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

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

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[(1)],

Having regard to the opinion of the Economic and Social Committee[(2)],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

Whereas:

(1) Several distinct transmissible spongiform encephalopathies (TSEs) have for a number of years been recognised as occurring separately in humans and animals. Bovine spongiform encephalopathy (BSE) was first recognised in bovine animals in 1986 and in the following years was recognised as occurring in other species of animal. A new variant of Creutzfeldt-Jakob Disease (CJD) was described in 1996. Evidence continues to grow of the similarity between the BSE agent and that of the new variant of Creutzfeld-Jakob Disease.

(2) Since 1990 the Community has adopted a series of measures to protect human and animal health from the risk of BSE. Those measures have been based on the safeguard provisions of Directives on animal-health measures. It is appropriate, in view of the magnitude of the risk posed to human and animal health by certain TSEs, to adopt specific rules for their prevention, control and eradication.

(3) This Regulation directly concerns public health and is relevant to the functioning of the internal market. It covers products which are included in Annex I to the Treaty as well as products which are not. Consequently, it is appropriate to choose Article 152(4)(b) of the Treaty as the legal basis.

(4) The Commission has obtained scientific opinions, in particular from the Scientific Steering Committee and the Scientific Committee on Veterinary Measures relating to Public Health, on several aspects of TSEs. Those opinions include advice on measures

to reduce the potential risk for humans and animals resulting from exposure to infected animal products.

(5) These rules should apply to the production and placing on the market of live animals and products of animal origin. However, it is not necessary for them to apply to cosmetic or medicinal products, medical devices or their starting materials or intermediate products, for which other specific rules, in particular on the non-use of specified risk material, apply. Nor should they apply to products of animal origin which do not pose a risk to animal or human health since they are intended for purposes other than the production of food, feed or fertiliser. It is appropriate to ensure that products of animal origin excluded from the scope of this Regulation are kept separate from those covered by it unless they meet at least the same health standards as the latter.

(6) Provision should be made for safeguard measures to be taken by the Commission in cases where a risk from a TSE has not been adequately addressed by the competent authority of a Member State or third country.

(7) A procedure should be established for the determination of the epidemiological status of a Member State, a third country and of one of their regions, hereinafter referred to as 'countries or regions' with respect to BSE, on the basis of the incident propagation and human exposure risk, using information available. Member States and third countries which choose not to apply for their status to be determined should be classified in a category by the Commission on the basis of all the information available to it.

(8) Member States should institute education programmes for those involved in the prevention and control of TSEs, as well as for veterinarians, farmers and workers involved in the transportation, marketing and slaughter of farm animals.

(9) Member States should carry out an annual programme for monitoring BSE and scrapie and should inform the Commission and the other Member States of the results and of the emergence of any other TSE.

(10) Certain ruminant tissues should be designated as specified risk material on the basis of the pathogenesis of TSEs and the epidemiological status of the country or region of origin or residence of the animal concerned. The specified risk material should be removed and disposed of in a manner which avoids any risk to human or animal health. In particular, it should not be placed on the market to be used in the production of food, feed or fertiliser. However, provision should be made for an equivalent level of health protection by means of a screening test for TSEs carried out on individual animals as soon as it has been fully validated. Slaughter techniques presenting a risk of causing brain material to contaminate other tissues should not be permitted in countries or regions other than those presenting the lowest risk of BSE.

(11) Measures should be taken to prevent the transmission of TSEs to humans or animals by prohibiting the feeding of certain categories of animal protein to certain categories of animal, and by prohibiting the use of certain ruminant materials in food. Those prohibitions should be proportionate to the risks involved.

(12) The suspected presence of any TSE in any animal should be notified to the competent authority, which should immediately take all appropriate measures, including placing

the suspect animal under movement restrictions while awaiting the results of the investigation or having it slaughtered under official supervision. If the competent authority cannot exclude the possibility of a TSE, it should have the appropriate investigations carried out and should keep the carcasse under official supervision until a diagnosis has been made.

(13) In the event of official confirmation of the presence of a TSE, the competent authority should take all the necessary measures, including having the carcasse destroyed, carrying out an investigation in order to identify all animals at risk and placing movement restrictions on the animals and the products of animal origin identified as such. Owners should be compensated, as soon as possible, for the loss of animals and products of animal origin destroyed pursuant to this Regulation.

(14) Member States should draw up contingency plans for the national measures to be implemented in the event of an outbreak of BSE. Those plans should be approved by the Commission. Provision should be made for extending this provision to TSEs other than BSE.

(15) Provisions should be laid down covering the placing on the market of certain live animals and products of animal origin. Existing Community rules on the identification and registration of bovine animals provide for a system enabling the animals to be traced back to the dam and herd of origin in accordance with international standards. Equivalent guarantees should be provided for bovine animals imported from third countries. The animals and products of animal origin covered by Community rules, moving in intra-Community trade or imported from third countries, should be accompanied by the certificates required by the said rules, supplemented as appropriate in accordance with this Regulation.

(16) The placing on the market of certain products of animal origin derived from bovine animals in high risk regions should be prohibited. However, that prohibition should not apply to certain products of animal origin produced under controlled conditions from animals which can be demonstrated not to pose a high risk of infection with a TSE.

(17) It is necessary, in order to ensure that the rules concerning the prevention, control and eradication of TSEs are observed, for samples to be taken for laboratory testing on the basis of an established protocol which would give a full epidemiological picture of the situation as regards TSE. In order to guarantee uniform testing procedures and results, national and Community Reference Laboratories and reliable scientific methods, including rapid tests specifically for TSEs, should be established. Rapid tests should be used as far as possible.

(18) Community inspections should be carried out in the Member States in order to ensure uniform implementation of the requirements concerning the prevention, control and eradication of TSEs and provision should also be made for the implementation of audit procedures. In order to ensure that guarantees equivalent to those applied by the Community are provided by third countries upon import into the Community of live animals and products of animal origin, Community on-the-spot inspections and audits should be carried out in order to verify that the import conditions are met by exporting third countries.

(19) Trade measures for TSEs should be based on international standards, guidelines or recommendations, where they exist. However, scientifically justified measures resulting in a higher level of health protection may be adopted if measures based on the relevant international standards, guidelines or recommendations would not achieve the appropriate level of health protection.

(20) This Regulation should be re-examined as new scientific information becomes available.

(21) The necessary transitional measures in particular for regulating the use of specified risk material should be provided for in the framework of this Regulation.

(22) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedure for the exercise of implementing powers conferred on the Commission[(4)].

(23) In order to implement this Regulation, procedures should be laid down establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee, the Standing Committee on Feedingstuffs, and the Standing Committee on Foodstuffs.

(24) Given that the provisions for the implementation of this Regulation are general measures within the meaning of Article 2 of Decision 1999/468/EC, they should be adopted in accordance with the regulatory procedure laid down in Article 5 of that Decision,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1 This Regulation lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It shall apply to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

2 This Regulation shall not apply to:

a cosmetic or medicinal products or medical devices, or to their starting materials or intermediate products;

b products which are not intended for use in human food, animal feed or fertilisers, or to their starting materials or intermediate products;

c products of animal origin intended for exhibition, teaching, scientific research, special studies or analysis, provided those products are not eventually consumed or used by humans or by animals other than those kept for the research projects concerned;

d live animals used in or intended for research.

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

Article 2

Separation of live animals and of products of animal origin

In order to avoid cross-contamination or substitution between the live animals or of the products of animal origin referred to in Article 1(1) and the products of animal origin referred to in Article 1(2)(a), (b) and (c), or the live animals referred to in Article 1(2)(d), they shall be kept separate at all times unless such live animals or products of animal origin are produced under at least the same conditions of health protection in respect of TSEs.

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

Article 3

Definitions

1 For the purposes of this Regulation the following definitions shall apply:

a TSEs: all transmissible spongiform encephalopathies with the exception of those occurring in humans;

b placing on the market: any operation the purpose of which is to sell live animals or products of animal origin covered by this Regulation to a third party in the Community, or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;

c products of animal origin: any product derived from or containing a product derived from any animal covered by the provisions of Directive 89/662/EEC[(5)] or Directive 90/425/EEC[(6)];

d starting materials: raw materials or any other product of animal origin out of which, or with the help of which, the products referred to in Article 1(2)(a) and (b) are produced;

e competent authority: the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that central authority has delegated that competence, in particular for the control of feedingstuffs; it shall also include, where appropriate, the corresponding authority of a third country;

f category: one of the classification categories referred to in Chapter C of Annex II;

g specified risk material: the tissues specified in Annex V; unless otherwise indicated, it does not include products containing or derived from those tissues;

h animal suspected of being infected by a TSE: live, slaughtered or dead animals, which show or have shown neurological or behavioural disorders or a progressive deterioration of the general condition linked to impairment of the central nervous system and for which the information gathered on the basis of a clinical examination, response to treatment, a post-mortem examination or an ante or post-mortem laboratory analysis do not allow an alternative diagnosis to be established. Bovine spongiform encephalopathies (BSE) shall be suspected in bovine animals which have produced a positive result from a rapid test specifically for BSE;

i holding: any place in which animals covered by this Regulation are held, kept, bred, handled or shown to the public;

j sampling: the taking of samples, ensuring a statistically correct representation, from animals or their environment, or from products of animal origin, for the purpose of establishing a disease diagnosis, familial relationships, for health surveillance, or for the monitoring of the absence of microbiological agents or of certain materials in products of animal origin;

k fertilisers: any substance containing products of animal origin utilised on land to enhance growth of vegetation; it may include digestion residues from bio-gas production or composting;

l rapid tests: the analysis methods referred to in Annex X, Chapter C, point 4, and for which the results are known within 24 hours;

m alternative test: the tests referred to in Article 8(2) which are used as an alternative to the withdrawal of specified risk material.

2 The specific definitions set out in Annex I shall also apply.

3 Where the terms in this Regulation are not defined in paragraph 1 or Annex I, the relevant definitions given in Regulation (EC) No 1760/2000[7] and those given in or pursuant to Directives 64/432/EEC[8], 89/662/EEC, 90/425/EEC and 91/68/EEC[9] shall apply insofar as reference is made to them in this text.

Article 4

Safeguard measures

1 With regard to the implementation of safeguard measures, the principles and provisions set out in Article 9 of Directive 89/662/EEC, Article 10 of Directive 90/425/EEC, Article 18 of Directive 91/496/EEC[10] and Article 22 of Directive 97/78/EC[11] shall apply.

2 The safeguard measures shall be adopted in accordance with the procedure referred to in Article 24(2) and shall be notified at the same time to the European Parliament, stating the reasons.

CHAPTER II

DETERMINATION OF BSE STATUS

Article 5

Classification

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, and 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.

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.

2 A decision on each application, placing the Member State or third country or region of the Member State or third country which submitted the application in one of the categories defined in Annex II, Chapter C, shall be adopted, taking account of the criteria and potential risk factors set out in paragraph 1, in accordance with the procedure referred to in Article 24(2).

This decision shall be taken within six months of the submission of the application and of the relevant information referred to in the second subparagraph of paragraph 1. If the Commission finds that the supporting evidence does not include the information laid down in Annex II, Chapters A and B, it shall ask for additional information to be provided within a period to be specified. The final decision shall then be taken within six months of the submission of all information.

After the International Office of Epizootic Diseases (OIE) has established a procedure for the classification of countries by category and if it has placed the applicant country in one of those categories, a re-assessment of the Community categorisation of the country concerned in accordance with the first subparagraph of this paragraph may be decided, if appropriate, in accordance with the procedure referred to in Article 24(2).

3 If the Commission finds that the information submitted by a Member State or a third country pursuant to Annex II, Chapters A and B, is insufficient or unclear, it may, in accordance with the procedure referred to in Article 24(2), determine the BSE status of the Member State or third country concerned on the basis of a full risk analysis.

Such a risk analysis must include a conclusive statistical survey of the epidemiological situation regarding TSEs in the applicant Member State or third country, on the basis of the use, in a screening procedure, of rapid tests. The Commission shall take into account the classification criteria used by the OIE.

The rapid tests shall be approved for that purpose in accordance with the procedure referred to in Article 24(2) and entered on a list set out in Annex X, Chapter C, point 4.

Such screening procedure may also be used by Member States or third countries which wish to have the classification they carried out on that basis approved by the Commission — in accordance with the procedure laid down in Article 24(2).

The cost of such screening procedure shall be borne by the Member State or third country concerned.

4 Member States or third countries which have not submitted an application in accordance with paragraph 1 within six months of 1 July 2001 shall, with respect to the dispatch from their territory of live animals and products of animal origin, be considered as countries in category 5, referred to in Annex II, Chapter C, until they have submitted such an application.

5 Member States shall notify the Commission as soon as possible of any epidemiological evidence or other information which might lead to a change in BSE status, in particular the results of the monitoring programmes provided for in Article 6.

6 The retention of a third country on one of the lists provided for by Community rules for the purpose of being allowed to export to the Community live animals and products of animal origin for which this Regulation provides specific rules shall be decided upon under the procedure laid down in Article 24(2) and shall be made conditional — in the light of the information available or where a TSE is presumed to be present — on the information provided for in paragraph 1 being supplied. In the event of refusal to supply the said information within three months of the date of the Commission's request, the provisions of paragraph 4 of this Article shall apply until this information has been submitted and evaluated in accordance with paragraphs 2 or 3.

