

EUROPEAN PARLIAMENT

2004



2009

Committee on the Environment, Public Health and Food Safety

PROVISIONAL
2004/0270(COD)

3.2.2006

*****I**

DRAFT REPORT

on the 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 (COM(2004) 775 – C6-0223/2004 – 2004/0270(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Dagmar Roth-Behrendt

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	4
EXPLANATORY STATEMENT	24

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the 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 (COM(2004) 775 – C6-0223/2004 – 2004/0270(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2004) 775)¹,
 - having regard to Article 251(2) and Article 152(4)(b) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0223/000),
 - having regard to Rule 51 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A6-0000/2006),
 - having regard to Regulation (EC) No 932/2005 on transitional measures²,
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

Amendment 1 RECITAL 2

(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 measures¹ 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***

(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 measures¹ prolonged the period of application of the transitional measures provided for in Regulation (EC) No 999/2001 until **1 July 2007** at the latest.

¹ Not yet published in OJ.

² OJ L 163, 23.6.2005, p. 1.

certain amendments to the permanent provisions of that Regulation before that date.

¹ OJ L 160, 28.6.2003, p. 1.

¹ OJ L 163, 23.6.2005, p. 1.

Justification

This amendment is a necessary adaptation of the Commission's proposal. The prolongation of the transitional measures was already decided by Parliament and Council in June 2005. The initial proposal was split into two parts for that purpose.

Amendment 2
RECITAL 3

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

(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.***

Justification

This amendment is a necessary adaptation after the OIE (International Organisation for Animal Health) General Assembly of May 2005 adopted a new BSE chapter. At the time of the transmission of the Commission's proposal this was expected but not assured.

Amendment 3
RECITAL 7

(7) ***It is necessary to introduce a harmonised breeding programme to select***

(7) A harmonised breeding programme to select for resistance to TSEs in ovine

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. Regulation (EC) No 999/2001 should be amended to provide a permanent legal basis for that programme.

animals has 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. 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.***

Justification

The proposed breeding programmes should be on a voluntary basis rather than obligatory. See amendment and justification on new Article 6a.

Amendment 4
RECITAL 16

(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, Regulation (EC) No 999/2001 should be amended to provide for such checks. ***deleted***

Justification

Regulation No 882/2004 has been adopted in the meantime. This recital and the proposed modification of Article 21 of this regulation should therefore be deleted.

Amendment 5
RECITAL 17

(17) Due to the developments in the World Organisation for Animal Health the final ***deleted***

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.

Justification

The transitional measures have been already prolonged until 1 July 2007 by Regulation 932/2005.

Amendment 6

ARTICLE 1, POINT - 1 (new)

Recital 11 a (new) (Regulation (EC) No 999/2001)

(-1) The following recital 11a is inserted:

"(11a) In its resolution of 28 October 2004¹, 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 food-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 the natural diet.

¹ OJ C 174 E, 14.7.2005, p. 178."

Amendment 7

ARTICLE 1, POINT - 1 A (new)

Recital 11 b (new) (Regulation (EC) No 999/2001)

(-1a) The following recital 11b is inserted:

"(11b) Mechanically separated meat is obtained by bevelling 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 needs to be reviewed."

Justification

The supply situation with meat and the pricing practice of the manufactures makes the marketing of "meat" possibly containing parts of bone skin and liquids superfluous. Assumingly consumers would not buy this kind of "meat" if they would be completely aware of the production methods. The use of MSM for human consumption shall, therefore, be reviewed.

Amendment 8

ARTICLE 1, POINT 1 (B)

Article 3, paragraph 1, point (n) (Regulation (EC) No 999/2001)

(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.***

(n) mechanically separated meat ***or "MSM" means 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.***

Justification

The definition should be explicitly laid down in the TSE-regulation instead of making a reference to Regulation 853/2004.

Amendment 9

ARTICLE 1, POINT 1 (B) a (new)

Article 3, paragraph 1, point (n) a (new) (Regulation (EC) No 999/2001)

(ba) the following point (na) shall be added:

"(na) passive surveillance: testing of all animals reported as suspected of being

infected by TSE."

