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 (Text with EEA relevance)

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

(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) Regulation (EC) No 999/2001 defines specified risk material ('SRM') as the tissues listed in Annex V thereto, and provides that SRM is to be removed and disposed of in accordance with Annex V thereto and with Regulation (EC) No 1069/2009[(2)]. SRM removal is a measure destined to address the BSE risk in bovine, ovine and caprine animals. The list of SRM in ovine and caprine animals is laid down in point 1(b) of Annex V to Regulation (EC) No 999/2001.

(3) The recommendations of the World Organisation for Animal Health ('OIE') concerning BSE, set out in Chapter 11.4 of the OIE Terrestrial Animal Health Code[(3)], apply to the BSE agent in cattle only. Thus, as far as ovine and caprine animals are concerned, the OIE does not define any list of tissues that should not be traded due to their BSE risk.

(4) The Commission Strategy Paper on TSEs for 2010-2015[(4)] envisages the possibility to review the current list of SRM based on scientific evidence and taking into account the evolution of the BSE epidemiological situation. The BSE epidemiological situation in the Union has improved significantly. In 2016, five cases of BSE were reported in cattle in the Union compared to 2 166 reported cases in 2001. This improvement of the BSE situation in the Union is reflected in the fact that 24 Member States and two

regions of a Member State are now recognised as having a negligible BSE risk status in accordance with Commission Decision 2007/453/EC[(5)], based on the BSE risk status recognised at by the OIE.

(5) As regards SRM from small ruminants, the Commission Strategy Paper on TSEs for 2010-2015 mentions an at-the-time ongoing risk assessment on the pertinence of the SRM list in small ruminants. The European Food Safety Authority (EFSA) published this risk assessment on 2 December 2010, in a Scientific Opinion on BSE/TSE infectivity in small ruminant tissues ('the 2010 EFSA opinion')[(6)]. In that opinion, EFSA estimated that the number of small ruminants infected with BSE that could enter the food chain in the Union each year is very limited, and confirmed that these estimates argue against any widespread BSE epidemic in the small ruminant population in the Union. This EFSA conclusion is valid for entire Union, independently of the BSE risk status of Member States.

(6) As mentioned in the Joint Scientific Opinion on any possible epidemiological or molecular association between TSEs in animals and humans adopted by EFSA and the European Centre for Disease Prevention and Control on 9 December 2010[(7)], only two cases of BSE occurring in natural conditions have been reported worldwide in caprine animals and no naturally occurring BSE case have been reported in ovine animals. The two natural BSE cases detected in goats were born before the introduction of the prohibition on the feeding of processed animal protein to farmed animals and at a time where the BSE epidemic in bovine animals was reaching a peak.

(7) On 5 August 2015, EFSA published a Scientific Opinion on a request for a review of a scientific publication concerning the zoonotic potential of ovine scrapie prions ('the 2015 EFSA opinion')[(8)]. In that opinion, EFSA concluded that there is no evidence of a causal link between scrapie and human TSEs and confirmed that the only TSE agent demonstrated to be zoonotic is the classical BSE agent. Furthermore, EFSA highlighted that there is no epidemiological evidence to suggest that scrapie is zoonotic, in particular since the incidence of sporadic Creutzfeldt Jakob disease in humans is similar in countries with minimal incidence of scrapie as in countries with high incidence of scrapie.

(8) It is therefore appropriate to amend the existing requirements for the removal of SRM in small ruminants so that only those tissues which concentrate the highest levels of BSE infectivity in an infected small ruminant are designated as SRM. According to the 2010 EFSA opinion, experimental data show that the highest levels of infectivity in ovine animals inoculated with BSE are found in the brain and in the spinal cord.

(9) Given the practical difficulties to ensure the absence of contamination of the bones of the skull with brain tissues, the skull of ovine and caprine animals over 12 months of age, or which have a permanent incisor erupted through the gum, should remain designated as SRM in Annex V to Regulation (EC) No 999/2001.

(10) Therefore, only the skull, including the brain and the eyes, and the spinal cord of animals over 12 months of age, or which have a permanent incisor erupted through the gum, should be considered as SRM in ovine and caprine animals.

(11) Due to the specificity of the farming of ovine and caprine animals, the determination of the exact date of birth of those 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[(9)]. Therefore, the removal of the brain, the skull and the eyes of ovine and caprine animals is currently required if the animal is aged over 12 months or if it has a permanent incisor erupted through the gum.

(12) The estimation of the age of ovine and caprine animals based on dentition provides only an approximation, given that the date of eruption of the first permanent incisor in an ovine and caprine animal can vary by several months. Other methods for estimating whether ovine and caprine animals sent for slaughter are over 12 months of age can provide an equivalent level of guarantee concerning the age of the animal. As such methods may depend on the particularity of the slaughter practices of ovine and caprine animals at national level, the reliability of such methods should be evaluated by the competent authority of the Member State of slaughter. Point 1(b) of Annex V to Regulation (EC) No 999/2001 should therefore be amended to provide the possibility of estimating whether an animal is over 12 months of age by a method approved by the competent authority of the Member State of slaughter.

(13) Annex V to Regulation (EC) No 999/2001 should be amended accordingly.

(14) 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 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, or aged over 12 months as estimated by a method approved by the competent authority of the Member State of slaughter..

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, 9 July 2018.

For the Commission

The President

Jean-Claude JUNCKER

(**1**) OJ L 147, 31.5.2001, p. 1.

(**2**) 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 (OJ L 300, 14.11.2009, p. 1).

(**3**) http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_bse.htm

(**4**) 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.

(**5**) 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).

(**6**) *EFSA Journal* 2010; 8(12):1875 [92 pp.].

(**7**) *EFSA Journal* 2011; 9(1):1945 [111 pp.].

(**8**) *EFSA Journal* 2015; 13(8):4197 [58 pp.].

(**9**) 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).

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2018/969.