The eligibility of third countries to export to the Community live animals, or products of animal origin for which this Regulation provides specific rules, under conditions based on their category as established by the Commission, shall be conditional upon their undertaking to notify the latter in writing as soon as possible of any epidemiological or other evidence which might lead to a change in BSE status.

7 A decision may be taken, under the procedure laid down in Article 24(2), to change the BSE classification of a Member State or third country, or of one of its regions, in accordance with the results of the checks provided for in Article 21.

8 The decisions referred to in paragraphs 2, 3, 4, 6 and 7 shall be based on a risk assessment, taking into consideration the recommended criteria set out in Annex II, Chapters A and B.

CHAPTER III

PREVENTION OF TSE

Article 6

Monitoring system

1 Each Member State shall carry out an annual programme for monitoring BSE and scrapie in accordance with Annex III, Chapter A. 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, Chapter C, point 4.

2 Each Member State shall inform the Commission and the other Member States, within the Standing Veterinary Committee, of the emergence of a TSE other than BSE.

3 All official investigations and laboratory examinations shall be recorded in accordance with Annex III, Chapter B.

4 Member States shall submit an annual report to the Commission covering at least the information referred to in Annex III, Chapter B, Part I. The report for each calendar year shall be submitted at the latest by 31 March of the following year. The Commission shall present a summary of the national reports covering at least the information referred to in Annex III, Chapter B, Part II, to the Standing Veterinary Committee within three months of the receipt of the said reports.

Article 7

Prohibitions concerning animal feeding

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

2 Furthermore, the prohibition referred to in paragraph 1 shall be extended to animals and products of animal origin in accordance with point 1 of Annex IV.

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

4 Member States, or regions thereof, in category 5 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, which contains processed protein derived from mammals.

Third countries, or regions thereof, in category 5 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 and cats, which contains processed protein derived from mammals.

5 Detailed 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).

Article 8

Specified risk material

1 The specified risk material shall be removed and destroyed in accordance with points 2, 3, 4 and 8 of Annex V.

That specified risk material or the material processed therefrom may be placed on the market or, if need be, exported only for final destruction in accordance with points 3 and 4 or as appropriate 7(c) or 8 of Annex V. It may not be imported into the Community. Transit of specified risk material through Community territory must take place in accordance with the requirements of Article 3 of Directive 91/496/EEC.

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) and listed in Annex X, Chapter C, point 5, and applied under the conditions listed in point 5 of Annex V — and where the results of the test were negative.

The Member States which authorise that alternative test must inform the other Member States and the Commission.

3 In Member States, or regions thereof, which are placed in categories 2, 3, 4 and 5 referred to in Annex II, Chapter C, the laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity shall not be used on bovine, ovine or caprine animals whose meat is destined for human or animal consumption.

4 The data relating to age set out in Annex V shall be adjusted regularly. 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.

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 effective enforcement of Article 7(1) or, as appropriate, in the third countries, the date of banning the use of mammalian protein in feed for ruminants in each country or region placed in category 3 or 4, in order to limit the application of this Article to animals born before that date in those countries or regions.

Similarly, by way of derogation from paragraphs 1 to 4, after consultation of the appropriate scientific committee and on the basis of an assessment of the incident, propagation and human exposure risk, a decision may be adopted in accordance with

the procedure referred to in Article 24(2) to allow the use for food, feed and fertilisers of vertebral column and dorsal root ganglia from bovine animals in or coming from each country or region thereof placed in category 5.

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

Article 9

Products of animal origin derived from or containing ruminant material

1 The products of animal origin listed in Annex VI shall not be produced from ruminant material from countries or regions thereof which are placed in category 5 unless they are produced in accordance with the 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, which are placed in categories 2, 3, 4 or 5, shall not be used for the production of mechanically recovered meat.

3 Paragraphs 1 and 2 shall not apply, in the light of the criteria set out in point 5 of Annex V, to ruminants which have undergone an alternative test which has been recognised in accordance with the procedure referred to in Article 24(2), where the results of the test were negative.

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

Article 10

Education programmes

1 Member States shall ensure that staff of the competent authority, of diagnostic laboratories and colleges of agriculture and veterinary medicine, official veterinarians, veterinary practitioners, slaughterhouse personnel and animal breeders, keepers and handlers have been given training in the clinical signs, epidemiology and, in the case of staff responsible for carrying out checks, in interpreting laboratory findings relating to TSEs.

2 To ensure effective implementation of the education programmes provided for in paragraph 1, financial assistance from the Community may be granted. The amount of such assistance shall be determined in accordance with the procedure referred to in Article 24(2).

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

CHAPTER IV

CONTROL AND ERADICATION OF TSEs

Article 11

Notification

Without prejudice to Directive 82/894/EEC[(12)], the Member States shall ensure that any animal suspected of being infected by a TSE is notified immediately to the competent authorities.

Member States shall regularly inform each other and the Commission of the cases of TSE notified.

The competent authority shall without delay take the measures laid down in Article 12 of this Regulation, together with any other necessary measures.

Article 12

Measures with respect to suspect animals

1 Any animal suspected of being infected by a TSE shall be 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 BSE is suspected in a bovine animal at a holding in a Member State, all other bovine animals from that holding shall be placed under an official movement restriction until the results of the examination are available.

If BSE is suspected in an ovine or caprine animal at a holding in a Member State on the basis of objective evidence such as the results of tests capable of differentiating in a practical way between the various TSEs, all other ovine and caprine animals from that holding shall be placed under an official movement restriction until the results of the examination are available.

If there is evidence that the holding where the animal was present when BSE was suspected is not likely to be the holding where the animal could have been exposed to BSE, 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 requirements of the second, third and fourth subparagraphs of this paragraph, a Member State may be exempted from the application of official restrictions on the movement of animals if it applies measures offering equivalent safeguards.

2 Where the competent authority decides that the possibility of infection with a TSE cannot be ruled out, the animal shall be killed, if it is still alive; its brain and all other tissues as the competent authority may determine shall be removed and sent to an officially approved laboratory, the national reference laboratory provided for in Article 19(1) or the Community

reference laboratory provided for in Article 19(2), for examination in accordance with the testing methods laid down in Article 20.

3 All parts of the body of the suspect animal including the hide shall be retained under official control until a negative diagnosis has been made or shall be destroyed in accordance with Annex V, point 3 or 4.

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

Article 13

Measures following confirmation of the presence of a TSE

1 When the presence of a TSE has been officially confirmed, the following measures shall be applied as soon as possible:

a all parts of the body of the animal shall be completely destroyed in accordance with Annex V apart from material retained for records in accordance with Annex III, Chapter B, III, 2;

b an inquiry shall be carried out to identify all animals at risk in accordance with Annex VII, point 1;

c all animals and products of animal origin referred to in Annex VII, point 2, that have been identified as being at risk by the inquiry referred to in (b), shall be killed and completely destroyed in accordance with Annex V, points 3 and 4.

By way of derogation from this paragraph, Member States may apply other measures offering an equivalent level of protection, if those measures have been approved in accordance with the procedure referred to in Article 24(2).

2 Pending the implementation of the measures referred to in paragraph 1(b) and (c), the holding on which the animal was present when the presence of a TSE was confirmed shall be placed under official control and all movement of animals susceptible to TSEs and products of animal origin derived from them from or to the holding shall be subject to authorisation by the competent authority, with a view to ensuring immediate tracing and identification of the animals and products of animal origin concerned.

If there is evidence that the holding where the affected animal was present when the TSE was confirmed is not likely to be the holding where the animal was exposed to the TSE, the competent authority may decide that both holdings or only the holding of exposure shall be placed under official control.

3 Member States which have implemented a substitute scheme offering equivalent safeguards provided for in the fifth subparagraph of Article 12(1) may, by way of derogation from the requirements of paragraph 1(b) and (c), be exempted in accordance with the procedure referred to in Article 24(2) from the requirement to apply official restrictions on the movement of animals and from the requirement to kill and destroy animals.

4 Owners shall be compensated without delay for the loss of the animals that have been killed or products of animal origin destroyed in accordance with Article 12(2) and paragraph 1(a) and (c) of this Article.

5 Without prejudice to Directive 82/894/EEC, the confirmed presence of any TSE other than BSE shall be notified to the Commission on an annual basis.

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

Article 14

Contingency plan

1 Member States shall draw up — in accordance with the general criteria of Community rules on the control of animal diseases — guidelines specifying the national measures to be implemented and indicating competences and responsibilities where cases of TSE are confirmed.

2 Where necessary to enable Community legislation to be applied uniformly, the guidelines may be harmonised in accordance with the procedure referred to in Article 24(2).

CHAPTER V

PLACING ON THE MARKET AND EXPORT

Article 15

Live animals, their semen, embryos and ova

1 Placing on the market or, if need be, export of bovine, ovine or caprine animals and their semen, embryos and ova shall be subject to the conditions laid down in Annex VIII, or, in the case of imports, to the conditions laid down in Annex IX. The live animals and their embryos and ova shall be accompanied by the appropriate animal health certificates as required by Community legislation, in accordance with Article 17 or, in the case of imports, Article 18.

2 The placing on the market of first generation progeny, semen, embryos and ova of TSE suspect or confirmed animals shall be subject to the conditions laid down in Annex VIII, Chapter B.

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

Article 16

Placing on the market of products of animal origin

1 The following products of animal origin derived from healthy ruminants shall not be subject to restrictions on placing on the market or, if need be, export pursuant to this Article, to Annex VIII, Chapters C and D, and to Annex IX, Chapters A, C, F and G:

a products of animal origin covered by Article 15, in particular semen, embryos and ova;

b (i) raw milk within the meaning of Directive 92/46/EEC[13];

(ii) milk for the manufacture of milk-based products within the meaning of Directive 92/46/EEC;

(iii) heat-treated drinking milk within the meaning of Directive 92/46/EEC;

(iv) di-calcium phosphate (without any trace of protein or fat);

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(v) hides and skins within the meaning of Directive 92/118/EEC[(14)];

(vi) gelatine within the meaning of Directive 92/118/EEC, derived from the hides and skins referred to in point (v);

(vii) collagen derived from the hides and skins referred to in point (v).

2 Products of animal origin imported from a third country placed in categories 2, 3, 4 and 5 must come from healthy bovine, ovine and caprine animals which have not been subjected to a laceration of the central nervous tissue as referred to in Article 8(3) or killed by means of a gas injected into the cranial cavity.

3 Products of animal origin containing materials obtained from bovine animals originating in a Member State, a region of a Member State or a third country classified in category 5 shall not be placed on the market unless they come from:

a animals born 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 classified in category 5 to another Member State or be imported from a third country classified in category 5. That 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.

4 When an animal is moved from a country or a region to country or region included in another category, it shall be classified in the highest category of the countries or regions in which it has stayed over twenty-four hours unless adequate guarantees can be provided certifying that the animal has not received feedingstuffs from the country or region classified in the highest category.

5 Products of animal origin for which this Article lays down specific rules shall be accompanied by the appropriate animal health certificates or commercial documents as required by Community legislation in accordance with Articles 17 and 18 or, if such certificates or documents are not provided for in Community legislation, by a health certificate or commercial document the specimens of which shall be established in accordance with the procedure referred to in Article 24(2).

6 For the purpose of import into the Community, products of animal origin shall comply with the conditions laid down in Annex IX, Chapters A, C, F and G.

7 In accordance with the procedure referred to in Article 24(2), the provisions of paragraphs 1 to 6 may be extended to other products of animal origin. Rules for the implementation of this Article shall be adopted by the same procedure.

Article 17

Under the procedure referred to in Article 24(2), the health certificates referred to in Annex F to Directive 64/432/EEC, Models II and III in Annex E to Directive 91/68/EEC and the appropriate health certificates laid down by Community legislation relating to trade in the semen, embryos and ova of bovine, ovine or caprine animals

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shall be supplemented, where necessary, by a reference to the category specifying the classification of the Member State or region of origin given in accordance with Article 5.

Appropriate commercial documents relating to trade in products of animal origin shall be supplemented, where necessary, by a reference to the category of the Member State or region of origin given by the Commission in accordance with Article 5.

Article 18

The appropriate health certificates relating to imports provided for by Community legislation shall, under the procedure referred to in Article 24(2), be supplemented in respect of third countries classified in a category pursuant to Article 5 by the specific requirements laid down in Annex IX, as soon as that classification decision has been taken.

CHAPTER VI

REFERENCE LABORATORIES, SAMPLING, TESTING AND CONTROLS

Article 19

Reference laboratories

1 The national reference laboratories in each Member State and their functions and duties shall be those indicated in Annex X, Chapter A.

2 The Community reference laboratory and its functions and duties shall be those laid down in Annex X, Chapter B.

Article 20

Sampling and laboratory methods

1 Sampling and laboratory testing for the presence of a TSE shall be carried out using the methods and protocols laid down in Annex X, Chapter C.

2 Where necessary to ensure the uniform application of this Article, implementing rules, including the method to confirm BSE in ovine and caprine animals, shall be adopted in accordance with the procedure referred to in Article 24(2).

Article 21

Community controls

1 Experts from the Commission may make on-the-spot checks in cooperation 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 checks are made 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 the checks made.

