COMMISSION OF THE EUROPEAN COMMUNITIES

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2004/0270 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

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] (TSE Regulation) provides measures targeting all animal and public health risks resulting from all animal TSE, and governing the entire chain of production and placing on the market of live animals and products of animal origin. This Regulation is applicable as of 1 July 2001.

It consolidated much of the previous legislation on BSE or TSE, including rules for the monitoring of TSE in bovine, ovine and caprine animals, removal of specified risk material and prohibitions concerning animal feeding. It also introduced new legislation for areas such as eradication of TSE and trade rules covering the domestic market, intra-community trade, import and export. Furthermore it provided for the procedure, criteria and categories for the classification of countries according to BSE status.

This proposal is an amendment to the TSE Regulation on various matters and in the light of new developments since the adoption of the Regulation.

1. DETERMINATION OF BSE STATUS

Regulation (EC) No 1128/2003 of the European Parliament and of the Council amending the TSE Regulation as regards the extension of the period for transitional measures[2] extended the application of the transitional measures under Article 23 of the TSE Regulation by two years, until 30 June 2005.

Maintaining the present level of public health protection, the two-year extension of time was intended to allow the Commission to continue its attempts to reach an agreement at international level on the determination of BSE status of countries.

The World Organisation for Animal health (OIE) presented a proposal to simplify the current criteria for the categorisation of countries according to their BSE risk for discussion at the General Session in May 2004. Since the Members did not express major objections to the proposal, a proposal for possible adoption will be presented at the OIE General session in May 2005 at the earliest. The intention is to reduce the number of categories, possibly in a step-wise way. To avoid multiple amendments to the Articles of the TSE Regulation pending the final modifications to the number of categories, it is proposed to transfer references to individual categories from the Articles to the Annexes.

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1 OJ L 147, 31.5.2001, p. 1; last amended Commission Regulation (EC) No 1492/2004 (OJ L 274, 24.8.2004, p. 3).

2 OJ L 160, 28.6.2003, p. 1.

Furthermore, a Resolution was adopted at the OIE General Session in May 2003 according to which OIE will classify all countries into one or other of the defined categories. It may be assumed that OIE will not conclude the final categorisation of countries according to their BSE risk before 1 July 2005. Therefore it is proposed to prolong the period of application of the transitional measures. Therefore it is proposed to prolong the period of application of the transitional measures until 1 July 2007.

2. PREVENTION OF TSE

In its opinion of 6-7 March 2003, the Scientific Steering Committee (SSC) recommended to start a monitoring programme for TSEs in cervids. The TSE Regulation establishes a monitoring programme for BSE and scrapie. It is proposed to extend this provision to other TSEs, in particular in order to follow the SSC recommendation on cervids.

Commission Decision No. 2003/100/EC[3] introduced a harmonised breeding programme to select for resistance to TSEs in ovine animals as a transitional measure. It is proposed to introduce a permanent legal basis for the breeding programme in the TSE Regulation.

The TSE Regulation prohibits the feeding of certain processed animal proteins to certain animals, with a possibility to extend the prohibition or lay down derogations in Annex IV. In order to make comprehensive amendments to the Annex, it is proposed to make certain technical amendments to the present wording of the corresponding Articles in order to develop the structure of the Annex.

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[4] establishes the rules for disposal of specified risk materials and animals infected by TSEs. It is proposed to replace the present rules in the TSE Regulation on the disposal of specified risk materials and animals infected by TSEs with a reference to Regulation (EC) No 1774/2002 laying down health rules concerning animal by-products not intended for human consumption.

New developments concerning specified risk materials have furthermore led to a need to make comprehensive amendments to the relevant Annex. It is proposed to make certain technical amendments to the present wording of the corresponding Articles in order to develop the structure of the Annex.

Although stunning by injection of gas into the cranial cavity is not authorised within the European Union, injection of gas may also occur after stunning. It is therefore proposed to revise the present provisions on slaughter methods with a view to prohibit gas injection into the cranial cavity in connection with stunning.

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3 OJ L 41, 14.2.2003, p. 41.

4 OJ L 273, 10.10.2002, p. 1.

It is proposed to align the definition of mechanically recovered meat with the definition used in other Community legislation on food safety.

