Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance)

REGULATION (EC) No 1923/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Economic and Social Committee[(1)],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Regulation (EC) No 999/2001[(3)] is intended to provide a single legal framework for transmissible spongiform encephalopathies (TSEs) in the Community.

(2) Regulation (EC) No 932/2005 of the European Parliament and of the Council of 8 June 2005 amending Regulation (EC) No 999/2001 as regards the extension of the period for transitional measures[(4)] prolonged the period of application of the transitional measures provided for in Regulation (EC) No 999/2001 until 1 July 2007 at the latest.

(3) During the General Session of the World Organisation for Animal Health in May 2003, a Resolution was adopted to simplify the current international criteria for the classification of countries according to their Bovine Spongiform Encephalopathy (BSE) risk. A proposal was adopted at the General Session in May 2005. The Articles of Regulation (EC) No 999/2001 should be adapted to reflect the new internationally agreed categorisation system.

(4) New developments concerning sampling and analysis will require comprehensive amendments to Annex X to Regulation (EC) No 999/2001. It is therefore necessary to make certain technical amendments to the existing definition of ‘rapid tests’ in Regulation (EC) No 999/2001 in order to facilitate amendment of the structure of that Annex at a later stage.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 1923/2006 of the European Parliament and of the Council. (See end of Document for details)*

(5) In the interests of clarity of Community legislation, it is appropriate to clarify that the definition of 'mechanically separated meat' provided for in other Community legislation on food safety should be applicable in Regulation (EC) No 999/2001 in the context of TSE eradication measures.

(6) Regulation (EC) No 999/2001 establishes a monitoring programme for BSE and scrapie. In its opinion of 6-7 March 2003, the Scientific Steering Committee recommended the introduction of a monitoring programme for TSEs in cervids. Therefore the monitoring system provided for in that Regulation should be extended to other TSEs, with the possibility to adopt further measures to implement that system at a later stage.

(7) A harmonised breeding programme to select for resistance to TSEs in ovine animals has been put in place as a transitional measure by Commission Decision 2003/100/EC of 13 February 2003 laying down minimum requirements for the establishment of breeding programmes for resistance to transmissible spongiform encephalopathies in sheep[(5)]. Regulation (EC) No 999/2001 should be amended to provide a permanent legal basis for that programme, as well as the possibility of amending such programmes to take account of the evaluated scientific results and overall consequences of their implementation.

(8) Regulation (EC) No 999/2001 prohibits the feeding of certain processed animal proteins to certain animals, with the possibility to provide for derogations. New developments concerning prohibitions on animal feeding may require amendments to be made to Annex IV to that Regulation. It is necessary to make certain technical amendments to the existing wording of the corresponding Article in order to facilitate amendment of the structure of that Annex at a later stage.

(9) 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[(6)] establishes rules for the disposal of specified risk materials and animals infected by TSEs. Rules on transit through the Community of products of animal origin have now been adopted. Accordingly, in the interests of consistency of Community legislation, the existing rules in Regulation (EC) No 999/2001 on the disposal of such materials and animals should be replaced by a reference to Regulation (EC) No 1774/2002, and the reference to rules on transit in Regulation (EC) No 999/2001 should be deleted.

(10) New developments concerning specified risk materials will also require comprehensive amendments to Annex V to Regulation (EC) No 999/2001. It is necessary to make certain technical amendments to the existing wording of the corresponding provisions of that Regulation in order to facilitate amendment of the structure of that Annex at a later stage.

(11) Although stunning by injection of gas in the cranial cavity is prohibited within the Community, injection of gas may also occur after stunning. It is therefore necessary to amend the relevant provisions on slaughter methods in Regulation (EC) No 999/2001 with a view to prohibiting gas injection into the cranial cavity after stunning.

(12) Commission Regulation (EC) No 1915/2003 amending Regulation (EC) No 999/2001[(7)] sets out new provisions on eradication of scrapie in ovine and caprine animals. Accordingly, it is necessary to prohibit the movement of ovine and caprine animals from holdings where scrapie is officially suspected.

(13) Based on evolving scientific knowledge, Regulation (EC) No 999/2001 should allow the extension to other species of the scope of the rules concerning the placing on the market and export of bovine, ovine and caprine animals, their semen, embryos and ova.

(14) The opinion of the Scientific Steering Committee of 26 June 1998 indicates that certain restrictions regarding sourcing of raw material for the manufacture of di-calcium phosphate should be observed. Accordingly, di-calcium phosphate should be removed from the list of products which are not subject to restrictions on placing on the market under Regulation (EC) No 999/2001. The absence of restrictions applicable to milk and dairy products should be clarified.

(15) Based on evolving scientific knowledge and risk classification, and notwithstanding the possibility to adopt safeguard measures, Regulation (EC) No 999/2001 should permit the adoption in accordance with the comitology procedure of more specific requirements for the placing on the market and export of products of animal origin originating from Member States or third countries with a controlled or undetermined risk of TSE.

(16) The measures necessary for the implementation of Regulation (EC) No 999/2001 should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(8)].