Justification

The OIE General Assembly adopted in May 2005 a new chapter on BSE containing three instead of formerly five BSE-risk categories, which was supported by the Commission. It is obvious that an international agreed BSE-approach is needed. Therefore, it is recommended to accept the Commission's proposal and adapt the TSE-regulation to the new OIE-code adopted by 168 Member States. However, such a reduction of risk categories is only feasible if it will be accompanied by comprehensive active and passive surveillance measures for both, as conditions for the categorisation of a country and as part of the annual monitoring programme of the Member States. This is the only way to get a clear picture of the BSE-situation in a Member State or third country. The amendment defines the term "passive surveillance."

Amendment 10

ARTICLE 1, POINT 1(B) b (new)

Article 3, paragraph 1, point (n) b (new) (Regulation (EC) No 999/2001)

(bb) the following point (nb) shall be added:

"(nb) active monitoring: animals subject to casualty or emergency slaughtering, animals with clinical symptoms at ante mortem inspection, fallen stock, healthy slaughtered animals and animals culled in connection with a BSE case in order to determine the evolution and prevalence of TSE in a country or region thereof."

Justification

See justification to the amendment introducing the term "passive surveillance". This amendment defines the term "active monitoring" which is subsequently used.

Amendment 11

ARTICLE 1, POINT 1 A (new)

Article 5, paragraph -1 (new) (Regulation (EC) No 999/2001)

(1a) In Article 5 the following paragraph shall be inserted before paragraph 1:

"-1. The BSE status of Member States or third countries or one of the regions thereof 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."*

Justification

This amendment lists the new BSE risk categories as adopted by the General assembly of the OIE in May 2005.

Amendment 12

ARTICLE 1, POINT 1 B (new)

Article 5, paragraph 1 (Regulation (EC) No 999/2001)

(1b) In Article 5, paragraph 1 shall be replaced by the following:

"1. The BSE status of a Member State, of a third country, or of one of their regions (hereinafter referred to as '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. 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."

Justification

See amendment on Article 3.

Amendment 13

ARTICLE 1, POINT 2

Article 5, paragraph 4 (Regulation (EC) No 999/2001)

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.

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 **an undetermined** BSE risk, until they have submitted such an application and a final decision has been taken on their BSE status.

Justification

This amendment is a necessary modification of the Commission's proposal from December 2004 which was presented before the concrete terms of the new BSE-risk categories have been agreed upon at the OIE's General Assembly in May 2005.

.

Amendment 14

ARTICLE 1, POINT 3 (A)

Article 6, paragraph 1, subparagraph 1 (Regulation (EC) No 999/2001)

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.

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.

Justification

See justification to the amendments introducing the terms "passive surveillance" and "active monitoring".

Amendment 15
ARTICLE 1, POINT 3 (A) a (new)
Article 6, paragraph 1 a (new) (Regulation (EC) No 999/2001)

(aa) the following paragraph 1a 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 month of age sent for emergency slaughter or with observations at ante mortem inspections such as displaying a neurological disorder (emergency slaughter),

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

c) all bovine animals above 24 months of age not slaughtered for human consumption, which have died or been killed on the farm, during transport or in an abattoir (fallen stock).

Member States may decide to derogate from the provision under point (c) in remote areas with a low animal density, where no collection of dead animals is organised. Member States making use of this possibility shall inform the Commission and submit a list of the areas concerned together with a justification for the derogation. The derogation shall not cover more than 10% of the bovine population in a Member State."

Justification

This amendment sets out minimum standards for the subpopulations of cattle which should be part of the Member States annual monitoring programme. The proposed provisions mirror the current BSE testing scheme but open the possibility for future modifications. However, strict preconditions for such modifications are set out. This amendment is part of the improved active and passive surveillance standards as asked for in the justification on the new Article 3.1.n).