3. CONTROL AND ERADICATION OF TSES

In order to avoid that animals are moved from holdings where scrapie is officially suspected, it is proposed to lay down the same rules regarding movement restrictions as for bovine animals following the detection of a BSE suspect.

4. PLACING ON THE MARKET

To take account of possible emerging TSEs in other species it is proposed to introduce a possibility to extend the scope of the current provisions on the placing on the market and export of bovine, ovine and caprine animals, their semen, embryos and ova in order to cover other species.

The Scientific Steering Committee (SSC) opinion of 26 June 1998 indicates that certain restrictions regarding sourcing of raw material for the manufacture of di-calcium phosphate should be observed. It is proposed to remove di-calcium phosphate from the list of products which the Regulation currently specifies shall not be subject to restrictions on placing on the market.

Since no restrictions apply for milk for human consumption, the same derogation should apply for milk not intended for human consumption within the meaning of Regulation (EC) No 1774/2002. The list of products which shall not be subject to restrictions on placing on the market by the Regulation shall be modified accordingly.

5. CONTROLS

The TSE Regulation provides a legal basis for inspections by the Food and Veterinary Office (FVO) only within the Member States. Although Commission Decision 98/140/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries[5] provides a general legal basis for Community inspections in Third countries, it should be advisable to provide within the TSE Regulation such legal provisions. It is proposed to amend the Regulation to provide for such checks.

The proposal has no implications for the budget of the European Community.

[5] OJ L 38 , 12.2.1998, p. 14.

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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[6],

Having regard to the opinion of the European Economic and Social Committee[7],

Having consulted the Committee of the Regions[8],

Whereas:

(1) 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[9] is intended to provide a single legal framework for transmissible spongiform encephalopathies (TSEs) in the Community.

(2) Regulation (EC) No 1128/2003 of the European Parliament and of the Council of 16 June 2003 amending Regulation (EC) No 999/2001 as regards the extension of the period for transitional measures[10] prolonged the period of application of the transitional measures provided for in Regulation (EC) No 999/2001 until 1 July 2005 at the latest. It is appropriate to make certain amendments to the permanent provisions of that Regulation before that date.

(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 for possible adoption will be presented to the General Session in May 2005. The intention is to reduce the number of categories, possibly in a step-by-step approach. To avoid multiple amendments to the Articles of Regulation (EC)

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6 OJ C […], […], p. […].
7 OJ C […], […], p. […].
8 OJ C […], […], p. […].
9 OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1492/2004 (OJ L 274, 24.8.2004, p. 3).
10 OJ L 160, 28.6.2003, p. 1.

No 999/2001 when following such developments, references to individual categories should be transferred from the Articles of that Regulation to the Annexes.

(4) New developments concerning sampling and analysis will require comprehensive amendments to the 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 amending the structure of this Annex at a later stage.

(5) In the interests of clarity of Community legislation, it is appropriate to clarify that the definition of 'mechanically separated meat' in Regulation (EC) No 999/2001 provided for in other Community legislation on food safety is applicable 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) It is necessary to introduce a harmonised breeding programme to select for resistance to TSEs in ovine animals. Such a programme has already been put in place as a transitional measure by Commission Decision No 2003/100/EC of 13 February 2003 laying down minimum requirements for the establishment of breeding programmes for resistance to transmissible spongiform encephalopathies[11]. Regulation (EC) No 999/2001 should be amended to provide a permanent legal basis for that programme.

(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 develop 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[12] 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.

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[11] OJ L 41, 14.2.2003, p. 41.

[12] OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 668/2004 (OJ L 112, 19.4.2004, p. 1).

(10) New developments concerning specified risk materials will also require comprehensive amendments to the 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 develop 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 that Regulation with a view to prohibit gas injection into the cranial cavity after stunning.

(12) Regulation (EC) No 999/2001, as amended by Commission Regulation (EC) No 1915/2003 amending Regulation (EC) 999/2001 of the European Parliament and of the Council as regards the trade and import of ovine and caprine animals and the measures following the confirmation of transmissible spongiform encephalopathies in bovine, ovine and caprine animals[13], 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, the Regulation should allow to extend to other species 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 (SSC) 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 high risk of TSE.