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

The rules for the application of this Article, and in particular those governing the procedure for cooperation with the national authorities, shall be adopted in accordance with the procedure referred to in Article 24(2).

2 Community checks concerning third countries shall be made in accordance with Articles 20 and 21 of Directive 97/78/EC.

CHAPTER VII

TRANSITIONAL AND FINAL PROVISIONS

Article 22

Transitional measures concerning specified risk material

1 The provisions of Annex XI, Part A shall apply for a period of at least six months from 1 July 2001 and shall cease to apply immediately following the date of adoption of a decision in accordance with Article 5(2) or (4), on which date Article 8 shall enter into force.

2 The results of a conclusive statistical survey carried out in accordance with Article 5(3) during the transitional period shall be used to confirm or overturn the risk analysis conclusions referred to in Article 5(1), while taking account of the classification criteria defined by the OIE.

3 After consultation of the appropriate scientific committee, detailed rules concerning that statistical survey shall be adopted in accordance with the procedure referred to in Article 24(2).

4 The minimum criteria to be met by this statistical survey shall be those laid down in Part B of Annex XI.

Article 23

Amendment of the annexes and transitional measures

After consultation of the appropriate scientific committee on any question which could have an impact on public health, the annexes shall be amended or supplemented and any appropriate transitional measures shall be adopted in accordance with the procedure referred to in Article 24(2).

[[F1]In accordance with that procedure, transitional measures shall be adopted for a period ending on 1 July 2005 at the latest, to permit the changeover from the current arrangements to the arrangements established by this Regulation.**]**

Textual Amendments

F1 Substituted by 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.

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

Article 24

Committees

1 The Commission shall be assisted by the Standing Veterinary Committee. However, for matters exclusively concerning animal feedingstuffs, the Commission shall be assisted by the Standing Committee on Feedingstuffs and, for matters exclusively concerning foodstuffs, by the Standing Committee on Foodstuffs.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, in compliance with Article 8 thereof.

The period referred to in Article 5(6) of that Decision shall be three months and, in the case of safeguard measures referred to in Article 4(2) of this Regulation, 15 days.

3 Each Committee shall adopt its rules of procedure.

Article 25

Consultation of the scientific committees

The appropriate scientific committees shall be consulted on any matter within the scope of this Regulation which could have an impact on public health.

Article 26

Entry into force

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Communities*.

It shall apply from 1 July 2001.

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

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

[F2 ANNEX I

SPECIFIC DEFINITIONS

Textual Amendments

F2 Substituted by Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (Text with EEA relevance).

1. For the purpose of this Regulation, the following definitions set out in Regulation (EC) No 1774/2002 of the European Parliament and of the Council[15], Regulation (EC) No 178/2002 of the European Parliament and of the Council[16] and Council Directive 79/373/EEC[17] shall apply:

(a) Regulation (EC) No 1774/2002:

(i) 'farmed animal' in Article 2(1)(f);

(ii) 'petfood' in point 41 of Annex I;

(iii) 'processed animal protein' in point 42 of Annex I;

(iv) 'gelatine' in point 26 of Annex I;

(v) 'blood products' in point 4 of Annex I;

(vi) 'bloodmeal' in point 6 of Annex I; and

(vii) 'fishmeal' in point 24 of Annex I.

(b) the definition of 'feedingstuff' in Article 3(4) of Regulation (EC) No 178/2002;

(c) the definition of 'complete feedingstuff' in Article 2(d) of Directive 79/373/EEC.

[F3 2. For the purpose of this Regulation, the following

(a) 'indigenous case of BSE' means a case of bovine spongiform encephalopathy which has not been clearly demonstrated to be due to infection prior to importation as a live animal;

(b) 'discrete adipose tissue' means internal and external body fat removed during the slaughter and cutting process, in particular fresh fat from the heart, caul and kidney of bovine animals, and fat from cutting rooms;

(c) 'cohort' means a group of bovine animals which includes both:

(i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal; and

(ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life;

(d) 'index case' means the first animal on a holding, or in an epidemiologically defined group, in which a TSE infection is confirmed.]]

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

Textual Amendments

F3 Substituted by Commission Regulation (EC) No 1492/2004 of 23 August 2004 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in bovine, ovine and caprine animals, the trade and importation of semen and embryos of ovine and caprine animals and specified risk material (Text with EEA relevance).

ANNEX II

DETERMINATION OF BSE STATUS

CHAPTER A

The BSE status of a Member State or a third country or of one of their regions, hereinafter referred to as 'country or region', shall be determined on the basis of the following criteria:

(a) the outcome of a risk analysis identifying all the potential factors for the appearance of BSE referred to in Chapter B and their development over time;

(b) an education programme for veterinarians, breeders and those who transport, trade in and slaughter bovine animals, which seeks to encourage them to report all cases of neurological manifestations in adult bovine animals;

(c) the compulsory reporting and examination of all bovine animals showing clinical signs of BSE;

(d) a system of continuous surveillance and monitoring of BSE with particular reference to the risks described in Chapter B, taking account of the guidelines in the table of Chapter A of Annex III or in accordance with the appropriate international standards; reports on the number of examinations carried out and the results thereof must be kept for at least seven years;

(e) the examination in an approved laboratory of samples of encephala or other tissues collected under the surveillance system mentioned in point (d).

CHAPTER B

The risk analysis referred to in Chapter A(a) shall be based on the following factors:

— the consumption by bovine animals of meat and bone meal or greaves derived from ruminants;
— the importation of meat and bone meal or greaves potentially contaminated by a TSE or animal feed containing meat and bone meal or greaves;
— the importation of animals or ova/embryos potentially infected by a TSE;
— the epidemiological status of the country or region in regard to animal TSEs;
— the extent of knowledge about the structure of the bovine, ovine and caprine population in the country or region;
— the source of animal waste, the parameters of the processes for treating such waste and the methods of producing animal feed.

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CHAPTER C

Definition of categories

The BSE status of Member States or third countries or one of the regions thereof shall be determined by classification into the following categories:

A. CATEGORY 1 : Country or region free of BSE

A country or region where a risk analysis based on the information laid down in Chapter B has been conducted which demonstrated that appropriate measures have been taken for the relevant period of time, to manage any risk identified and

1. EITHER no BSE case has been recorded and:

   (i) the criteria in Chapter A(b) to (e) have been complied with for at least seven years, or

   (ii) the criteria in Chapter A(c) have been complied with for at least seven years and it has been demonstrated that for at least eight years no meat and bone meal or greaves derived from ruminants or mammals has been fed to ruminants;

2. OR where all cases of BSE have been clearly demonstrated to originate directly from the importation of live bovine animals or bovine embryos/ova, and all the affected bovine animals as well as, if these are females, their last progeny born within two years prior to, or after, the first clinical signs of onset of the disease, if alive in the country or region, have been killed and completely destroyed and, either

   (i) the criteria in Chapter A(b) to (e) have been complied with for at least seven years, or

   (ii) the criteria in Chapter A(c) have been complied with for at least seven years and it has been demonstrated that for at least eight years no meat and bone meal or greaves have been fed to ruminants;

3. OR where the last indigenous case of BSE was reported more than seven years ago, the criteria in Chapter A(b) to (e) have been complied with for at least seven years and the feeding of ruminants with meat and bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced for at least eight years.

B. CATEGORY 2 : BSE provisionally free country or region where no indigenous case has been reported

Country or region where a risk analysis as described in Chapter B has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified, and

1. EITHER where there has been no case of BSE and:

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(i) the criteria in Chapter A(b) to (e) are complied with, but have not been complied with for seven years, or

(ii) it has been demonstrated that for at least eight years no meat and bone meal or greaves has been fed to ruminants, but the criteria in Chapter A(c) have not been complied with for seven years;

2. OR where all cases of BSE have been clearly demonstrated to originate directly from the importation of live bovine animals or bovine embryos/ova, and all the affected bovine animals as well as, if these are females, their last progeny born within two years prior to, or after, the first clinical signs of onset of the disease, if alive in the country or region, have been killed and completely destroyed, and either:

(i) the criteria in Chapter A(b) to (e) are complied with, but have not been complied with for seven years, or

(ii) it has been demonstrated that for at least eight years no meat and bone meal or greaves has been fed to ruminants, but the criteria in Chapter A(c) have not been complied with for seven years.

C. CATEGORY 3 : BSE provisionally free country or region where at least one indigenous case has been reported

Any country or region where a risk analysis based on the information referred to in Chapter B has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified and:

1. EITHER the last indigenous case of BSE was reported more than seven years ago, the criteria in Chapter A(b) to (e) are complied with and the ban on feeding ruminants with meat and bone meal and greaves derived from ruminants is effectively enforced, but:

(i) the criteria in Chapter A(b) to (e) have not been complied with for seven years, or

(ii) the ban on feeding ruminants with meat and bone meal and greaves derived from ruminants has not been effectively enforced for eight years;

2. OR where the last indigenous case has been reported less than seven years ago, the BSE incidence rate, calculated on the basis of indigenous cases, has been less than one case per million during each of the last four consecutive twelve-month periods within the bovine animal population over 24 months of age in the country or region or — when in a country or a region the bovine animal population over 24 months of age is less than 1 million animals — one case per real number of this population (calculated on the basis of Eurostat statistics), and where:

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(i) the ban on feeding ruminants with meat and bone meal and greaves derived from ruminants has been effectively enforced for at least eight years;

(ii) the criteria in Chapter A(b) to (e) have been complied with for at least seven years;

(iii) the affected bovine animals as well as:

— if these are females, their last progeny born within two years prior to, or after, clinical onset of the disease;

— all bovine animals from the cohort,

are killed and completely destroyed if they are still alive in the country or region concerned.

For this classification account may be taken, by way of derogation from point (iii), of the existence of other measures offering an equivalent level of protection in relation to the killing of animals at risk.

D. CATEGORY 4 : Country or region with low incidence of BSE

Any country or region where:

1. the criteria listed in Chapter A are complied with, and the BSE incidence rate, calculated over the past 12 months, has been greater than or equal to one indigenous case per million and less than or equal to one hundred cases per million within the bovine animal population over 24 months of age in the country or region; or

2. the criteria listed in Chapter A are complied with and the BSE incidence rate, calculated as specified in point 1 has been less than one indigenous case per million for less than four consecutive 12 month periods and the affected cattle as well as:

— if these are females, their last progeny born within two years prior to, or after the first clinical signs of onset of the disease,

— all bovine animals from the cohort,

if alive in the country or region, are killed and completely destroyed.

For this classification account may be taken, by way of derogation from this point, of the existence of other measures offering an equivalent level of protection in relation to the killing of animals at risk.

Countries or regions where the BSE incidence rate, calculated over the past 12 months, has been less than one indigenous case per million within the cattle population over 24 months of age in the country or region, but where a risk analysis as described in Chapter A has been conducted which

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demonstrates that at least one of the criteria enabling the country or region to be classified in category 2 or 3 is not complied with, must be regarded as countries or regions belonging to category 4.

E. CATEGORY 5 : Country or region with high incidence of BSE

Any country or region where:

1. the criteria listed in Chapter A are complied with, and the BSE incidence rate, calculated over the past 12 months, has been greater than one hundred cases per million within the bovine animal population over 24 months of age in the country or region; or

2. the BSE incidence rate, calculated over the past 12 months, has been greater than or equal to one case per million and less than or equal to one hundred cases per million within the bovine animal population over 24 months of age in the country or region, and at least one of the criteria listed in Chapter A is not complied with.

[F4 ANNEX III

MONITORING SYSTEM

Textual Amendments

F4 Substituted by Commission Regulation (EC) No 2245/2003 of 19 December 2003 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine and caprine animals.

CHAPTER A

I. MONITORING IN BOVINE ANIMALS

1. General

Monitoring in bovine animals shall be carried out in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3(1)(b).

2. Monitoring in animals slaughtered for human consumption

2.1. All bovine animals over 24 months of age:

— subject to ‘special emergency slaughtering’ as defined in Article 2(n) of Council Directive 64/433/EEC[18], or

— slaughtered in accordance with Annex I, Chapter VI, point 28(c), to Directive 64/433/EEC, except animals without clinical signs of disease slaughtered in the context of a disease eradication campaign,

shall be tested for BSE.

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2.2. All bovine animals over 30 months of age:

— subject to normal slaughter for human consumption, or

— slaughtered in the context of a disease eradication campaign in accordance with Annex I, Chapter VI, point 28(c), to Directive 64/433/EEC, but showing no clinical signs of disease,

shall be tested for BSE.

2.3. By way of derogation from point 2.2, and with regard to bovine animals born, reared and slaughtered on its territory, Sweden may decide to examine only a random sample. The sample shall comprise at least 10 000 animals per year.

3. Monitoring in animals not slaughtered for human consumption

3.1. All bovine animals over 24 months of age which have died or been killed but which were not:

— killed for destruction pursuant to Commission Regulation (EC) No 716/96[19],

— killed in the framework of an epidemic, such as foot-and-mouth disease,

— slaughtered for human consumption,

shall be tested for BSE.

3.2. Member States may decide to derogate from the provisions of point 3.1 in remote areas with a low animal density, where no collection of dead animals is organised. Member States making use of this derogation shall inform the Commission thereof, and submit a list of the derogated areas. The derogation shall not cover more than 10 % of the bovine population in the Member State.

