Commission Regulation (EC) No 162/2009 of 26 February 2009 amending Annexes III 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 (EC) No 162/2009

of 26 February 2009

amending Annexes III 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 COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 third subparagraph of Article 5(3) and the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs) in animals. It provides that each Member State is to carry out an annual monitoring programme for TSEs based on active and passive surveillance.

(2) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002, laying down health rules concerning animal by-products not intended for human consumption[(2)] lays down the animal and public health rules for the collection, transport, storage, handling, processing and use or disposal of animal by-products, to prevent these products from presenting a risk to animal or public health.

(3) Article 4(2) of Regulation (EC) No 1774/2002 sets out the means of disposing of Category 1 material, as defined in Article 2(1)(b) of that Regulation.

(4) Part I of Chapter A of Annex III to Regulation (EC) No 999/2001 lays down rules for the monitoring in bovine animals as well as measures to be applied following testing of the animals.

(5) According to those rules, all parts of the body of an animal tested for bovine spongiform encephalopathy (BSE), including the hide, are to be retained under official control until a negative result to the rapid test has been obtained, unless they are disposed of in accordance with two of the means set out in Article 4(2) of Regulation (EC) No 1774/2002. Also, all parts of the body of an animal found positive or inconclusive to a

rapid test including the hide are to be disposed of in accordance with the same means of disposal.

(6) Regulation (EC) No 1774/2002 provides for the possibility of additional means of disposal to be approved for Category 1 material, in the light of developments in scientific knowledge. Such alternative means are approved and laid down in Commission Regulation (EC) No 92/2005[3].

(7) In the interest of consistency of Community legislation, points 6.3 and 6.4 of Part I of Chapter A of Annex III to Regulation (EC) No 999/2001 should be amended to cover also those additional means of disposal.

(8) Chapter C of Annex X to Regulation (EC) No 999/2001 lays down rules for the sampling and laboratory testing for the presence of TSEs.

(9) According to those rules, the first diagnostic method to be used for the confirmation of a clinical suspect case of BSE is based on histopathological examination, which is the method recommended in an earlier edition of the Manual for diagnostic tests and vaccines for terrestrial animals of the World Organisation for Animal Health (OIE) ('the Manual').

(10) In the latest edition of the Manual, adopted in May 2008, histopathological examination is no longer considered as the reference diagnostic method for investigation of animals suspected of being infected by BSE. According to the Manual, immunohistochemical and immunochemical methods, including rapid tests, may now be used for that purpose. The Community reference laboratory for TSEs considers that applying the same approach for the investigation of ovine and caprine animals suspected of being infected by a TSE is relevant and scientifically robust.

(11) The methods and protocols to be used for the BSE active surveillance in bovine animals should therefore be amended to reflect the recent modification of the Manual.

(12) Point 3.2(c) of Chapter C of Annex X to Regulation (EC) No 999/2001 provides for further examination of positive scrapie cases in ovine and caprine animals in order to investigate the possible presence of BSE.

(13) In its opinion on classification of atypical Transmissible Spongiform Encephalopathy (TSE) cases in small ruminants[4], of 26 October 2005, the European Food Safety Authority states that atypical scrapie cases are clearly distinguishable from BSE. In addition, in its guidelines[5], the Community reference laboratory for TSEs considers that if a TSE is confirmed as an atypical scrapie case, no further testing is required.

(14) Diagnosed atypical scrapie cases should therefore be exempted from the requirement of further examination set out in point 3.2(c) of Chapter C of Annex X to Regulation (EC) No 999/2001.

(15) Point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001 sets out a list of rapid tests approved for the monitoring of TSEs in bovine, ovine and caprine animals.

(16) The commercial denomination of some currently approved TSE tests has recently changed. For the sake of transparency, these changes should be reflected in Point 4 of Chapter C of Annex X.

(17) In addition, the companies manufacturing certain rapid tests do not exist anymore. Other companies producing rapid tests have not submitted the details of their quality system to the Community reference laboratory for review. Certain other rapid tests have been withdrawn from the market.