Amendment 16

ARTICLE 1, POINT 3 (A) b (new)
Article 6, paragraph 1 b (new) (Regulation (EC) No 999/2001)

(ab) The following paragraph 1b shall be inserted:

"1b. a) After consultation of the appropriate scientific committee, the age laid down in paragraph 1a (a) and (c) may be adapted according to scientific progress in accordance with the procedure referred to in Article 24(2).

b) Upon request of a Member State which can demonstrate the improvement of the epidemiological situation of the country, according to certain criteria to be laid down in accordance with the procedure referred to in Article 24 (2), the monitoring programmes for that particular Member State may be revised. The Member State concerned shall provide proof of its capability to determine the effectiveness of the measures in place and ensure protection of human and animal health based on a comprehensive risk analysis. In particular the Member State shall demonstrate:

- a clearly declining or consistently low BSE prevalence, based on up-to-date testing results;

- that it has implemented and enforced for at least six years a full BSE testing scheme (Community legislation on traceability and identification of live animals and BSE surveillance);

- that it has implemented and enforced for at least eight years Community legislation prohibiting the feeding of animal proteins as laid down in Annex IV."

Justification

See justification to the amendment on Article 6, paragraph 1 a (new).

Amendment 17
ARTICLE 1, POINT 4
Article 6 a (Regulation (EC) No 999/2001)

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.**

1. Member States **may** 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 **and** may be extended to include other animal species based on scientific evidence corroborating the resistance to TSE of particular genotypes of those species.

2. Specific rules for the programmes provided for in paragraph 1 of this Article shall be adopted in accordance with the procedure referred to in Article 24(2).

3. The scientific results and overall consequences of the breeding programmes shall be evaluated regularly, and when necessary, those programmes shall be amended.

Justification

The scientific value of breeding programmes for resistance to TSE is questionable. These programmes should only be introduced on a voluntary basis.

Amendment 18

ARTICLE 1, POINT 4 A (new)

Article 7, paragraph 1 (Regulation (EC) No 999/2001)

(4a) In Article 7, paragraph 1 shall be replaced by the following:

"1. The feeding to ruminants of protein derived from animals is prohibited."

Justification

This amendment takes into account the fact that adult ruminants are herbivores and should not be fed at all with animal proteins, in forms not constituting part of the natural diet.

Amendment 19
ARTICLE 1, POINT 5
Article 7, paragraph 4 (Regulation (EC) No 999/2001)

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.

4. Member States, or regions thereof, with an undetermined BSE risk shall not be permitted to export or store feed intended for farmed animals which contains protein derived from mammals or feed intended for mammals, except for dogs and cats and fur animals, which contains processed protein derived from animals.

Third countries, or regions thereof, with an undetermined BSE risk shall not be permitted to export to the Community feed intended for livestock which contains protein derived from mammals or feed intended for mammals, except for dogs, cats and fur animals, which contains processed protein derived from mammals.

On the request of a Member State or third country a decision may be taken, under the procedure referred to in Article 24(2), to grant individual exemptions from the restrictions in this paragraph. Any exemption shall take due account of the ethical aspects of animal nutrition and stockbreeding.

Justification

Reflecting the change from five to three categories the possibility of Member States or third countries to import and export feed containing animal proteins from mammals need to be amended. However, the principle shall be maintained that this feeding stuff shall not be imported or exported when it comes from a country or region falling into the highest risk category.

Amendment 20
ARTICLE 1, POINT 5 A (new)
Article 7, paragraph 4 a (new) (Regulation (EC) No 999/2001)

(5a) In Article 7, the following paragraph 4a is inserted:

"4a. Based on a favourable risk assessment taking into account at least

the amount and possible source of contamination and the final destination of the consignment, a decision may be taken to introduce a tolerance level for insignificant amounts of animal proteins in feedingstuffs caused through adventitious contamination."

Justification

A legal base for defining tolerance levels for adventous cross-contamination of feeding stuff with animal proteins should be introduced.

Amendment 21

ARTICLE 1, POINT 5 B (new)

Article 7, paragraph 5 (Regulation (EC) No 999/2001)

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

"5. Rules for the implementation of this Article, in particular rules on the prevention of cross-contamination and on the methods of sampling and analysis required to check compliance with this Article, shall be adopted in accordance with the procedure referred to in Article 24(2). Those rules shall be based on a report of the Commission covering sourcing, processing, control and traceability of feedingstuffs of animal origin."

Justification

Changes to the existing feeding ban of animal proteins to non-ruminants shall be based on a report of the Commission taking particularly into account the control systems in place, the production methods, traceability systems and all the requirements set out in Regulation 1774/2002.