4. Monitoring in animals purchased for destruction pursuant to Regulation (EC) No 716/96

4.1. All animals subject to casualty slaughter or found sick at ante mortem inspection shall be tested for BSE.

4.2. All animals over 42 months of age born after 1 August 1996 shall be tested for BSE.

4.3. A random sample comprising at least 10 000 animals annually of animals not covered by point 4.1 or 4.2 shall be tested for BSE.

5. Monitoring in other animals

In addition to the testing referred to in points 2 to 4, Member States may on a voluntary basis decide to test other bovine animals on their territory, in particular where those animals originate from countries with indigenous BSE, have consumed potentially contaminated feedingstuffs or were born or derived from BSE infected dams.

6. Measures following testing

6.1. Where an animal slaughtered for human consumption has been selected for testing for BSE, the health marking provided for in Chapter XI of Annex I to Directive 64/433/EEC shall not be carried out on the carcase of that animal until a negative result to the rapid test has been obtained.

6.2. Member States may derogate from the provisions of point 6.1 where an official system is in place in the slaughterhouse ensuring that no parts of examined animals bearing

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the health mark leave the slaughterhouse until a negative result to the rapid test has been obtained.

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) and (b) of Regulation (EC) No 1774/2002 of the European Parliament and of the Council[(20)].

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

6.5. Where an animal slaughtered for human consumption is found positive to the rapid test, at least the carcase immediately preceding the test-positive carcase and two carcases immediately following the test-positive carcase on the same slaughterline shall be destroyed in accordance with point 6.4, in addition to the test-positive carcase.

6.6. Member States may derogate from the provisions of point 6.5 where a system is in place in the slaughterhouse preventing contamination between carcase.

[F5II. MONITORING IN OVINE AND CAPRINE ANIMALS

1. General

Monitoring in ovine and caprine animals shall be carried out in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2.(b).

[F62. Monitoring in ovine and caprine animals slaughtered for human consumption

(a) *Ovine animals*

Member States, in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals, shall test a minimum annual sample of 10 000 ovine animals slaughtered for human consumption in accordance with the sampling rules set out in point 4[(21)].

(b) *Caprine animals*

Member States shall test healthy slaughtered caprine animals in accordance with the sampling rules set out in point 4 and the minimum sample sizes listed in Table A.

Where a Member State experiences difficulty in collecting sufficient numbers of healthy slaughtered caprine animals to reach its allotted minimum sample size, it may choose to replace a maximum of 50 % of its minimum sample size by testing dead caprine animals over the age of 18 months at the ratio of one to one and in addition to the minimum sample size set out in point 3.

TABLE A

Member State	**Minimum sample size in healthy slaughtered caprine animals**[a]

a Minimum sample sizes are set to take account of the size of the number of healthy slaughtered caprine animals and the prevalence of BSE in the individual Member State. They are also intended to provide achievable targets. The minimum sample sizes above 60 000 allow the detection of a prevalence of 0,0017 % with a 95 % confidence.

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

Spain	125 500
France	93 000
Italy	60 000
Greece	20 000
Cyprus	5 000
Austria	5 000
Other Member States	all

a Minimum sample sizes are set to take account of the size of the number of healthy slaughtered caprine animals and the prevalence of BSE in the individual Member State. They are also intended to provide achievable targets. The minimum sample sizes above 60 000 allow the detection of a prevalence of 0,0017 % with a 95 % confidence.

Textual Amendments

F6 Substituted by Commission Regulation (EC) No 214/2005 of 9 February 2005 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in caprine animals (Text with EEA relevance).

3. Monitoring in ovine and caprine animals not slaughtered for human consumption

Member States shall test in accordance with the sampling rules set out in point 4 and the minimum sample sizes indicated in table B and table C, ovine and caprine animals which have died or been killed, but which were not:

— killed in the framework of a disease eradication campaign, or

— slaughtered for human consumption.

TABLE B

Member State population of ewes and ewe lambs put to the ram	**Minimum sample size of dead ovine animals[a]**
>750 000	10 000
100 000750 000	1 500
40 000100 000	500
<40 000	100

a Minimum sample sizes are set to take account of the size of the ovine populations in the individual Member States and are intended to provide achievable targets. The minimum sample sizes of 10 000, 1 500, 500 and 100 animals will allow the detection of a prevalence of 0,03 %, 0,2 %, 0,6 % and 3 % respectively with a 95 % confidence.

TABLE C

Member State population of goats which have already kidded and goats mated	**Minimum sample size of dead caprine animals[a]**
>750 000	10 000

a Minimum sample sizes are set to take account of the size of the caprine populations in the individual Member States and are intended to provide achievable targets. The minimum sample sizes of 10 000, 3 000, 1 000 and 200 animals will allow the detection of a prevalence of 0,03 %, 0,1 %, 0,3 % and 1,5 % respectively with a 95 % confidence.]

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

250 000750 000	3 000
40 000250 000	1 000
<40 000	100 % up to 200

a Minimum sample sizes are set to take account of the size of the caprine populations in the individual Member States and are intended to provide achievable targets. The minimum sample sizes of 10 000, 3 000, 1 000 and 200 animals will allow the detection of a prevalence of 0,03 %, 0,1 %, 0,3 % and 1,5 % respectively with a 95 % confidence.**]**

4. Sampling rules applicable to the animals referred to in points 2 and 3

The animals shall be over 18 months of age or have more than two permanent incisors erupted through the gum.

The age of the animals shall be estimated on the basis of dentition, obvious signs of maturity, or any other reliable information.

The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, age, breed, production type or any other characteristic.

Multiple sampling in the same flock shall be avoided, wherever possible.

The Member States shall put in place a system to check, on a targeted or other basis, that animals are not being diverted from sampling.

The sampling shall be representative for each region and season.

However, Member States may decide to exclude from the sampling remote areas with a low animal density, where no collection of dead animals is organised. Member States making use of this derogation shall inform the Commission thereof, and shall submit a list of those remote areas where the derogation applies. The derogation shall not cover more than 10 % of the ovine and caprine population in the Member State concerned.

5. Monitoring in infected flocks

From 1 October 2003, animals over 12 months or which have a permanent incisor erupted through the gum, and which are killed for destruction in accordance with the provisions of Annex VII, point 2(b)(i) or (ii) or point 2(c), shall be tested based on the selection of a simple random sample, in accordance with the sample size indicated in the following table.

Number of animals over 12 months or which have a permanent incisor erupted through the gum, killed for destruction in the herd or flock	**Minimum sample size**
70 or less	All eligible animals
80	68
90	73
100	78
120	86
140	92
160	97

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

180	101
200	105
250	112
300	117
350	121
400	124
450	127
500 or more	150

Where possible, the killing and subsequent sampling shall be delayed until the result of primary molecular testing carried out for the further examination of positive scrapie cases under the provisions of Annex X, Chapter C, point 3.2.(c)(i) is known.

6. Monitoring in other animals

In addition to the monitoring programmes set out in points 2, 3 and 4, Member States may on a voluntary basis carry out monitoring in other animals, in particular:

— animals used for dairy production,
— animals originating from countries with indigenous TSEs,
— animals which have consumed potentially contaminated feedingstuffs,
— animals born or derived from TSE infected dams.

7. Measures following testing of ovine and caprine animals

7.1. Where an ovine or caprine animal slaughtered for human consumption has been selected for TSE testing in accordance with point 2, its carcase shall not be marked with the health marking provided for in Chapter XI of Annex I to Directive 64/433/EEC until a negative result to the rapid test has been obtained.

7.2. Member States may derogate from point 7.1. where a system approved by the competent authority is in place in the slaughterhouse ensuring that all parts of an animal can be traced and that no parts of the animals tested bearing the health mark can leave the slaughterhouse until a negative result to the rapid test has been obtained.

7.3. All parts of the body of a tested animal, including the hide, shall be retained under official control until a negative result has been obtained to the rapid test, except for animal by-products directly disposed of in accordance with Articles 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

7.4. Except for the material to be retained in conjunction with the records provided for in Chapter B, Part III of this Annex, all parts of the body of an animal found positive to the rapid test, including the hide, shall be directly disposed of in accordance with Articles 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

8. Genotyping

8.1. The prion protein genotype shall be determined for each positive TSE case in sheep. TSE cases found in resistant genotypes (sheep of genotypes which encode alanine on both alleles at codon 136, arginine on both alleles at codon 154 and arginine on both alleles at codon 171) shall immediately be reported to the Commission. Where possible, such cases shall be submitted for strain-typing. Where strain-typing of such

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cases is not possible, the herd of origin and all other herds where the animal has been kept shall be subjected to enhanced monitoring with a view to finding other TSE cases for strain-typing.

8.2. In addition to the animals genotyped under the provisions of point 8.1., the prion protein genotype of a minimum sample of ovine animals shall be determined. In the case of Member States with an adult sheep population of more than 750 000 adult animals, this minimum sample shall consist of at least 600 animals. In the case of other Member States the minimum sample shall consist of at least 100 animals. The samples may be chosen from animals slaughtered for human consumption, from animals dead-on farm or from live animals. The sampling should be representative of the entire ovine population.

Textual Amendments

F5 Substituted by Commission Regulation (EC) No 36/2005 of 12 January 2005 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemio-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals (Text with EEA relevance).

III. MONITORING IN OTHER ANIMAL SPECIES

Member States may on a voluntary basis carry out monitoring for TSEs in animal species other than bovine, ovine and caprine animals.**]**

[F5CHAPTER B

Reporting and recording requirements

I. REQUIREMENTS ON MEMBER STATES

A. Information to be presented by Member States in their annual report as provided for in Article 6(4)

1. The number of suspected cases placed under official movement restrictions in accordance with Article 12(1), per animal species.

2. The number of suspected cases subject to laboratory examination in accordance with Article 12(2), per animal species, including the results of the rapid and confirmatory tests (number of positives and negatives) and, with regard to bovine animals, an estimation of the age distribution of all tested animals. The age distribution should be grouped whenever possible as follows: ‘below 24 months’, distribution per 12 months between 24 and 155 months, and ‘above 155 months’ of age.

3. The number of flocks where suspected cases in ovine and caprine animals have been reported and investigated pursuant to Article 12(1) and (2).

4. The number of bovine animals tested within each subpopulation referred to in Chapter A, Part (I), points 2.1., 2.2., 2.3., 3.1., 4.1., 4.2., 4.3. and 5. The method for the sample selection, the results of the rapid and confirmatory tests and an estimation of the age distribution of the tested animals grouped as set out in point 2 shall be provided.

5. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, Part II, points 2, 3 and 5 together with the method for sample selection and the results of the rapid and confirmatory tests.

6. The geographical distribution, including the country of origin if not the same as the reporting country, of positive cases of BSE and scrapie. The year, and where possible the month of birth shall be given for each TSE case in bovine, ovine and caprine animals. TSE cases which have been considered atypical and the reasons why shall be indicated. For scrapie cases, the results of the primary molecular testing with a discriminatory immuno-blotting, referred to in Annex X, Chapter C, point 3.2.(c)(i), shall be reported.

7. In animals other than bovine, ovine and caprine, the number of samples and confirmed TSE cases per species.

8. The genotype, and where possible the breed, of each ovine animal either found positive to TSE or sampled in accordance with Chapter A, Part II, points 8.1. and 8.2.

B. Reporting periods

The compilation of reports containing the information referred to in A and forwarded to the Commission on a monthly basis or, with regard to the information referred to in point 8 on a quarterly basis, may constitute the annual report as required by Article 6(4), provided that the information is updated whenever additional information becomes available.**]**

II. INFORMATION TO BE PRESENTED BY THE COMMISSION IN ITS SUMMARY

The summary shall be presented in a tabled format covering at least the information referred to in part I for each Member State.

III. RECORDS

1. The competent authority shall keep, for seven years, records of:

— the number and types of animals placed under movement restrictions as referred to in Article 12(1),

— the number and outcome of clinical and epidemiological investigations as referred to in Article 12(1),

— the number and outcome of laboratory examinations as referred to in Article 12(2),

— the number, identity and origin of animals sampled in the framework of the monitoring programmes as referred to in Chapter A and, where possible, age, breed and anamnestic information,

— the prion protein genotype of positive TSE cases in sheep.

2. The investigating laboratory shall keep, for seven years, all records of testing, in particular laboratory workbooks and, where appropriate, paraffin blocks and photographs of western blots.**]**

[[F2]ANNEX IV

ANIMAL FEEDING

Extension of the prohibition provided for in Article 7(1)

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

1. The prohibition provided for in Article 7(1) shall be extended to the feeding:

(a) to farmed animals, with the exception of the feeding of carnivorous fur producing animals, of:

  (a) processed animal protein;

  (b) gelatine of ruminant origin;

  (c) blood products;

  (d) hydrolysed protein;

  (e) dicalcium phosphate and tricalcium phosphate of animal origin;

  (f) feedingstuffs containing the proteins listed in points (a) to (e);

(b) to ruminants of animal protein and feedingstuffs containing such protein.

2. I. Derogations from the prohibitions provided for in Article 7(1) and (2), and specific conditions for the application of such derogations.