(18) It is therefore appropriate to amend accordingly the lists of rapid tests approved for the monitoring of BSE and TSEs, set out in point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001.

(19) In the interest of clarity and legal certainty, the wording of the heading of point 3.2(c) of Annex X, Chapter C, should be amended to be consistent with the general scope of paragraph 3.2 of Annex X, Chapter C which is related to laboratory testing for the presence of TSE in ovine and caprine animals.

(20) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(21) 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 III 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*.

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

Done at Brussels, 26 February 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 162/2009. (See end of Document for details)*

ANNEX

Annexes III and X to Regulation (EC) No 999/2001 are amended as follows:

1. in Part I of Chapter A of Annex III, points 6.3 and 6.4 are replaced by the following:

6.3. All parts of the body of an animal tested for BSE including the hide shall be retained under official control until a negative result to the rapid test has been obtained, unless they are disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002 of the European Parliament and of the Council.

6.4. All parts of the body of an animal found positive or inconclusive to the rapid test including the hide shall be disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002, apart from material to be retained in conjunction with the records provided for in Chapter B(III).;

2. in Annex X, Chapter C is amended as follows:

(a) In Point 3.1, points (a) and (b) are replaced by the following:

(a) Suspect cases

Samples from bovine animals sent for laboratory testing pursuant to the provisions of Article 12(2) shall immediately be subjected to confirmatory examinations using at least one of the following methods and protocols laid down in the latest edition of the Manual:

(i) the immunohistochemical (IHC) method;

(ii) SAF-immunoblot or OIE approved alternative;

(iii) the demonstration of characteristic fibrils by electron microscopy;

(iv) the histopathological examination;

(v) the combination of rapid tests as laid down in the third subparagraph.

In case the histopathological examination is inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

Rapid tests may be used for both primary screening of suspect cases and, if inconclusive or positive, for subsequent confirmation, according to the guidelines from the Community reference laboratory and provided that:

(i) the confirmation is carried out in a national reference laboratory for TSEs; and

(ii) one of the two rapid tests is a Western blot; and

(iii) the second rapid test used:

— includes a negative tissue control and a bovine BSE sample as positive tissue control,

— is of a different type than the test used for the primary screening; and

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(iv) if a rapid Western blot is used as the first test, the result of that test must be documented and submitted to the national reference laboratory for TSEs; and

(v) where the result of the primary screening is not confirmed by the subsequent rapid test, the sample must be subjected to an examination by one of the other confirmatory methods; in case the histopathological examination is used for that purpose but proves to be inconclusive or negative, the tissues must be submitted to a further examination by one of the other confirmatory methods and protocols.

If the result of one of the confirmatory examinations referred to in points (i) to (v) of the first subparagraph is positive, the animals shall be regarded a positive BSE cases.

(b) BSE monitoring

Samples from bovine animals sent for laboratory testing pursuant to the provisions of Annex III, Chapter A, Part I shall be examined by a rapid test.

When the result of the rapid test is inconclusive or positive, the sample shall immediately be subjected to confirmatory examinations using at least one of the following methods and protocols laid down in the latest edition of the Manual:

(i) the immunohistochemical (IHC) method;

(ii) SAF-immunoblot or OIE approved alternative;

(iii) the demonstration of characteristic fibrils by electron microscopy;

(iv) the histopathological examination;

(v) the combination of rapid tests as laid down in the fourth subparagraph.

In case the histopathological examination is inconclusive or negative, the tissues shall be submitted to a further examination by one of the other confirmatory methods and protocols.

Rapid tests may be used for both primary screening and, if inconclusive or positive, for subsequent confirmation, according to the guidelines from the Community reference laboratory and provided that:

(i) the confirmation is carried out in a national reference laboratory for TSEs; and

(ii) one of the two rapid tests is a Western blot; and

(iii) the second rapid test used:

— includes a negative tissue control and a bovine BSE sample as positive tissue control,

— is of a different type than the test used for the primary screening; and