Amendment 22

ARTICLE 1, POINT 6

Article 8, paragraphs 1 to 3 (Regulation (EC) No 999/2001)

1. The specified risk material shall be removed and disposed of in accordance with Annex V to this Regulation and

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 rod shaped 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.

Regulation (EC) No 1774/2002. It shall not be imported into the Community. ***The list of specified risk material referred to in Annex V shall include at least the brain, spinal cord, eyes and tonsils of bovine animals of all ages and the vertebral column above an age to be determined in accordance with the procedure referred to in Article 24 (2). Taking into account the different risk categories laid down in Article 5(-1) and the requirements of Article 6(1a) and (1b) (b), the list of specified risk material in Annex V shall be amended accordingly.***

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, ***with a controlled or undetermined BSE risk***, the laceration, after stunning, of central nervous tissue by means of an elongated rod shaped 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.

Justification

This amendment sets a minimum list of SRMs which shall be removed before giving bovine animals into the food chain, it also contains a necessary modification of the Commission's proposal from December 2004 which was presented before the concrete names of the new BSE-risk categories have been agreed on the OIE'S General Assembly in May 2005.

Amendment 23 ARTICLE 1, POINT 6 A (new)

(6a) In Article 8, paragraph 4 shall be replaced by the following:

"4. The data relating to age set out in Annex V can be adjusted. Such adjustments shall be based on the latest proven scientific findings concerning the statistical probability of the occurrence of a TSE in the relevant age groups of the Community's bovine, ovine and caprine population."

Justification

See justification to the amendment on Article 8, paragraphs 1 to 3.

Amendment 24

ARTICLE 1, POINT 7

Article 8, paragraph 5 (Regulation (EC) No 999/2001)

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. '

5. ***In specific cases, exemptions*** from paragraphs 1 to 4 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 ***controlled*** BSE risk, the date of the effective enforcement of the ban of mammalian protein in feed for ruminants with a view to limiting ***individual requirements*** to remove and destroy specified risk material to animals born before that date in those countries or regions.

Justification

This amendment is a necessary modification of the Commission's proposal from December 2004 which was presented before the concrete names of the new BSE-risk categories have been agreed on the OIE'S General Assembly in May 2005. It also limits the scope of exemptions provided for in this paragraph.

Amendment 25

ARTICLE 1, POINT 8

Article 9, paragraph 2 (Regulation (EC) No 999/2001)

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.

2. Bones of bovine, ovine and caprine animals from countries or regions with a controlled or undetermined BSE risk, and bones of the head, and vertebral columns of bovine, ovine and caprine animals from countries, or regions thereof, with a negligible BSE risk shall not be used for the production of mechanically separated meat (MSM). Before 1 July 2009, the Member States shall submit a report to the Commission on the use and the production method of MSM in their territory. This report shall include a statement as to whether the Member State intends to continue with the production of MSM. The Commission shall thereupon present a communication to the European Parliament and the Council on the future necessity and use of MSM in the European Union, including the information policy towards consumers.

Justification

Currently the use of bones from bovine, ovine and caprine animals is prohibited for the production of mechanically separated meat. (Safeguard measure in Annex XI Nr.3 based on Articles 22 and 23). This measure is appropriate and shall be taken over into the legislative part as it is not possible to determine from which part of the animal MSM is gained. Overall, it should be looked closely at the use of MSM and further discussion is needed.

Amendment 26

ARTICLE 1, POINT 10 (B) a (new)

Article 13, paragraph 1, subparagraph 1 a (new) (Regulation (EC) No 999/2001)

(ba) the following subparagraph shall be added after the first subparagraph:

"On the request of a Member State and based on a favourable risk assessment taking particularly into account the control measures in that Member State, a decision may be taken in accordance with Article 24 (2) to allow the use of bovine animals referred to in this paragraph until the end of their productive life."

Justification

There is no scientific evidence that BSE can be transmitted via milk or from bovine animals to its calves. Therefore, a provision should be included to allow the use of so called cohort animals until the end of their productive life if certain criteria are fulfilled.

Amendment 27

ARTICLE 1, POINT 11

Article 15, paragraph 3 (Regulation (EC) No 999/2001)

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.

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
- rules for implementing this Article may be adopted.