A. The prohibitions provided for in Article 7(1) and (2) shall not apply to:

(a) the feeding to non-ruminants of the proteins referred to in (i), (ii) and (iii), and of feedingstuffs derived from such proteins, provided that those proteins have been processed where applicable in accordance with Article 19 of Regulation (EC) No 1774/2002:

  (i) fishmeal, in accordance with the conditions laid down in point B;

  (ii) hydrolysed proteins derived from non-ruminants and ruminant hides and skins, in accordance with the conditions laid down in point C;

  (iii) dicalcium phosphate and tricalcium phosphate, in accordance with the conditions laid down in point D;

(b) the feeding to ruminants of the proteins referred to in (i), (ii) and (iii), and of products derived from such proteins, provided that the proteins have been processed where applicable in accordance with the provisions in Article 19 of Regulation (EC) No 1774/2002:

  (i) milk, milk-based products and colostrum;

  (ii) eggs and egg products;

  (iii) gelatine derived from non-ruminants;

(c) the feeding to fish of blood products and bloodmeal derived from non-ruminants, provided that they have been processed where applicable in accordance with Article 19 of Regulation (EC) No 1774/2002 and of feedingstuffs derived from such proteins, in accordance with the conditions laid down in point E.

B. Conditions for the use of fishmeal and feedingstuffs containing fishmeal in the feeding of non-ruminant farmed animals with the exception of carnivorous fur producing animals.

(a) The fishmeal shall be produced in processing plants dedicated exclusively to the production of fish derived products, which shall be approved for this purpose by the competent authority in accordance with Article 17 of Regulation (EC) No 1774/2002.

(b) Before release for free circulation in the Community, each consignment of imported fishmeal shall be analysed in accordance with Commission Directive 98/88/EC[(22)].

(c) Feedingstuffs containing fishmeal shall be produced in establishments which do not produce feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

However, by way of derogation from that condition:

(i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing fishmeal is not required for home compounders:
- — registered by the competent authority,
- — keeping only non-ruminants,
- — producing complete feedingstuffs for use only in the same holding, and
- — provided that the feedingstuffs containing fishmeal used in the production contain less than 50 % crude protein;

(ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing fishmeal for other animal species may be authorised by the competent authority subject to the following conditions:
- — bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing fishmeal are manufactured,
- — bulk feedingstuffs destined for ruminants are kept in facilities physically separate from facilities where bulk fishmeal and bulk feedingstuffs containing fishmeal are kept during storage, transport and packaging,
- — records detailing the purchases and uses of fishmeal and the sales of feedingstuffs containing fishmeal are kept available to the competent authority for at least five years, and
- — routine tests are carried out on feedingstuffs destined to ruminants to ensure that prohibited proteins including fishmeal are not present.

(d) The label and accompanying document of feedingstuffs containing fishmeal shall clearly indicate the words ‘contains fishmeal — cannot be fed to ruminants’.

(e) Bulk feedingstuffs containing fishmeal shall be transported by means of vehicles which do not transport at the same time feedingstuffs for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure approved by the competent authority to avoid cross-contamination.

(f) The use and storage of feedingstuffs containing fishmeal shall be prohibited in farms where ruminants are kept.

By way of derogation from that condition, the competent authority may permit the use and storage of feedingstuffs containing fishmeal in farms where ruminants are kept, if

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they are satisfied that on-farm measures are implemented to prevent that feedingstuffs containing fishmeal are fed to ruminants.

C. Conditions for the use of hydrolysed proteins derived from non-ruminants or from ruminant hides and skins, and feedingstuffs containing such proteins, in the feeding of non-ruminant farmed animals, with the exception of the feeding of carnivorous fur producing animals.

(a) The hydrolysed proteins shall be produced in a processing plant approved by the competent authority in accordance with Article 17 of Regulation (EC) No 1774/2002.

(b) Feedingstuffs containing hydrolysed proteins shall be produced in establishments which do not prepare feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

However, by way of derogation from that condition:

(i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing hydrolysed proteins is not required for home compounders:

— registered by the competent authority,

— keeping only non-ruminants,

— producing complete feedingstuffs for use only in the same holding, and

— provided that the feedingstuffs containing hydrolysed proteins used in the production contain less than 50 % crude protein;

(ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing hydrolysed proteins for other animal species may be authorised by the competent authority subject to the following conditions:

— bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing hydrolysed proteins are manufactured,

— bulk feedingstuffs destined for ruminants are kept in facilities physically separate from facilities where bulk hydrolysed proteins and bulk feedingstuffs containing hydrolysed proteins are kept during storage, transport and packaging,

— records detailing the purchases and uses of hydrolysed proteins, and the sales of feedingstuffs containing hydrolysed proteins are kept available to the competent authority for at least five years.

(c) The label and the accompanying document of the feedingstuffs containing hydrolysed proteins shall clearly indicate the words ‘contains hydrolysed proteins — cannot be fed to ruminants’.

(d) Bulk feedingstuffs containing hydrolysed proteins shall be transported by mean of vehicles which do not transport at the same time feedingstuffs for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure approved by the competent authority to avoid cross-contamination.

(e) The use and storage of feedingstuffs containing hydrolysed proteins shall be prohibited in farms where ruminants are kept.

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By way of derogation from that condition, the competent authority may permit the use and storage of feedingstuffs containing hydrolysed proteins in farms where ruminants are kept, if they are satisfied that on-farm measures are implemented to prevent the feeding of feedingstuffs containing hydrolysed proteins to ruminants.

D. Conditions for the use of dicalcium phosphate, tricalcium phosphate and feedingstuffs containing such proteins in the feeding of non-ruminant farmed animals with the exception of the feeding of carnivorous fur producing animals.

(a) Dicalcium phosphate and tricalcium phosphate shall be produced in a processing plant approved by the competent authority in accordance with Article 17 of Regulation (EC) No 1774/2002.

(b) Feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be produced in establishments which do not prepare feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

However, by way of derogation from that condition:

(i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing dicalcium phosphate or tricalcium phosphate is not required for home compounders:
- registered by the competent authority,
- keeping only non-ruminants,
- producing complete feedingstuffs for use only in the same holding, and
- provided that the feedingstuffs containing dicalcium phosphate or tricalcium phosphate used in the production contain less than 10 % total phosphorus;

(ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing dicalcium phosphate or tricalcium phosphate for other animal species may be authorised by the competent authority subject to the following conditions:
- bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing dicalcium phosphate or tricalcium phosphate are manufactured,
- bulk feedingstuffs destined for ruminants are kept in facilities physically separate from facilities where bulk dicalcium phosphate and bulk tricalcium phosphate and bulk feedingstuffs containing dicalcium phosphate and tricalcium phosphate are kept during storage, transport and packaging,
- records detailing the purchases and uses of dicalcium phosphate or tricalcium phosphate and the sales of feedingstuff containing dicalcium phosphate or tricalcium phosphate are kept available to the competent authority for at least five years.

(c) The label and accompanying document of the feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall clearly indicate the words ‘contains dicalcium/tricalcium phosphate of animal origin — cannot be fed to ruminants’.

(d) Bulk feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be transported by mean of vehicles which do not transport at the same time feedingstuffs

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for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure approved by the competent authority to avoid cross-contamination.

(e) The use and storage of feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be prohibited in farms where ruminants are kept.

By way of derogation from that condition, the competent authority may permit the use and storage of feedingstuffs containing dicalcium phosphate or tricalcium phosphate in farms where ruminants are kept, if they are satisfied that on-farm measures are implemented to prevent that feedingstuffs containing dicalcium phosphate or tricalcium phosphate are fed to ruminants.

E. Conditions for the use of blood products, bloodmeal and feedingstuffs containing such proteins of non-ruminant origin in the feeding of farmed fish:

(a) the blood shall be derived from EU approved slaughterhouses not slaughtering ruminants which are registered as not slaughtering ruminants and shall be transported directly to the processing plant in vehicles dedicated exclusively to the transport of non-ruminant blood. If the vehicle was used for the transport of ruminant blood, it shall be, following cleaning, inspected by the competent authority before the transport of non-ruminant blood.

By way of derogation from that condition, the competent authority may permit the slaughter of ruminants in slaughterhouses collecting non-ruminant blood intended for the production of blood meal and blood products for use in fish feed if these slaughterhouses have a recognised control system. The control system shall at least include:

— the slaughtering of non-ruminants physically separate from the slaughtering of ruminants,

— collection, storage, transport and packaging of blood from non-ruminant origin in facilities physically separate from facilities where blood of ruminant origin is collected, stored, transported and packaged, and

— regular sampling and analysis of blood from non-ruminant origin for the presence of ruminant proteins;

(b) the blood products and the bloodmeal shall be produced in an establishment exclusively processing non-ruminant blood and approved by the competent authority in accordance with Article 17 of Regulation (EC) No 1774/2002.

By way of derogation from that condition, the competent authority may permit the production of blood products for use in fish feed in establishments processing ruminant blood, which have a recognised control system in place preventing cross-contamination. The control system shall at least include:

— processing of non-ruminant blood in a closed system physically separate from the processing of ruminant blood,

— transport, storage and packaging of bulk raw material and bulk finished blood products of non-ruminant origin in facilities physically separate from facilities where bulk raw material and bulk finished products of ruminant origin are kept during storage, transport and packaging, and

— regular sampling and analysis of non-ruminant blood products for the presence of ruminant proteins;

(c) feedingstuffs containing blood products or bloodmeal shall be produced in establishments manufacturing fish feed which do not prepare feedingstuffs for other farmed animals, with the exception of carnivorous fur producing animals, and which are authorised for that purpose by the competent authority;

(d) the label, accompanying commercial document or health certificate, as appropriate, of the feedingstuffs containing blood products or bloodmeal shall clearly indicate the words 'contains blood products — shall only be fed to fish' or 'contains bloodmeal — shall only be fed to fish', as appropriate;

(e) transport vehicles used for the transport of bulk fish feed containing blood products or bloodmeal shall not be used for the transport of feedingstuffs for other farmed animals, with the exception of carnivorous fur producing animals, unless the transport vehicle, following cleaning, has been inspected by the competent authority;

(f) the use and storage of fish feed containing blood products or bloodmeal shall be prohibited in farms where other farmed animals, with the exception of carnivorous fur producing animals, are kept.

3. II. General implementing conditions

A. Member States shall make available to the other Member States and to the Commission an up-to-date list of EU approved slaughterhouses registered as not slaughtering ruminants and approved processing establishments producing hydrolysed proteins, dicalcium phosphate, tricalcium phosphate, fishmeal, blood products or bloodmeal and establishments, with the exception of home compounders, authorised for manufacturing feedingstuffs containing these proteins, which operate in accordance with the conditions laid down by this Regulation within 60 days from the date of entry into force of this Regulation. Any amendments to the list shall immediately be made available to the other Member States and to the Commission.

B.

(a) Bulk processed animal protein, with the exception of fishmeal, and bulk feedingstuffs containing such proteins, shall be stored and transported in dedicated facilities. The store or vehicle can only be used for other purposes, following cleaning, after having been inspected by the competent authority.

(b) Bulk fishmeal, bulk hydrolysed proteins referred to in point A(a)(ii) of part I, bulk dicalcium phosphate and bulk tricalcium phosphate referred to in point A(a)(iii) of part I, and bloodmeal and blood products referred to in point A(c) of part I shall be stored and transported in stores and vehicles dedicated to that purpose.

(c) By way of derogation from point (b):

(i) stores or vehicles may be used for the storage and transport of feedingstuffs containing the same protein;

(ii) stores or vehicles, following cleaning, may be used for other purposes after having been inspected by the competent authority; and

(iii) vehicles transporting fishmeal may be used for other purposes if the company has a control system in place, recognised by the competent authority, to prevent cross-contamination. The control system shall at least include:

— records on material transported and cleaning of the vehicle, and

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— regular sampling and analysis of feedingstuffs transported for the presence of fishmeal.

The competent authority shall carry out frequent spot checks to verify the correct application of the control plan.

C. Feedingstuffs, including petfood, which contain processed animal proteins, other than fishmeal or bloodmeal of non-ruminant origin, or blood products of ruminant origin shall not be manufactured in establishments which produce feedingstuffs for farmed animals, with the exception of carnivorous fur producing animals.

Petfood and feedingstuffs intended for carnivorous fur producing animals containing fishmeal, hydrolysed proteins referred to in point A(a)(ii) of part I, dicalcium phosphate and tricalcium phosphate referred to in point A(a)(iii) of part I, and bloodmeal and blood products referred to in point A(c) of part I shall be manufactured and transported in accordance with the provisions referred to in points B(c) and (e), C(b) and (d), D(b) and (d) and E(c) and (e), respectively of part I.

D. The export to third countries of processed animal proteins derived from ruminants, and of products containing such processed animal proteins, shall be prohibited.

The export of other processed animal proteins and blood products and products containing such proteins shall only be permitted subject to the following conditions:

— they are destined for uses not prohibited by Article 7,

— a written agreement with the third country is made prior to exportation, which includes an undertaking from the third country to respect the final use and not to re-export the processed animal protein, blood products and products containing such proteins for uses prohibited by Article 7.

Member States which allow such exportation shall inform the Commission and the other Member States of all terms and conditions as agreed with the third country concerned, for the effective implementation of this Regulation, in the context of the Standing Committee on the Food Chain and Animal Health.

The measures in this point shall not apply to fishmeal, provided it fulfils the conditions set out in point B, products containing such fishmeal, and petfood.

