. As Finland and Sweden should now be listed in point 2.3 of that Section as Member States with a negligible risk of classical scrapie, they should be deleted from the list of Member States with an approved national control programme for classical scrapie in

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point 3.2 of that Section, as that status offers guarantees exceeding those provided by an approved national control programme.

(17) Points 1.2 and 1.3 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 set out the conditions to be fulfilled for a holding to be recognised as having a negligible risk or a controlled risk of classical scrapie. Point 4 of that Section sets out the scrapie-related conditions to be fulfilled for intra-Union trade in ovine and caprine animals and semen and embryos thereof.

(18) In addition, Article 3(1)(i) of Regulation (EC) No 999/2001 defines a holding as any place in which animals covered by that Regulation are held, kept, bred, handled or shown to the public. Semen collection centres, as well as zoos, must therefore be considered as holdings, and subject to conditions set out in Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(19) Given that the risk of spreading scrapie via male ovine and caprine animals kept at semen collection centres approved and supervised in accordance with the conditions set out in Annex D to Council Directive 92/65/EEC[8] is limited, it is appropriate to establish specific conditions for semen collection centres in Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(20) These specific conditions should provide that a holding with a negligible, respectively controlled, risk of classical scrapie may introduce ovine and caprine animals from a semen collection centre provided that: (i) the semen collection centre is approved and supervised in accordance with Annex D to Directive 92/65/EEC; (ii) the semen collection centre has had no case of classical scrapie for the last seven, respectively three years; (iii) only the following ovine and caprine animals were introduced into the semen collection centre for the last seven, respectively three years: ovine and caprine animals from holdings where ovine and caprine animals are permanently marked and records are maintained, where records of movements of ovine and caprine animals in and out the holding are maintained, where no case of classical scrapie have been detected in the last seven, respectively three years, and which were subjected to regular checks by an official veterinarian or a veterinarian authorised by the competent authority; (iv) the semen collection centre has biosecurity measures in place to ensure that ovine and caprine animals coming from holdings with different scrapie statuses are not in contact in the semen collection centre. Points 1.2.(c) and 1.3.(c) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 should be amended accordingly.

(21) In addition, the scrapie-related intra-Union trade conditions for semen and embryos, laid down in point 4.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001, should be amended to take into account the specific conditions for semen collection centres mentioned in the above recital. Furthermore, reference to those specific conditions should also be introduced in the conditions for import of semen and embryos of ovine and caprine animals set out in Chapter H of Annex IX to Regulation (EC) No 999/2001.

(22) The conditions for intra-Union trade in ovine and caprine animals provided for in point 4.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 are aimed at preventing the spread of classical scrapie in farmed animals kept on holdings.

Since the movement of ovine and caprine animals exclusively between zoos has no impact on the scrapie status of the Union ovine and caprine farmed animals, those specific conditions should not apply to ovine and caprine animals kept in and moved exclusively between zoos as covered by the definition of approved bodies, institutes or centres provided in Article 2(1)(c) to Council Directive 92/65/EEC. Those animals should therefore be exempted from the conditions set out in point 4.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(23) The scrapie requirements for intra-Union trade in live ovine and caprine animals set out in point 4.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 is difficult to comply with for intra-Union trade in certain rare breeds. In order to avoid inbreeding and to preserve the genetic diversity in rare breed populations, regular exchange of such animals between Member States is necessary. Specific conditions for intra-Union trade in ovine and caprine animals of rare breeds should therefore be laid down. Those specific conditions should allow intra-Union trade in ovine or caprine animals of rare breeds which do not comply with the requirements of point 4.1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

(24) The term ‘rare breed’ is not specifically defined in the Union legislation. However, Article 7(2) and (3) of Commission Delegated Regulation (EU) No 807/2014[(9)] establish the conditions under which commitments under the agri-environment-climate measure to rear local breeds in danger of being lost to farming can be made. Those conditions notably require that a duly recognised relevant technical body registers and keeps up-to-date the herd or flock book for the breed. In accordance with Council Directive 89/361/EEC[(10)], such a technical body is to be a breeders' organisation or association officially approved by the Member State in which that breeders' organisation or association is established, or an official agency of the Member State in question.

(25) Therefore, for the purpose of Regulation (EC) No 999/2001, local breeds in danger of being lost to farming should be defined as those sheep and goat breeds that fulfil the conditions of Article 7(2) and (3) of Delegated Regulation (EU) No 807/2014, and which are subject to a preservation programme carried out by a breeders' organisation or association approved in accordance with Directive 89/361/EEC or by an official agency of the Member State in question.

(26) Section B of Chapter C of Annex IX to Regulation (EC) No 999/2001 should be amended so as to allow the import into the Union of products of bovine, ovine or caprine origin from third countries with a negligible BSE risk also when these products are derived from raw materials coming, in part or in total, from countries with controlled or undetermined BSE risk, provided that specified risk material has been removed from those raw materials originating from countries with controlled or undetermined BSE risk.

(27) Annexes II, III, V, VII, VIII and IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.

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