

COMMISSION REGULATION (EU) 2021/1176**of 16 July 2021****amending Annexes III, V, VII and IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards genotyping of positive TSE cases in goats, the determination of age in ovine and caprine animals, the measures applicable in a herd or flock with atypical scrapie and the conditions for imports of products of bovine, ovine and caprine origin**

(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,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It categorises Member States, third countries or regions thereof, depending on their bovine spongiform encephalopathy (BSE) risk, into those with a negligible BSE risk, a controlled BSE risk or an undetermined BSE risk.
- (2) Annex III to Regulation (EC) No 999/2001 lays down rules concerning a monitoring system for the prevention of TSEs, including the monitoring of ovine and caprine animals. Point 8 of Part II of Chapter A of Annex III to Regulation (EC) No 999/2001 provides for the compulsory genotyping of positive TSE cases in sheep, and an obligation to immediately report to the Commission any TSE case found in a sheep of the ARR/ARR genotype. Sheep of the ARR/ARR genotype are considered to be resistant to classical scrapie, and therefore any case of the disease in such a sheep is an unexpected finding which requires attention. For this reason it should be immediately notified so that it can be subject to further investigation.
- (3) Regulation (EC) No 999/2001 was amended by Commission Regulation (EU) 2020/772 ⁽²⁾, in accordance with the recommendations of the Scientific Opinion of the European Food Safety Authority (EFSA) of 5 July 2017 on Genetic resistance to transmissible spongiform encephalopathies (TSE) in goats ⁽³⁾, in order to recognise that goats can also be genetically resistant to classical scrapie strains known to occur naturally in the Union's goat population, when they have the K222, D146 or S146 alleles. Regulation (EU) 2020/772 amended Annex VII to Regulation (EC) No 999/2001 by introducing rules restricting the killing and destruction of caprine animals, in a herd where a case of classical scrapie has been confirmed, to only those which are susceptible to this disease. However, the amendments made to Annex VII to Regulation (EC) No 999/2001 by Regulation (EU) 2020/772 did not cover the genotyping of positive TSE cases in goats. Point 8 of Part II of Chapter A of Annex III and point 8 of Part I.A of Chapter B of Annex III should therefore be amended to provide for an appropriate monitoring and reporting of the genotype of positive TSE cases in goats.
- (4) In addition, Regulation (EC) No 999/2001 lays down rules concerning specified risk material, and provides, inter alia, that specified risk material is to be removed and disposed of in accordance with Annex V thereto and with Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽⁴⁾. More particularly, point 1(b) of

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

⁽²⁾ Commission Regulation (EU) 2020/772 of 11 June 2020 amending Annexes I, VII and VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in goats and endangered breeds (OJ L 184, 12.6.2020, p. 43).

⁽³⁾ EFSA Journal 2017;15(8):4962.

⁽⁴⁾ 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).

Annex V to Regulation (EC) No 999/2001 defines specified risk material, in ovine and caprine animals over 12 months of age, that is to be removed and disposed of in accordance with Annex V thereto and with Regulation (EC) No 1069/2009.

- (5) Due to the specificity of the farming of ovine and caprine animals, the determination of the exact date of birth of ovine and caprine animals is rarely feasible and thus such data is not included in the holding register required in accordance with Council Regulation (EC) No 21/2004 ⁽⁵⁾. Therefore, prior to the amendment of Annex V to Regulation (EC) No 999/2001 by Commission Regulation (EU) 2018/969 ⁽⁶⁾, the removal of specified risk material was required in ovine and caprine animals aged over 12 months or in ovine and caprine animals with a permanent incisor erupted through the gum.
- (6) Regulation (EU) 2018/969 amended Annex V to Regulation (EC) No 999/2001 by adding the possibility to use a method approved by the competent authority of the Member State of slaughter to identify ovine and caprine animals aged over 12 months. That possibility was added in 2018 but since that amendment no Member State has availed of it. Also, that possibility was intended to be only applied in the Member States and not to be extended to third countries. Accordingly, in the interests of legal certainty and clarity, it is now appropriate to delete it. Therefore, the possibility to use a method approved by the competent authority of the Member State of slaughter to identify ovine and caprine animals aged over 12 months should be deleted from point 1(b) of Annex V to Regulation (EC) No 999/2001.
- (7) Annex VII to Regulation (EC) No 999/2001 lays down measures for the control and eradication of TSEs, including atypical scrapie. In particular, Chapter B of that Annex lays down the measures to be applied following confirmation of the presence of a TSE in bovine, ovine and caprine animals. Commission Regulation (EU) No 630/2013 ⁽⁷⁾ amended Annex VII to Regulation (EC) No 999/2001 in order to lift all restriction measures on the movement of ovine and caprine animals where a case of atypical scrapie has been confirmed, but maintained an increased surveillance for two years in those flocks or herds in order to gather more scientific data on atypical scrapie. Since the date of adoption of Regulation (EU) No 630/2013 a significant amount of data has been collected. The measure laid down in point 2.2.3 of Chapter B of Annex VII to Regulation (EC) No 999/2001, which is not related to public health concerns, should therefore now be deleted.
- (8) Chapter C of Annex IX to Regulation (EC) No 999/2001 lays down the requirements for the importation into the Union of products of bovine, ovine and caprine animals. These requirements vary according to the BSE status of the country or region of origin of the products, as well as according to the BSE status of the country or region of origin of the animals from which the products were derived. The BSE status of countries or regions according to their BSE risk is set out in Commission Decision 2007/453/EC ⁽⁸⁾, which lists the countries or regions with a negligible BSE risk and with a controlled BSE risk, and provides that all other countries or regions are to be regarded as having an undetermined BSE risk.
- (9) Specific requirements are laid down in points (g) and (h) of Section B of Chapter C of Annex IX to Regulation (EC) No 999/2001, to address the case of the importation of products from a country or region with a negligible BSE risk derived from animals originating from a country or region with an undetermined BSE risk: point (g) establishes that the animals must not have been fed with meat-and-bone meal or greaves; and point (h) establishes that the products must have been produced and handled in a manner which ensures that they did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.