(17) In particular, the Commission should be empowered to adopt decisions approving the rapid tests, adapting the age of the animals, introducing the tolerance level, allowing feeding of young animals of ruminant species with proteins derived from fish and extending certain provisions to other animal species; to establish rules providing for exemptions from the requirement to remove and destroy specific risk material; to establish criteria to demonstrate improvement of the epidemiological situation and criteria for granting exemptions from certain restrictions as well as production processes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 999/2001 and/or to supplement that Regulation by the addition of new non-essential elements, those measures should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(18) Regulation (EC) No 999/2001 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 999/2001 is hereby amended as follows:

1) the following recital shall be inserted:

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 1923/2006 of the European Parliament and of the Council. (See end of Document for details)*

(8a) The feeding to non-ruminants of certain processed animal proteins originating from non-ruminants should be allowed taking into account the prohibition on intra-species recycling as laid down in 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[(9)] and the control aspects in particular linked to the differentiation of processed animal proteins specific to certain species as laid down in the Communication on the TSE Road map adopted by the Commission on 15 July 2005.;

2) the following recitals shall be inserted:

(11a) In its resolution of 28 October 2004[(10)], the European Parliament expressed concerns about feeding animal proteins to ruminants as they do not form part of the natural nutrition of adult cattle. In the wake of the BSE crisis and the foot-and-mouth disease crisis it has increasingly become accepted that the best way to ensure human and animal health is to keep and nourish animals in a way that respects the particularities of each species. Pursuant to the precautionary principle and in keeping with the natural diet and living conditions of ruminants, it is therefore necessary to maintain the prohibition on the feeding of animal proteins to ruminants in forms not normally constituting part of their natural diet.

(11b) Mechanically separated meat is obtained by removing meat from bones in such a way that the muscle fibre structure is destroyed or modified. It can contain parts of the bones and the periosteum (bone skin). Thus, mechanically separated meat is not comparable with regular meat. Consequently its use for human consumption should be reviewed.;

3) in Article 3, paragraph 1 shall be amended as follows:

(a) point (l) shall be replaced by the following:

(l) rapid tests: the screening methods listed in Annex X, for which the results are known within 24 hours;;

(b) the following points shall be added:

(n) mechanically separated meat or "MSM": the product obtained by removing meat from flesh-bearing bones after boning, using mechanical means resulting in the loss or modification of the muscle fibre structure;

(o) passive surveillance: the reporting of all animals suspected of being infected by a TSE and, where TSE cannot be excluded by clinical investigation, the laboratory testing of such animals;

(p) active surveillance: the testing of animals not reported as suspected of being infected by a TSE, such as emergency slaughtered animals, animals with observations at ante mortem inspection, fallen stock, healthy slaughtered animals and animals culled in connection with a TSE case, in particular in order to determine the evolution and prevalence of TSE in a country or region thereof.;

4) Article 5 is hereby amended as follows:

(a) paragraph 1 shall be replaced by the following:

1. The BSE status of Member States or third countries or regions thereof (hereinafter referred to as "countries or regions") shall be determined by classification into one of the following three categories:

— negligible BSE risk as defined in Annex II,

— controlled BSE risk as defined in Annex II,

— undetermined BSE risk as defined in Annex II.

The BSE status of countries or regions may be determined only on the basis of the criteria set out in Annex II, Chapter A. These criteria shall include the outcome of a risk analysis on the basis of all the potential factors for the appearance of bovine spongiform encephalopathy as defined in Annex II, Chapter B, and their development over time, as well as comprehensive active and passive surveillance measures taking into account the risk category of the country or region.

Member States, and third countries wishing to be retained on the list of third countries approved for the export to the Community of the live animals or of the products covered by this Regulation, shall submit to the Commission an application for their BSE status to be determined, accompanied by the relevant information on the criteria set out in Annex II, Chapter A, and on the potential risk factors specified in Annex II, Chapter B, and their development over time.;

(b) paragraph 4 shall be replaced by the following:

4. Member States and third countries which have not submitted an application in accordance with the third subparagraph of paragraph 1 shall, with respect to the dispatch from their territory of live animals and products of animal origin, comply with the import requirements applicable to countries with an undetermined BSE risk, until they have submitted such an application and a final decision has been taken on their BSE status.;

5) Article 6 is hereby amended as follows:

(a) paragraph 1 shall be replaced by the following:

1. Each Member State shall carry out an annual monitoring programme for TSEs based on active and passive surveillance in accordance with Annex III. If available for the animal species, that programme shall include a screening procedure using rapid tests.

Rapid tests shall be approved for that purpose in accordance with the procedure referred to in Article 24(3) and listed in Annex X.;

(b) the following paragraphs shall be inserted:

1a. The annual monitoring programme referred to in paragraph 1 shall cover as a minimum the following subpopulations:

a all bovine animals above 24 months of age sent for emergency slaughter or with observations at ante mortem inspections;

b all bovine animals above 30 months of age slaughtered normally for human consumption;