Amendment 28

ARTICLE 1, POINT 12 (B)

Article 16, paragraph 2 (Regulation (EC) No 999/2001)

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).

2. Products of animal origin imported from a third country with a **controlled or undetermined** 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).

Justification

This amendment is a necessary modification of the Commission's proposal from December 2004 which was presented before the concrete terms of the new BSE-risk categories have been agreed upon at the OIE's General Assembly in May 2005.

Amendment 29

ARTICLE 1, POINT 12 (B)

Article 16, paragraph 3 (Regulation (EC) No 999/2001)

3. **Further conditions applicable to the**

3. Products of animal origin **containing**

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).

material obtained from bovine animals originating in a Member State, a region of a Member State or a third country with an undetermined BSE risk shall not be placed on the market unless they come from:

(a) animals born eight years after the date from which the prohibition on the feeding to ruminants of animal protein derived from mammals was effectively enforced;

or

(b) animals which were born, raised and have stayed in herds with a certified history of freedom from BSE for at least seven years.

Furthermore, products of animal origin shall not be despatched from a Member State or a region of a Member State with an undetermined BSE risk to another Member State or be imported from a third country with an undetermined BSE risk.

This prohibition shall not apply to products of animal origin listed in Annex VIII, Chapter C, and fulfilling the requirements of Annex VIII, Chapter C. They must be accompanied by an animal health certificate issued by an official veterinarian certifying that they have been produced in conformity with this Regulation.

Justification

The reduction of BSE risk categories leads to problems with the existing provisions. In this case the Commission proposes to replace the existing principle (import ban of animal products containing materials from bovine animals) by a far more general provision making just reference to the import conditions. This is acceptable as a result of the fewer and therefore less defined categories. Notwithstanding the principle import ban of those products from countries falling into the highest risk category shall be maintained together with the possibility to grant derogations

Amendment 30
ARTICLE 1, POINT 13
Article 21 (Regulation (EC) No 999/2001)

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

"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)."

Amendment 31
ARTICLE 1, POINT 14 A (new)
Article 24, paragraph 1 (Regulation (EC) No 999/2001)

(14a) In Article 24, paragraph 1 shall be replaced by the following:

"1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health. However, for matters exclusively concerning zootechnics, the Standing Committee on Zootechnics shall be consulted by the Commission."

Justification

Amendment 32

ARTICLE 1, POINT 14 B (new)

Article 24 a (new) (Regulation (EC) No 999/2001)

(14b) The following Article 24a shall be inserted:

"Article 24a

Decisions to be adopted in accordance with the procedure set out in Article 24 (2), referred to in Article 5(2), first and third subparagraphs, Article 6(1), (1a), (1b) (a) and (b) and (3), Article 7(2), (3), (4), (4a) and (5), Article 8(1), (4), (5) and (6), Article 9(1), Article 12(1), second subparagraph, Article 13(1), subparagraph 1a, and (6), and Article 15(3), shall be based on an assessment of the possible risks for human and animal health and shall, taking into account existing scientific evidence, maintain, or if scientifically justified increase, the level of protection of human and animal health ensured in the Community."

Justification

This amendment shall ensure that crucial aspects of this Regulation can only be changed by the Commission and Member States in the comitology procedure if a justification is given that a reduction of the level of human and animal health is excluded. At the bottom line the amendment declares certain provisions of the Regulation as particularly sensitive and wants to sensibilise the regulators not to focus in an inappropriate manner on economic aspects.

EXPLANATORY STATEMENT

The Commission's proposal from December 2004 initially had two main objectives:

1. To prolong the transitional measures based on this regulation for another two years. The first prolongation was decided by Parliament and Council in 2003. Otherwise, these transitional measures would have expired on 1 July 2005 without the finalisation of the categorisation of countries according to this regulation by the Commission.
2. To make certain amendments to this regulation with regard to the expected adoption of a new BSE-chapter of the OIE animal health codex (OIE - World organisation for animal health, 167 Member States). This new chapter would reduce the BSE risk categories from five to three.