E. The competent authority shall carry out documentary and physical checks including tests on feedingstuffs throughout the production and distribution chain in accordance with Council Directive 95/53/EC[23], to control compliance with its provisions and the provisions of this Regulation. Where any presence of prohibited animal protein is detected, Council Directive 95/53/EC shall apply.

F. The provisions on the production and the use of processed animal protein of Regulation (EC) No 1774/2002 shall apply to the feedingstuffs covered by this Annex.**]**

ANNEX V

SPECIFIED RISK MATERIAL

1. The following tissues shall be designated as specified risk material depending on the category of the Member State or third country of origin or residence of the animal, determined in accordance with Article 5:

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CATEGORIES 1 AND 2

None.

CATEGORIES 3 AND 4

(a) the skull including the brain and eyes, the tonsils and the spinal cord of bovine animals aged over 12 months, and the intestines from the duodenum to the rectum of bovine animals of all ages;

(b) the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum, and the spleen of ovine and caprine animals of all ages.

CATEGORY 5

(a) the entire head (excluding the tongue), including the brain, eyes, trigeminal ganglia and tonsils; the thymus; the spleen and the spinal cord of bovine animals aged over six months, and the intestines from the duodenum to the rectum of animals of all ages;

(b) the vertebral column, including dorsal root ganglia, of bovine animals aged over 30 months;

(c) the skull including the brain and eyes, the tonsils, the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum, and the spleen of ovine and caprine animals of all ages.

2. Specified risk material must be removed at:

(a) slaughterhouses;

(b) cutting plants, high-risk processing plants or premises referred to in Articles 3 and 7 of Directive 90/667/EEC[(24)], under the supervision of a designated agent appointed by the competent authority. Those establishments shall be approved for that purpose by the competent authority.

However, the vertebral column may be removed at points of sale to the consumer situated in the territory of the Member State concerned.

Where specified risk material is not removed from dead animals which have not been slaughtered for human consumption, the parts of the body containing specified risk material or the entire body will be treated as specified risk material.

3. All specified risk material must be stained with a dye and, as appropriate, marked with a marker immediately on removal, and completely destroyed:

(a) by incineration without pre-processing; or,

(b) provided that the dye or marker remains detectable, after pre-processing:

(i) in accordance with the systems described in Chapters I to IV, VI and VII of the Annex to Decision 92/562/EEC[(25)]:
— by incineration;
— by co-incineration;

(ii) in accordance with at least the standards referred to in Annex I to Decision 1999/534/EC[(26)], by burial in an approved landfill site.

4. Member States may derogate from the provisions of points 2 and 3 to allow the incineration or burial of specified risk material or entire bodies, without prior staining,

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or, as appropriate, removal of the specified risk materials, in the circumstances set out in Article 3(2) of Directive 90/667/EEC and by a method which precludes all risk of transmission of a TSE and is authorised and supervised by the competent authority, in particular where animals have died or have been killed in the context of disease control measures and without prejudice to Articles 12 and 13.

5. The use of an alternative test to the removal of specified risk material may be authorised under the following conditions:

(a) tests must be carried out in slaughterhouses on all animals eligible for the removal of specified risk material;

(b) no bovine, ovine or caprine product intended for human food or animal feed may leave the slaughterhouse before the competent authority has received and accepted the results of the tests on all slaughtered animals potentially contaminated if BSE has been confirmed in one of them;

(c) when an alternative test gives a positive result, all bovine, ovine and caprine material which has been potentially contaminated in the slaughterhouse is destroyed in accordance with point 3, unless all parts of the body including the hide of the affected animal can be identified and kept separate.

6. Member States are to carry out frequent official inspections to verify the correct application of this Annex and ensure that measures are taken to avoid contamination, particularly in slaughterhouses, cutting plants, animal waste processing plants, high risk processing plants or premises authorised by the Member States in accordance with Article 7 of Directive 90/667/EEC, points of sale to the consumer, landfill sites and other facilities for storage or incineration.

7. Member States shall in particular set up a system to ensure and check that:

(a) specified risk material used in the production of products referred to in Article 1(2) are used solely for the authorised purpose;

(b) where bovine, ovine or caprine animals enter a Member State placed in a numerically lower category, indicating a better BSE status, than that of the animals that enter, those animals remain under official supervision until slaughter or dispatch from its territory;

(c) specified risk material, in particular where disposal takes place at establishments or premises other than slaughterhouses, is completely separated from other waste not destined for incineration, is collected separately and is disposed of in accordance with points 2, 3 and 4. Member States may allow dispatch of heads or carcasses containing specified risk material to another Member State after agreement with that other Member State both to receive the material and to apply the specific conditions applicable to such movements.

8. Member States may send specified risk material or the material processed therefrom to other Member States for incineration only under the conditions laid down in Article 4(2) of Decision 97/735/EC[27], where applicable.

These points may be amended at the request of a Member State to allow the dispatch of specified risk material or the material processed therefrom to third countries for incineration. The conditions governing export shall be adopted at the same time, by the same procedure.

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ANNEX VI

STANDARDS FOR CERTAIN PRODUCTS OF ANIMAL ORIGIN DERIVED FROM OR CONTAINING RUMINANT MATERIAL

The use of ruminant material for the production of the following products of animal origin is prohibited as referred to in Article 9(1):

(a) mechanically recovered meat;

(b) dicalcium phosphate intended as feedingstuffs for livestock;

(c) gelatine, unless it is produced from ruminant hides;

(d) derivatives made from rendered ruminant fat;

(e) rendered ruminant fat, unless it was produced from:

(i) discrete adipose tissue declared fit for human consumption;

(ii) raw materials which were processed in accordance with the standards referred to in Directive 90/667/EEC.

[F3ANNEX VII

ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

1. The inquiry referred to in Article 13(1)(b) must identify:

(a) in the case of bovine animals:
- all other ruminants on the holding of the animal in which the disease was confirmed,
- where the disease was confirmed in a female animal, its progeny born within two years prior to, or after, clinical onset of the disease,
- all animals of the cohort of the animal in which the disease was confirmed,
- the possible origin of the disease,
- other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
- the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;

(b) in the case of ovine and caprine animals:
- all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,
- in so far as they are identifiable, the parents, and in the case of females all embryos, ova and the last progeny of the female animal in which the disease was confirmed,
- all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those referred to in the second indent,

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— the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,

— the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the BSE agent to or from the holding in question.

2. The measures laid down in Article 13(1)(c) shall comprise at least:

(a) in the case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in the second and third indents of point 1(a); however, the Member State may decide:

— not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,

— to defer the killing and destruction of animals in the cohort referred to in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death;

(b) in the case of confirmation of TSE in an ovine or caprine animal, from 1 October 2003, according to the decision of the competent authority:

(i) either the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b) or

(ii) the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:

— breeding rams of the ARR/ARR genotype,

— breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,

— sheep carrying at least one ARR allele which are intended solely for slaughter,

— if the competent authority so decides, sheep and goats less than two months old which are intended solely for slaughter;

(iii) if the infected animal has been introduced from another holding, a Member State may decide, based on the history of the case, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed; in the case of land used for common grazing by more than one flock, Member States may decide to limit the application of those measures to a single flock, based on a reasoned consideration of all the epidemiological factors; where more than one flock is kept on a single holding, Member States may decide to limit the application of the measures to the flock in which scrapie has been confirmed, provided it has been verified that the flocks have been kept isolated from each other and that the spread of infection between the flocks through either direct or indirect contact is unlikely;

(c) in the case of confirmation of BSE in an ovine or caprine animal, killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b).

3. If scrapie is suspected in an ovine or caprine animal at a holding in a Member State, all other ovine and caprine animals from that holding shall be placed under official movement restriction until the results of the examination are available. If there is evidence that the holding where the animal was present when scrapie was suspected is not likely to be the holding where the animal could have been exposed to scrapie, the competent authority may decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

4. Only the following animals may be introduced to the holding(s) where destruction has been undertaken in accordance with point 2(b)(i) or (ii):

(a) male sheep of the ARR/ARR genotype;

(b) female sheep carrying at least one ARR allele and no VRQ allele;

(c) caprine animals, provided that:

(i) no ovine animals for breeding other than those of the genotypes referred to in points (a) and (b) are present on the holding,

(ii) thorough cleaning and disinfection of all animal housing on the premises has been carried out following destocking,

(iii) the holding shall be subjected to intensified TSE monitoring, including the testing of all caprine animals which are over the age of 18 months and:

— either are slaughtered for human consumption at the end of their productive lives, or

— which have died or been killed on the holding, and which meet the criteria referred to in Annex III, Chapter A, Part II, point 3.

5. Only the following ovine germinal products may be used in the holding(s) where destruction has been undertaken in accordance with point 2(b)(i) or (ii):

(a) semen from rams of the ARR/ARR genotype;

(b) embryos carrying at least one ARR allele and no VRQ allele.

6. During a transitional period until 1 January 2006 at the latest, and by way of derogation from the restriction set out in point 4(b), where it is difficult to obtain replacement ovine animals of a known genotype, Member States may decide to allow non-pregnant ewes of an unknown genotype to be introduced to the holdings referred to in point 2(b)(i) and (ii).

7. Following the application on a holding of the measures referred to in point 2(b)(i) and (ii):

(a) movement of ARR/ARR sheep from the holding shall not be subject to any restriction;

(b) sheep carrying only one ARR allele may be moved from the holding only to go directly for slaughter for human consumption or for the purposes of destruction; however,

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— ewes carrying one ARR allele and no VRQ allele may be moved to other holdings which are restricted following the application of measures in accordance with point 2(b)(ii),

— if the competent authority so decides, lambs carrying one ARR allele and no VRQ allele may be moved to one other holding solely for the purposes of fattening prior to slaughter; the destination holding shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter;

(c) if the Member State so decides, sheep and goats less than two months old may be moved from the holding to go directly for slaughter for human consumption; the head and organs of the abdominal cavity of such animals shall however be disposed of in accordance with Article 4(2)(a), (b) or (c) of Regulation (EC) No 1774/2002 of the European Parliament and of the Council[(28)],

(d) without prejudice to subparagraph (c), sheep of genotypes not referred to in subparagraphs (a) and (b) may only be moved from the holding for the purposes of destruction.

8. The restrictions referred to in points 4, 5 and 7 shall continue to apply to the holding for a period of three years from:

(a) the date of attainment of ARR/ARR status by all ovine animals on the holding or

(b) the last date when any ovine or caprine animal was kept on the premises or

(c) in the case of point 4(c), the date when the intensified TSE monitoring commenced or

(d) the date when all breeding rams on the holding are of ARR/ARR genotype and all breeding ewes carry at least one ARR allele and no VRQ allele, provided that during the three-year period, negative results are obtained from TSE testing of the following animals over the age of 18 months:

— an annual sample of ovine animals slaughtered for human consumption at the end of their productive lives in accordance with the sample size indicated in the table in Annex III, Chapter A, Part II, point 4; and

— all ovine animals referred to in Annex III, Chapter A, Part II, point 3 which have died or been killed on the holding.

9. Where the frequency of the ARR allele within the breed or holding is low, or where it is deemed necessary in order to avoid inbreeding, a Member State may decide to:

(a) delay the destruction of animals as referred to in point 2(b)(i) and (ii) for up to five breeding years;

(b) allow ovine animals other than those referred to in point 4 to be introduced to the holdings referred to in point 2(b)(i) and (ii), provided that they do not carry a VRQ allele.

10. Member States applying the derogations provided for in points 6 and 9 shall notify to the Commission an account of the conditions and criteria used for granting them.**]**

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

ANNEX VIII

PLACING ON THE MARKET AND EXPORT

[F7CHAPTER A

[F3Conditions for intra-Community trade in live animals, semen and embryos]

I. CONDITIONS WHICH APPLY IRRESPECTIVE OF THE CATEGORY OF THE MEMBER STATE OR THIRD COUNTRY OF ORIGIN OR RESIDENCE OF THE ANIMAL

The following conditions shall apply to trade in ovine and caprine animals:

(a) [F8ovine and caprine animals for breeding shall either be sheep of the ARR/ARR prion protein genotype, as defined in Annex I of Commission Decision 2002/1003/EC[29], or they shall have been kept continuously since birth or for the last three years on a holding or holdings which have satisfied the following requirements for at least three years:

(i) until 30 June 2007:

— it is subject to regular official veterinary checks,

— the animals are marked,

— no case of scrapie has been confirmed,

— checking by sampling of old female animals intended for slaughter is carried out,

— females, with the exception of sheep of the ARR/ARR prion protein genotype, are introduced into the holding only if they come from a holding which complies with the same requirements.

From 1 July 2004 at the latest, the holding or holdings shall begin to satisfy the following additional requirements:

— all animals referred to in Annex III, Chapter A, Part II, point 3 over the age of 18 months which have died or been killed on the holding shall be examined for scrapie in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b), and

— ovine and caprine animals, with the exception of sheep of the ARR/ARR prion protein genotype, shall be introduced into the holding only if they come from a holding which complies with the same requirements.

(ii) from 1 July 2007:

— it is subject to regular official veterinary checks,

— the animals are identified in conformity with Community legislation,

— no case of scrapie has been confirmed,

— all animals referred to in Annex III, Chapter A, Part II, point 3 over the age of 18 months which have died or been killed on the holding have been examined for scrapie in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b),

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— ovine and caprine animals, with the exception of sheep of the ARR/ARR prion protein genotype, are introduced into the holding only if they come from a holding which complies with the same requirements.