(16) Regulation (EC) No 999/2001 does not provide for on-the-spot checks in third countries to verify the criteria for classification and the fulfilment of requirements for the export of animals and animal products to the Community. Pending the application of Regulation (EC) No 882/2004[14], Regulation (EC) No 999/2001 should be amended to provide for such checks.

(17) Due to the developments in the World Organisation for Animal Health the final classification of countries according to their BSE risk is not expected to be completed by 1 July 2005. Therefore it is necessary to further prolong the period of application of the transitional measures provided for in Regulation (EC) No 999/2001.

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[13] OJ L 283, 31.10.2003, p. 29.

[14] OJ L 165, 30.4.2004, p. 1. Regulation of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

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

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) Article 3, paragraph 1 is 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 point (n) shall be added:

'(n) mechanically separated meat: meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council [15].'

(2) In Article 5, paragraph 4 shall be replaced by the following:

'4. Member States or third countries which have not submitted an application in accordance with the second 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 a high BSE risk, until they have submitted such an application and a final decision has been taken on their BSE status.'

(3) Article 6 is 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 in accordance with Annex III. Where appropriate, 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(2) and listed in Annex X.'

(b) the following paragraph 5 shall be added:

'5. Rules for the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 24(2).'

[15] OJ L 139, 30.4.2004, p. 55.

(4) The following Article 6a shall be inserted:

'Article 6a
Breeding Programmes

1. Member States shall introduce breeding programmes to select for resistance to TSEs in their ovine populations. Those programmes shall include a framework to recognise the TSE-resistant status of certain flocks.

2. The breeding programmes provided in paragraph 1 may be extended to include other animal species based on scientific evidence corroborating the resistance to TSE of particular genotypes of those species.

3. Specific rules for the programmes provided for in paragraphs 1 and 2 of this Article shall be adopted in accordance with the procedure referred to in Article 24(2). Those rules shall set a harmonised framework for the programmes provided for in paragraphs 1 and 2 of this Article. They may provide for certain Member States to be exempted from the requirements of paragraphs 1 and 2, based on epidemiological factors.'

(5) In Article 7, paragraphs 2, 3 and 4 shall be replaced by the following:

'2. The prohibition provided for in paragraph 1 shall be extended to animals and products of animal origin in accordance with Annex IV.

3. Paragraphs 1 and 2 shall apply without prejudice to the provisions set out in Annex IV.

4. A decision may be taken, under the procedure referred to in Article 24(2), to restrict the placing on the market or export of protein derived from mammals where such restriction is necessary to prevent the transmission of TSEs.'

(6) In Article 8, paragraphs 1, 2 and 3 shall be replaced by the following:

'1. The specified risk material shall be removed and disposed of in accordance with Annex V to this Regulation and Regulation (EC) No 1774/2002. It shall not be imported into the Community.

2. Paragraph 1 shall not apply to tissues from animals which have undergone an alternative test approved for that distinct purpose in accordance with the procedure referred to in Article 24(2) provided that this test is listed in Annex X, is applied under the conditions provided for in Annex V and the test results are negative.

The Member States which authorise an alternative test pursuant to this paragraph shall inform the other Member States and the Commission.

3. In Member States, or regions thereof, where the removal of specified risk material is required as set out in Annex V, the laceration, after stunning, of central nervous tissue by means of an elongated rodshaped instrument introduced into the cranial cavity, or by means of gas injection into the cranial cavity in connection to stunning, shall not be used on bovine, ovine or caprine animals whose meat is destined for human or animal consumption.'

(7) In Article 8, paragraph 5 shall be replaced by the following:

'5. By way of derogation from paragraphs 1 to 4, a decision may be adopted in accordance with the procedure referred to in Article 24(2), with regard to the date of the effective enforcement of the feeding prohibition provided for in Article 7(1) or, as appropriate for a third country or region thereof with a BSE risk, the date of the effective enforcement of the ban of mammalian protein in feed for ruminants with a view to limiting the requirement to remove and destroy specified risk material to animals born before that date in those countries or regions. '

(8) In Article 9, paragraphs 1 and 2 shall be replaced by the following:

'1. The products of animal origin listed in Annex VI shall be produced in accordance with production processes approved in accordance with the procedure referred to in Article 24(2).