⁽⁵⁾ Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC (OJ L 5, 9.1.2004, p. 8).

⁽⁶⁾ Commission Regulation (EU) 2018/969 of 9 July 2018 amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the requirements for the removal of specified risk materials from small ruminants (OJ L 174, 10.7.2018, p. 12).

⁽⁷⁾ 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).

⁽⁸⁾ 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).

- (10) The specific requirements laid down in points (g) and (h) of Section B of Chapter C of Annex IX to Regulation (EC) No 999/2001 are consistent with the requirements laid down in points 1(a) and 1(c)(ii) of Section D of that Chapter, for the direct importation into the Union from a country or region with an undetermined BSE risk. However, those specific requirements are not currently laid down in Section C of Chapter C of Annex IX to Regulation (EC) No 999/2001, which lays down the requirements for imports from a country or region with a controlled BSE risk. Consequently, it is currently permitted, by reason of that unintentional omission, to import into the Union, from a country or region with a controlled BSE risk, products derived from animals originating from a country or region with an undetermined BSE risk which do not comply with those specific requirements. The specific requirements laid down in points (g) and (h) of Section B of Chapter C of Annex IX to Regulation (EC) No 999/2001 should therefore be inserted in Section C of Chapter C of that Annex.
- (11) Annexes III, V, VII and IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (12) 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

Annexes III, V, VII and IX 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*.

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

Done at Brussels, 16 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes III, V, VII and IX to Regulation (EC) No 999/2001 are amended as follows:

(1) Annex III is amended as follows:

(a) in Chapter A, in Part II, point 8 is replaced by the following:

‘8. Genotyping

8.1. The prion protein genotype for the codons 136, 154 and 171 shall be determined for each positive TSE case in sheep. TSE cases found in sheep of genotypes which encode alanine (A) on both alleles at codon 136, arginine (R) on both alleles at codon 154 and arginine (R) on both alleles at codon 171 shall immediately be reported to the Commission. Where the positive TSE case is an atypical scrapie case the prion protein genotype for the codon 141 shall also be determined.

8.2. The prion protein genotype for the codons 146 and 222 shall be determined for each positive TSE case in goats. TSE cases found in goats of genotypes which encode serine (S) or aspartic acid (D) on at least one allele at codon 146 and/or lysine (K) on at least one allele at codon 222, shall immediately be reported to the Commission.’;

(b) in Chapter B, in Part I.A., point 8 is replaced by the following:

‘8. The genotype, and, where possible, the breed, of each ovine and caprine animal found positive to TSE and sampled in accordance with Chapter A, Part II, point 8.’;

(2) in Annex V, point 1(b) is replaced by the following:

‘(b) as regards ovine and caprine animals: the skull, including the brain and eyes, and the spinal cord of animals aged over 12 months or which have a permanent incisor erupted through the gum.’;

(3) in Annex VII, Chapter B is amended as follows:

(a) point 2.2.3 is deleted;

(b) in point 3.5, sub-point (d) is replaced by the following:

‘(d) for a period of two years from the date when all the measures referred to in point 2.2.1, point 2.2.2(b), or point 2.2.2(c) have been completed, provided that no TSE case other than atypical scrapie is detected during this two-year period.’;

(c) point 4.6 is replaced by the following:

‘4.6. The restrictions set out in points 4.1 to 4.5 shall apply for a period of two years following the detection of the last TSE case, other than atypical scrapie, on the holdings where option 3 laid down in point 2.2.2(d) has been implemented.’;

(4) in Annex IX, in Chapter C, in Section C, in point 1, the following sub-points are added:

(e) if the animals, from which the products of bovine, ovine and caprine animal origin were derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, the animals have not been fed with meat-and-bone meal or greaves, as defined in the OIE Terrestrial Animal Health Code;

(f) if the animals, from which the products of bovine, ovine and caprine animal origin were derived, originate from a country or region classified in accordance with Decision 2007/453/EC as a country or region posing an undetermined BSE risk, the products were produced and handled in a manner which ensures that they did not contain and were not contaminated with nervous and lymphatic tissues exposed during the deboning process.’