If they are destined for a Member State which benefits, for all or part of its territory, from the provisions laid down in point (b) or (c), ovine and caprine animals for breeding shall comply with the additional guarantees, general or specific, which have been defined in accordance with the procedure referred to in Article 24(2).**]**

(b) a Member State which has a compulsory or voluntary national scrapie control program for all or part of its territory:

(i) may submit the said program to the Commission, outlining in particular:
— the distribution of the disease in the Member State,
— the reasons for the program, taking into consideration the importance of the disease and the cost/benefit ratio,
— the geographical area in which the program will be implemented,
— the status categories defined for holdings and the standards which must be attained in each such category,
— the test procedures to be used,
— the program monitoring procedures,
— the action to be taken if, for any reason, a holding loses its status,
— the measures to be taken if the results of checks carried out in accordance with the provisions of the program are positive,

(ii) the program referred to in point (i) may be approved if it complies with the criteria laid down in that point, in accordance with the procedure referred to in Article 24(2). The additional guarantees, general or specific, which may be required in intra-Community trade, shall be defined at the same time or at the latest three months after approval of the program in accordance with the procedure referred to in Article 24(2). Such guarantees must not exceed those which the Member State implements nationally,

(iii) amendments or additions to the programmes submitted by Member States may be approved in accordance with the procedure referred to in Article 24(2). Amendments to the guarantees which have been defined in accordance with point (ii) may be approved in accordance with that procedure,

(c) where a Member State considers that its territory or part of its territory is free from scrapie:

(i) it is to submit to the Commission appropriate supporting documentation, setting out in particular:
— the history of the occurrence of the disease in its territory,
— the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation,
— the period over which the surveillance was carried out,
— the arrangements for verifying the absence of the disease,

(ii) the additional guarantees, general or specific, which may be required in intra-Community trade are to be defined in accordance with the procedure

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referred to in Article 24(2). Such guarantees must not exceed those which the Member State implements nationally,

(iii) the Member State concerned is to notify the Commission of any change in the details specified in point (i) which relate to the disease. The guarantees defined in accordance with point (ii) may, in the light of such notification, be amended or withdrawn in accordance with the procedure referred to in Article 24(2)**[**[F3],**]**

(d) **[**[F9]from 1 January 2005 semen and embryos of ovine and caprine animals shall:

(i) be collected from animals which have been kept continuously since birth or for the last three years of their life on a holding or holdings which have satisfied the requirements of subparagraph (a)(i) or, as appropriate, (a)(ii) for three years or

(ii) in the case of ovine semen, be collected from male animals of the ARR/ARR prion protein genotype as defined in Annex I to Commission Decision 2002/1003/EC[(30)]or

(iii) in the case of ovine embryos, be of the ARR/ARR prion protein genotype as defined in Annex I to Decision 2002/1003/EC.**]]**

Textual Amendments

F8 Substituted by Commission Regulation (EC) No 876/2004 of 29 April 2004 amending Annex VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards trade in ovine and caprine animals for breeding (Text with EEA relevance).

F9 Inserted by Commission Regulation (EC) No 1492/2004 of 23 August 2004 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in bovine, ovine and caprine animals, the trade and importation of semen and embryos of ovine and caprine animals and specified risk material (Text with EEA relevance).

II. CONDITIONS WHICH APPLY DEPENDING ON THE CATEGORY OF THE MEMBER STATE OF ORIGIN OR RESIDENCE OF THE ANIMAL DETERMINED IN ACCORDANCE WITH ANNEX II, CHAPTER C

1. Dispatch to other Member States is to follow the rules of Article 15(1).

2. The BSE category of the Member State of origin of bovine, ovine and caprine animals are to be communicated to the Member State of destination.

3. The following conditions are to apply to movements as referred to in point 1 of bovine animals coming from or having resided in the Member States or one of the regions thereof placed in:

CATEGORIES 3 AND 4

The animals must have:

(a) been born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years; or

(b) been born after the date from which the ban on the feeding of ruminants with proteins derived from mammals has been effectively enforced.

CATEGORY 5

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

The animals must have:

(a) been born after the date from which the ban on the feeding of farmed animals with proteins derived from mammals has been effectively enforced; and

(b) been born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years, and which contain only bovine animals born on the farm or coming from a herd of equivalent status.

Textual Amendments

F7 Substituted by Commission Regulation (EC) No 260/2003 of 12 February 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos (Text with EEA relevance).

CHAPTER B

Conditions relating to progeny of TSE suspect or confirmed animals referred to in Article 15(2)

It shall be prohibited to place on the market the last-born progeny to which female bovine animals infected with a TSE or BSE-confirmed ovine or caprine animals gave birth during the preceding two-year period or during the period that followed the appearance of the first clinical signs of the onset of the disease.

CHAPTER C

Conditions for intra-Community trade in certain products of animal origin

I. The following products of animal origin are exempt from the prohibition referred to in Article 16(3), provided that they are derived from bovine animals that satisfy the requirements of Parts II or III below:

— fresh meat;
— minced meat;
— meat preparations;
— meat products;
— petfood which is destined for domestic carnivores.

Date-based Scheme

II. Deboned fresh meat from which all adherent tissues, including obvious nervous and lymphatic tissue, has been removed, and products of animal origin referred to in Part I deriving therefrom obtained from eligible animals from countries or regions in category 5 may be marketed in accordance with the second subparagraph of Article 16(3) when they are obtained from animals born after the date from which the animal feeding standards laid down in Article 7(2) were effectively enforced and certified as meeting the conditions laid down in point 1 and they are produced in establishments which meet the condition laid down in point 9. The competent authority shall ensure that the conditions with respect to controls laid down in points 2 to 8 and point 10 are complied with.

1. A bovine animal shall be eligible for the Date-based Scheme if it was born and raised in the Member State concerned and if at the time of slaughter it is shown that the following conditions are fulfilled:

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(a) the animal has been clearly identifiable throughout its life, enabling it to be traced back to its dam and herd of origin; its unique eartag number, date and holding of birth and all movements after birth are recorded either in the animal's official passport or in an official computerised identification and tracing system; the identity of its dam is known;

(b) the animal is more than six months but less than 30 months of age, determined by reference to an official computer record of its date of birth, or to the animal's official passport;

(c) the competent authority has obtained and verified positive evidence that the dam of the animal has lived for at least six months after the birth of the eligible animal;

(d) the dam of the animal has not developed BSE and is not suspected of having contracted BSE.

Controls

2. If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Regulation, the animal must be automatically rejected and its passport confiscated. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates and cancel certificates issued. If dispatch has already taken place, the competent authority must notify the competent authority of the place of destination. The competent authority of the place of destination must take the appropriate measures.

3. Slaughter of eligible animals must take place in slaughterhouses which are not used for the slaughter of bovine animals other than those slaughtered under a Date-based Scheme or under a Certified Herd Scheme.

4. The competent authority must satisfy itself that procedures used in the cutting plants ensure that the following lymph nodes have been removed:

popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal, prefemoral, lumbar, costocervical, sternal, prescapular, axilliary, caudal and deep cervical.

5. Meat must be traceable back to the eligible animal, or after cutting, to the animals cut in the same batch, by means of an official tracing system until the time of slaughter. After slaughter, labels must be capable of tracing fresh meat and products referred to in Part I back to the eligible animal to enable the consignment concerned to be recalled. In the case of petfood, accompanying documents and records must allow tracing.

6. All approved eligible carcasses must have individual numbers correlated with the eartag number.

7. The Member State must have detailed protocols in place covering:

(a) tracing and controls prior to slaughter;

(b) controls during slaughter;

(c) controls during processing of petfood;

(d) all labelling and certification requirements after slaughter to the point of sale.

8. The competent authority must set up a system for recording checks on compliance so that control can be demonstrated.

The establishment

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

9. To obtain approval, the establishment must devise and implement a system whereby the eligible meat and/or eligible product is identifiable and all meat can be traced back to the eligible animal, or after cutting, to the animals cut in the same batch. The system must allow full traceability of the meat or products of animal origin at all stages and records must be retained for at least two years. Details of the system employed must be given, in writing, by the management of the establishment to the competent authority.

10. The competent authority must assess, approve and monitor the system provided by the establishment in order to ensure that it provides full segregation and traceability both backwards and forwards.

Certified herd Scheme

III. Deboned fresh meat from which all adherent tissues, including obvious lymphatic and nervous tissue, has been removed, and products of animal origin referred to in Part I, deriving therefrom which are obtained from eligible animals from countries or regions in category 5, may be marketed in accordance with the second subparagraph of Article 16(3) when obtained from animals which are certified as meeting the conditions laid down in point 2 and coming from herds in which no case of BSE has occurred in the last seven years and which are certified as meeting the conditions laid down in point 1 and produced in establishments which meet the condition laid down in point 11. The competent authority shall ensure that the conditions laid down in points 3 to 10 and 12 with respect to the computerised tracing system and the controls are complied with.

Conditions relating to herds

1.

(a) A herd is a group of animals forming a separate and distinct unit, that is a group of animals which is managed, housed and kept separately from any other group of animals and which is identified with unique herd and animal identification numbers.

(b) A herd is eligible when for at least seven years there has been no confirmed case of BSE, nor a suspect case for which the diagnosis of BSE has not been ruled out, in any animal which was still in or had moved through or from the herd.

(c) As an exception to the provisions in point (b), a herd that has been in existence for less than seven years may be considered eligible, after a thorough investigation by the competent veterinary authority, on condition that:

  (i) all animals born or moved into the newly established herd complied with the conditions set out in point (2)(a), (d) and (e); and,

  (ii) the herd has complied with the conditions set out in point (b) during its entire existence.

(d) If a herd is newly established on a holding which experienced a confirmed case of BSE in any animal which was still in or had moved through or from a herd on that holding, the newly established herd can only be eligible after a thorough investigation by the competent veterinary authority, certifying compliance with each of the following conditions to the satisfaction of that authority:

  (i) all animals of the affected herd previously held on the same holding have been removed or killed;

  (ii) all feed has been removed and destroyed and all feed containers thoroughly cleansed;

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(iii) all buildings have been emptied and thoroughly cleansed before the new animals were admitted;

(iv) all conditions set out in point (c) have been complied with.

Conditions relating to the animal

2.

(a) all records of the animal's birth, identity and movements are recorded on an official computerised tracing system;

(b) the animal is more than six months but less than 30 months of age, determined by reference to an official computer record of its date of birth;

(c) its dam has lived for at least six months after its birth;

(d) its dam has not developed BSE and is not suspected of having contracted BSE;

(e) the herd of birth of the animal and all herds through which it has moved are eligible.

Computerised tracing system

3. The official computerised tracing system referred to in point 2(a) will be approved only where it has been in operation for sufficient time to contain all the information, relating to the lifetime and movements of the animals, needed to check compliance with the requirements of this Regulation, and concerns only animals born after the system came into operation. Historical data loaded into a computer for any period before the system was operational will not be accepted for this purpose.

Controls

4. If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Regulation, the animal must be automatically rejected and its passport confiscated. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates, and cancel certificates issued. If dispatch has already taken place, the competent authority must notify the competent authority of the place of destination. The competent authority of the place of destination must take the appropriate measures.

5. Slaughter of eligible animals must take place in slaughterhouses used exclusively for the slaughter of animals under a Date-based Scheme or under a Certified Herd Scheme.

6. The competent authority must satisfy itself that procedures used in the cutting plants ensure that the following lymph nodes have been removed:

popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal, prefemoral, lumbar, costocervical, sternal, prescapular, axilliary, caudal and deep cervical.

7. Meat must be traceable back to the herd of the eligible animal, or after cutting, to the animals cut in the same batch, by means of the computerised tracing system until the time of slaughter. After slaughter, labels must be capable of tracing fresh meat and products referred to in Part I back to the herd to enable the consignment concerned to be recalled. In the case of petfood, accompanying documents and records must allow tracing.

8. All approved eligible carcasses must have individual numbers correlated with the eartag number.

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9. The Member State must have detailed protocols in place covering:

(a) tracing and controls prior to slaughter;

(b) controls during slaughter;

(c) controls during processing of petfood;

(d) all labelling and certification requirements after slaughter to the point of sale.

10. The competent authority must set up a system for recording checks on compliance so that control can be demonstrated.

The establishment

11. To obtain approval, the establishment must devise and implement a system whereby the eligible meat and/or eligible product is identifiable and all meat can be traced back to its herds of origin, or after cutting, to the animals cut in the same batch. The system must facilitate full traceability of the meat or products of animal origin at all stages and records must be retained for at least two years. Details of the system employed must be given, in writing, by the management of the establishment to the competent authority.

12. The competent authority must assess, approve and monitor the system provided by the establishment in order to ensure that it provides full segregation and traceability both backwards and forwards.

CHAPTER D

Conditions applicable to exports

Live bovine animals and products of animal origin derived therefrom are to be subject — as regards exports to third countries — to the rules laid down in this Regulation for intra-Community trade.