2. Bones of the head, and vertebral columns of bovine, ovine and caprine animals from countries, or regions thereof, with a BSE risk, shall not be used for the production of mechanically separated meat.'

(9) Article 12 is amended as follows:

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

'1. Any animal suspected of being infected by a TSE shall be either placed under an official movement restriction until the results of a clinical and epidemiological examination carried out by the competent authority are known, or killed for laboratory examination under official control.

If a TSE is suspected in a bovine, ovine or caprine animal at a holding in a Member State, all other bovine, ovine or caprine animals from that holding shall be placed under an official movement restriction until the results of that examination are available.

However, if there is evidence that the holding where the animal was present when the TSE was suspected is unlikely to be the holding where the animal could have been exposed to the TSE, the competent authority may decide that only the animal suspected of being infected shall be placed under an official movement restriction.

If considered necessary, the competent authority may also decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

Under the procedure referred to in Article 24(2) and by way of derogation from the official movement restrictions provided for in this paragraph, a Member State may be exempted from implementing such restrictions if it applies measures offering equivalent safeguards.'

(b) paragraph 3 shall be replaced by the following:

'3. All parts of the body of the suspect animal shall be either retained under official control until a negative diagnosis has been made, or disposed of in accordance with Regulation (EC) No 1774/2002. '

(10) In Article 13, paragraph 1 is amended as follows:

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

'(a) all parts of the body of the animal shall be disposed of in accordance with Regulation (EC) No 1774/2002 except for material retained for records in accordance with Annex III, Chapter B of this Regulation.'

(b) point (c) shall be replaced by the following:

'(c) all animals and products thereof at risk, as listed in Annex VII, point 2 to this Regulation, identified by the inquiry referred to in point (b) of this paragraph shall be killed and disposed of in accordance with Regulation (EC) No 1774/2002.'

(11) In Article 15, paragraph 3 shall be replaced by the following:

'3. In accordance with the procedure referred to in Article 24(2), the provisions of paragraphs 1 and 2 may be extended to other animal species, and detailed rules for implementing this Article may be adopted.'

(12) Article 16 is amended as follows:

(a) in paragraph 1, point (b) shall be replaced by the following:

'(b) milk and dairy products, hides and skins, and gelatine and collagen derived from hides and skins.'

(b) paragraphs 2 and 3 shall be replaced by the following:

'2. Products of animal origin imported from a third country with a BSE risk shall come from healthy bovine, ovine and caprine animals which have not been subjected to a laceration of the central nervous tissue or gas injection into the cranial cavity as referred to in Article 8(3).

3. Further conditions applicable to the placing on the market and export of products of animal origin originating in a Member State or third country, or a region thereof, with a high risk of BSE, shall be adopted in accordance with the procedure laid down in Article 24(2).'

(13) Article 21 shall be replaced by the following:

'Article 21
Community controls

1. Experts from the Commission may carry out on-the-spot checks in co-operation with the competent authorities of the Member States, insofar as is necessary for the uniform application of this Regulation. The Member State in whose territory those checks are carried out shall provide the experts with all the assistance necessary for carrying out their duties. The Commission shall inform the competent authority of the results of those checks.

   Experts from the Commission and the Member States may carry out on-the-spot checks in third countries in order to verify whether the conditions relevant for the export from such countries are fulfilled.

   The experts from the Member States responsible for those checks shall be appointed by the Commission, acting on a proposal from the Member States. The checks shall be made on behalf of the Community which shall bear the cost of any expenditure in this connection

2. Community checks concerning third countries shall be made in accordance with Directive 97/78/EC.

3. Rules for the application of paragraph 1 shall be adopted in accordance with the procedure referred to in Article 24(2)."

(14) In Article 23, the second paragraph shall be replaced by the following:

'In accordance with that procedure, transitional measures shall be adopted for a period ending on 1 July 2007 at the latest, to permit the change-over from the current arrangements to the arrangements established by 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, […]

For the European Parliament	*For the Council*
The President	*The President*