At the time of the first discussions on the proposal in early 2005 it was not foreseeable if the OIE would in fact eventually find an agreement on a new BSE-chapter. It was also unclear if the reduction of BSE risk categories would be accompanied by the adoption of a new chapter on surveillance of the OIE-codex which provides strict and coherent active and passive surveillance measures in order to get a clear picture of the TSE-situation in a Member State or third country.

The rapporteur proposed to split the proposal in such a way that the necessary prolongation of the transitional measures could be adopted in June 2005 in a first reading agreement with Council. The rest of the proposal kept pending for discussions in Parliaments first reading in order to allow a profound discussion on potential changes. To facilitate these discussions, the rapporteur asked the Commission to present its views and perspective for the future fight against TSE/ BSE. The reason for this was that many changes on the TSE-regulation have been adopted in the last years in form of comitology decisions what lead to a patchwork of measures giving no clear picture of the overall strategy on this important issue.

The Commission followed this proposal and presented in July 2005 a "roadmap on the future fight against TSE". This comprehensive paper was very much appreciated from all stakeholders, Parliament and Council and gives a clear view on what the Commission intends to do in the coming years on TSE. The roadmap, which is not necessary identical with the issues addressed in the Commissions proposal for changing this regulation, was also basis for discussions during a Roundtable on BSE/TSE organised by the rapporteur in the European Parliament on 22 and 23 September 2005 with participation of all Chief Veterinary Officers from the 25 Member States as well as Commission and Council General Secretariat. The roadmap was also presented during a stakeholder meeting in the European Commission in November 2005 and subsequently discussed on this occasion with the rapporteur. Many other exchanges of views with the British and Austrian Presidencies, scientists or practioners gave a clear picture on what changes are reasonable and necessary.

The rapporteur agrees with some of the changes in the proposal. Particularly the most important issue, the reduction of the BSE-risk categories, is acceptable as an internationally agreed scheme for BSE/ TSE-measures is needed and finally, after years of discussions, could be agreed on OIE-level. Thus, it will be possible in the future to get a picture of TSE-

prevalence from countries for which currently no data is available. The changes naturally lead much less defined categories; this is why the most important provisions of the regulation should be ring fenced to ensure a certain standard. This applies e.g. for active and passive TSE monitoring measures or for minimum standards on the list of specified risk material.

The following are the main points raised by the amendments:

1. Adaptation of the legislative text on the new BSE Chapter of the OIE's animal health codex as agreed in May 2005.
2. Defining strict passive and active surveillance standards in the articles of the regulation in order to ensure that the reduction of categories does not lead to fewer or inaccurate information on the epidemiological situation in a country. This is a very important point as the consumers can only be protected appropriate if reliable data on the actual situation in the different countries and regions are available. A provision is proposed to allow Member States with a very positive TSE-prevalence to apply a more flexible testing scheme if this is based on the highest scientific standards.
3. The conviction that the respect of the natural living and nutrition conditions of farmed animals is key to protect human and animal health is widespread amongst regulators and consumers. The TSE-regulation shall reflect this as the BSE-crisis was largely contributing to this new approach.
A provision shall be introduced to allow the Commission to set - if necessary - tolerance levels for the presence of minimal sources of animal proteins caused through adventous contamination in feeding stuff.
4. Setting up a minimal list of Specified Risk Materials (SRM). The removal of SRM (Specified risk material) is one of the most important and effective measures against TSEs. A positive TSE/BSE prevalence makes changes to list of SRMs according to the scientific progress necessary. The list can, therefore, not be static. Amendments like the recent lift of the age from which the vertebral column has to be removed will be necessary in future.
5. Changes to the culling policy compared to the current situation. During many discussions it became clear that the strict culling of cohort animals is not always justified. As long as it is assured that those animals do not reach the food chain, the provision in Article 13 shall open the possibility for using those cohort animals until the end of their productive life.
6. The scope of comitology authorisations granted by this regulation was already a major issue during the negotiations between the institutions when adopting the regulation in 2000/2001. Since then the Commission together with the Member States piecewise adopted a complex list of modifications, often without Parliament really being in the position to pay due attention to those changes. As comitology decisions often have a considerable political impact, a new article 24a shall list the most sensible comitology authorisations of the regulation and oblige the regulators to profoundly justify that the level of animal or human health will in no circumstances be reduced when proposing future changes.