COMMISSION REGULATION (EU) 2020/1593

of 29 October 2020

amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards further examination of positive cases of transmissible spongiform encephalopathies in ovine and caprine animals

(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 Article 23a(m) 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 X to Regulation (EC) No 999/2001 lays down the sampling and laboratory methods for detection of TSEs.

(3) Point 3.2(a) and (b) of Chapter C of Annex X to Regulation (EC) No 999/2001 requests further examination of samples from suspect cases and samples from TSE monitoring that resulted positive in the confirmatory examination. This requirement was introduced by Commission Regulation (EC) No 36/2005 ([2]) to investigate the possible presence of BSE in small ruminants.

(4) On 28 January 2005, the first case of BSE in a small ruminant under natural conditions was confirmed in a goat slaughtered in France. Consequently, Commission Regulation (EC) No 214/2005 ([3]) increased the testing requirements for goats.

(5) Due to the identification of two possible BSE-like cases in sheep in France and one in Cyprus in 2006, Commission Regulation (EC) No 1041/2006 ([4]) extended the monitoring programme in sheep based on a statistically valid survey in order to determine the likely prevalence of BSE in sheep. These cases were subsequently confirmed to be scrapie and not BSE.

(6) These monitoring programmes were reviewed by Commission Regulation (EC) No 727/2007 ([5]) in the light of the results of two years of intensified testing which led to the detection of no additional BSE cases in ovine or caprine animals.

(7) After further systematic examination of positive TSE cases in ovine and caprine animals since 2005, no more BSE positive or suspicious cases have been detected.

([1]) OJ L 147, 31.5.2001, p. 1.

([2]) Commission Regulation (EC) No 36/2005 of 12 January 2005 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemio-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals (OJ L 10, 13.1.2005, p. 9).

([3]) Commission Regulations (EC) No 214/2005 of 9 February 2005 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in caprine animals (OJ L 37, 10.2.2005, p. 9).

([4]) Commission Regulation (EC) No 1041/2006 of 7 July 2006 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine animals (OJ L 187, 8.7.2006, p. 10).

([5]) Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII 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 (OJ L 165, 27.6.2007, p. 8).

(8) In view of the absence of BSE positive or suspicious cases in ovine and caprine animals since 2005, it is appropriate that the discriminatory testing in case of positive TSE cases in ovine and caprine animals is limited to the 'index case' as defined in point 2(c) of Annex I to Regulation (EC) No 999/2001.

(9) Furthermore, point 3.2(c)(ii) of Chapter C of Annex X to Regulation (EC) No 999/2001 requests that the TSE cases in which BSE cannot be excluded by the primary molecular testing should be submitted to a secondary molecular test in one of the three laboratories listed in that point.

(10) This list was established by Regulation (EC) No 36/2005 based on the methods and laboratory expertise available in 2005. It has never been updated since then.

(11) It is appropriate to ensure more flexibility as regards the method of secondary molecular testing, the design of which should be approved on a case-by-case basis by the EU reference laboratory taking into account the latest scientific knowledge. The choice of the performing laboratory should also be more flexible in order to make the best use of the latest scientific knowledge and laboratory expertise

(12) Point 3.2 (a), (b) and (c) of Chapter C of Annex X to 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 Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex X to Regulation (EC) No 999/2001 is 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, 29 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Point 3.2 of Chapter C of Annex X to Regulation (EC) No 999/2001 is amended as follows:

(1) in point (a) the last paragraph is replaced by the following:

'If the result of one of the confirmatory examinations referred to in points (i) to (iv) of the first subparagraph is positive, the animal shall be regarded as a positive TSE case.';

(2) in point (b) the third paragraph is replaced by the following:

'If the result of one of the confirmatory examinations is positive, the animal shall be regarded as a positive TSE case.';

(3) point (c) is amended as follows:

(a) the following paragraph is inserted after the title:

'Samples that, following the examinations referred to in points (a) or (b), are regarded as positive TSE cases, but which are not considered atypical cases, shall be examined to exclude the presence of BSE only when they come from an index case. Other cases, which display characteristics that, according to the testing laboratory, merit investigation, shall also be examined to exclude the presence of BSE.';

(b) point (i) is replaced by the following:

'(i) Primary molecular testing with a discriminatory Western blotting method

For the exclusion of the presence of BSE, samples shall be examined by a discriminatory Western blotting method, listed in the guidelines of the EU reference laboratory. The discriminatory examination shall be performed by an official laboratory, designated by the competent authority, which has participated successfully in the latest proficiency testing organised by the EU reference laboratory for the use of such a method.';

(c) point (ii) is replaced by the following:

'(ii) Secondary molecular testing with additional molecular testing methods

TSE cases in which the presence of BSE cannot be excluded according to the guidelines issued by the EU reference laboratory by the primary molecular testing referred to in point (i), shall be referred immediately to the EU reference laboratory, with all the relevant information available. The samples shall be submitted to further investigation and confirmation by at least one alternative method, differing immunochemically from the original primary molecular method. The design of the secondary molecular testing, in accordance with the latest scientific knowledge and laboratory expertise, shall be approved on a case-by-case basis by the EU reference laboratory, as described in its guidelines. The EU reference laboratory shall be assisted by a panel of experts referred to as the Strain Typing Expert Group (STEG), as well as by a representative of the relevant national reference laboratory.

The results shall be interpreted by the EU reference laboratory assisted by the STEG, as well as a representative of the relevant national reference laboratory. The Commission shall be informed immediately about the outcome of that interpretation.'.