ANNEX IX

IMPORTATION INTO THE COMMUNITY OF LIVE ANIMALS, EMBRYOS, OVA AND PRODUCTS OF ANIMAL ORIGIN

CHAPTER A

When importing from countries or regions placed in category 1, the competent authority is, for bovine animals and all commodities of bovine origin for which this Regulation lays down specific rules, to take account of the presentation of an international animal health certificate attesting that the country or region complies with the conditions in Annex II, Chapter C, to be placed in that category.

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

CHAPTER B

Imports of bovine animals

A. Imports of bovine animals from a country or a region placed in category 2 are to be subject to the presentation of an international animal health certificate attesting that:

(a) the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

(b) the bovine animals intended for export to the Community are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE-suspected females.

B. Imports of bovine animals from countries or regions placed in category 3 are to be subject to the presentation of an international animal health certificate attesting that:

1. the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

2. bovine animals intended for export to the Community:
   - — are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and making it possible to establish that they are not the progeny of BSE suspect or confirmed females;
   - — were born, raised and had remained in herds in which no case of BSE had been confirmed for at least seven years; or
   - — were born after the date from which the ban on the feeding of ruminants with proteins derived from mammals has been effectively enforced.

C. Imports of bovine animals from countries or regions placed in category 4 are to be subject to the presentation of an international animal health certificate attesting that:

1. the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

2. bovine animals intended for export to the Community:

   (a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and making it possible to establish that they are not the progeny of BSE suspect or confirmed females; and

   (b) were born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years; or

   (c) were born after the date from which the ban on the feeding of ruminants with proteins derived from mammals has been effectively enforced.

D. Imports of bovine animals from countries or regions placed in category 5 are to be subject to the presentation of an international animal health certificate attesting that:

1. the feeding of farmed animals with proteins derived from mammals has been banned and the ban has been effectively enforced;

2. the affected bovine animals are killed and completely destroyed as well as:

   (a) if these are females, their last progeny born within two years prior to, or after the first clinical signs of the onset of the disease;

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(b) all bovine animals from the same cohort

if such animals are still alive in the country or region;

3. the animals intended for export to the Community:

(a) were born after the date from which the ban on the feeding of farmed animals with proteins derived from mammals was effectively enforced;

(b) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

AND

(c) either were born, raised and have remained in herds in which no case of BSE has ever been confirmed, and which contain only bovine animals born on the farm or coming from a herd of equal health status; or

(d) were born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years, and which contain only bovine animals born on the farm or coming from a herd of equal health status.

CHAPTER C

Imports of fresh meat and products of bovine animal origin

A. Imports of fresh meat (on the bone or deboned) and products of bovine animal origin from countries or regions placed in category 2 are to be subject to the presentation of an international health certificate attesting that the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced.

B. Imports of fresh meat (on the bone or deboned) and products of bovine animal origin from countries or regions placed in category 3 are to be subject to the presentation of an international health certificate attesting that:

(a) the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

(b) the fresh meat and products of bovine animal origin intended for export to the Community do not contain or are not derived from specified risk material referred to in Annex V or mechanically recovered meat obtained from the bone of the head or vertebral column.

C. Imports of fresh meat (on the bone or deboned) and meat products of bovine origin from countries or regions placed in category 4 are to be subject to the presentation of an international health certificate attesting that:

1. the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

2. the fresh meat and products of bovine animal origin intended for export to the Community do not contain or are not derived from specified risk material referred to in Annex V or mechanically recovered meat obtained from the head or vertebral column.

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

D. Imports of fresh meat and products of bovine animal origin from countries or regions placed in category 5 are to be prohibited except for the products of animal origin listed in section I of Chapter C, Annex VIII. These imports are to be subject to the presentation of an international health certificate attesting that:

1. they fulfil the conditions of Article 16(2) and those set out in sections II or III of Chapter C of Annex VIII;

2. the meat products intended for export to the Community do not contain or are not derived from any product referred to in Chapter F, nor from any specified risk material as defined in Annex V;

3. a system is in operation enabling the fresh meat and products of bovine animal origin intended for export to the Community to be traced back to the establishments from which they are derived;

4. the bovine animals from which the meat or meat products intended for export to the Community originate:

   (a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

   (b) are not the progeny of BSE-suspect or confirmed females; and either:
   - were born after the date from which the ban on the feeding of farmed animals with proteins derived from mammals was effectively enforced; or
   - were born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years;

5. the feeding of farmed animals with proteins derived from mammals has been banned and the ban has been effectively enforced;

6. the affected bovine animals are slaughtered and completely destroyed as well as:

   (a) if these are females, their last progeny born within two years prior to, or after, the first clinical signs of the onset of the disease;

   (b) all bovine animals from the same cohort

   if they are still alive in the country or region.

CHAPTER D

Imports of bovine embryos and ova

A. Imports of bovine embryos/ova from countries or regions placed in category 2 are to be subject to the presentation of an international animal health certificate attesting that:

1. the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

2. the embryos/ova were collected, processed and stored in conformity with the provisions of Annexes A and B to Directive 89/556/EC[(31)].

B. Imports of bovine ova/embryos from countries or regions placed in category 3 are to be subject to the presentation of an international animal health certificate attesting that:

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

1. the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

2. ova/embryos destined for export to the Community are derived from females which:

   (a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the progeny of BSE-confirmed females;

   (b) are not the progeny of BSE-suspect or confirmed females;

   (c) were not suspected of being affected by BSE at the time of embryo collection;

3. the ova/embryos were collected, processed and stored in accordance with the provisions of Annexes A and B to Directive 89/556/EEC.

C. Imports of ova/embryos from countries or regions placed in category 4 are to be subject to the presentation of an international animal health certificate attesting that:

1. the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

2. the ova/embryos intended for export to the Community are derived from females which:

   (a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the progeny of BSE-suspected or affected females;

   (b) are not affected with BSE;

   (c) were not suspected of being affected with BSE at the time of embryo collection; and

      (i) either were born after the date from which the ban on the feeding of ruminants with proteins derived from mammals was effectively enforced; or

      (ii) were born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years;

3. the ova/embryos were collected, processed and stored in conformity with the provisions of Annexes A and B to Directive 89/556/EEC.

D. Imports of bovine ova/embryos from countries or regions placed in category 5 are to be subject to the presentation of an international animal health certificate attesting that:

1. the feeding of animals for breeding with proteins derived from mammals has been banned and the ban has been effectively enforced;

2. the affected bovine animals, and, if these are females, their last progeny born within two years prior to, or after, clinical onset of the disease, if alive in the country or region, are killed and completely destroyed;

3. ova/embryos intended for export to the Community are derived from females which:

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the progeny of BSE-suspected or confirmed females;

(b) are not affected with BSE;

(c) were not suspected of being affected with BSE at the time of embryo collection; and

(i) either were born after the date from which the ban on the feeding of animals for breeding with proteins derived from mammals was effectively enforced;

(ii) or have never been fed with proteins derived from mammals and were born, raised and have remained in herds in which no case of BSE has been confirmed for at least seven years, and which contain only bovine animals born on the farm or coming from a herd of equal health status;

4. the ova/embryos were collected, processed and stored strictly in conformity with the provisions of Annexes A and B to Directive 89/556/EEC.

[F10CHAPTER E

Imports of ovine and caprine animals

Ovine and caprine animals imported into the Community after 1 October 2003 are to be subject to the presentation of an animal health certificate attesting that:

(a) either they were born in and continuously reared on holdings in which a case of scrapie has never been diagnosed, and, in the case of ovine and caprine animals for breeding, they satisfy the requirements of subparagraph (i) of point (a) of Chapter A(I) of Annex VIII;

(b) or they are sheep of the ARR/ARR prion protein genotype, as defined in Annex I to Commission Decision 2002/1003/EC, coming from a holding where no case of scrapie has been reported in the last six months.

If they are destined for a Member State which benefits, for all or part of its territory, from the provisions laid down in point (b) or (c) of Chapter A(I) of Annex VIII, they shall comply with the additional guarantees, general or specific, which have been defined in accordance with the procedure referred to in Article 24(2).**]**

Textual Amendments

F10 Substituted by Commission Regulation (EC) No 1915/2003 of 30 October 2003 amending Annexes VII, VIII and IX to Regulation (EC) No 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 (Text with EEA relevance).

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

CHAPTER F

Imports into the Community from third countries or regions thereof, placed in category 5, of the products of animal origin referred to in Annex VIII, Chapter C, in accordance with Article 16(3) are to be prohibited if they contain or are derived from the following products or material derived from ruminant animals:

— mechanically recovered meat;

— dicalcium phosphate intended for feeding livestock;

— gelatine unless produced from hides or skins;

— rendered ruminant fat and derivatives made from it unless they were produced from discrete adipose tissue which was itself declared fit for human consumption, or from raw materials which were processed in accordance with the standards referred to in Decision 1999/534/EC.

CHAPTER G

When importing products of animal origin from third countries or regions thereof which are not placed in category 1, the appropriate certificates, as required by Community legislation, are to be supplemented by a declaration signed by the competent authority of the country of production, worded as follows:

> The product of animal origin does not contain, and is not derived from, specified risk material as defined in Annex V 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 or mechanically recovered meat obtained from bones of the head or vertebral column of bovine animals. The animals have not been slaughtered after stunning by means of a gas injected into the cranial cavity or killed instantaneously by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

[F9CHAPTER H

Import of ovine and caprine semen and embryos

Semen and embryos of ovine and caprine animals imported into the Community from 1 January 2005 shall satisfy the requirements of Annex VIII, Chapter A(I)(d).]

ANNEX X

REFERENCE LABORATORIES, SAMPLING AND LABORATORY ANALYSIS METHODS

CHAPTER A

National reference laboratories

1. The designated national reference laboratory is to:

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(a) have at its disposal facilities and expert personnel enabling it to show at all times, and especially when the disease in question first appears, the type and strain of the agent of TSE, and to confirm results obtained by regional diagnostic laboratories. Where it is not capable of identifying the strain-type of the agent, it shall set up a procedure to ensure that the identification of the strain is referred to the Community reference laboratory;

(b) verify diagnostic methods used in regional diagnostic laboratories;

(c) be responsible for coordination of diagnostic standards and methods within the Member State. To this end, it:

— may provide diagnostic reagents to laboratories approved by the Member State;

— is to control the quality of all diagnostic reagents used in the Member State;

— is to periodically arrange comparative tests;

— is to hold isolates of the agents of the disease in question, or corresponding tissues containing such agents, coming from cases confirmed in the Member State;

— is to ensure confirmation of results obtained in diagnostic laboratories designated by the Member State;

(d) is to cooperate with the Community reference laboratory.

2. However, by way of derogation from point 1, Member States which do not have a national reference laboratory are to use the services of the Community reference laboratory or of national reference laboratories in other Member States.

[[F11]3. The national reference laboratories are:

Austria:	Bundesanstalt für Tierseuchenbekämpfung, Mödling Robert Koch Gasse 17 A-2340 Mödling
Belgium:	CERVA-CODA-VAR Centre d'Étude et de Recherches Vétérinaires et Agrochimiques Centrum voor Onderzoek in Diergeneeskunde en Agrochemie Veterinary and Agrochemical Research Centre Groeselenberg 99 B-1180 Bruxelles
[[F12]Cyprus:	Εργαστήριο Αναφοράς για τις Ασθένειες των Ζώων, Κτηνιατρικές Υπηρεσίες,1417 Λευκωσία (National Reference Laboratory for Animal Health Veterinary Services CY-1417 Nicosia)
Czech Republic:	Státní veterinární ústav Jihlava, Rantířovská 93, 586 05 Jihlava**]**

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

Denmark:	Danish Veterinary Laboratory Bülowsvej 27 DK-1790 Copenhagen V
[[F12]Estonia:	Veterinaar- ja Toidulaboratoorium Kreutzwaldi 30 51006 Tartu**]**
Finland:	Eläinlääkintä- ja elintarvikelaitos Hämeentie 57 FIN-00550 Helsinki
France:	Agence Française de Sécurité Sanitaire des Aliments Laboratoire de pathologie bovine 31, avenue Tony Garnier BP 7033 F-69342 Lyon Cedex
Germany:	Bundesforschungsanstalt für Viruskrankheiten der Tiere Anstaltsteil Insel Riems Boddenblick 5A D-17498 Insel Riems
[[F13]Greece:	Ministry of Agriculture Veterinary Laboratory of Larisa 7th km of Larisa — Trikala Highway GR-411 10Larisa (rapid tests and immunological tests) Laboratory of Gross Pathology Faculty of Veterinary Medicine Aristotelian University of Thessaloniki Giannitson & Voutyra St. GR-546 27 Thessaloniki (histopathology)**]**
[[F12]Hungary:	Országos Állategészségügyi Intézet (OÁI) Pf. 2. Tábornok u. 2. HU-1581-Budapest**]**
Ireland:	Central Veterinary Research Laboratory Abbotstown Castleknock Dublin 15 Ireland
Italy:	Istituto Zooprofilattico Sperimentale del Piemonte Liguria e Valle d'Aosta CEA Via Bologna I-148-10150 Torino
[[F12]Latvia:	Valsts veterinārmedicīnas diagnostikas centrs Lejupes iela 3

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

	LV-1076 Rīga
Lithuania:	Nacionalinė veterinarijos laboratorija J. Kairiūkščio g. 10 LT-2021 Vilnius**]**
Luxembourg:	CERVA-CODA-VAR Centre d'Étude et de Recherches Vétérinaires et Agrochimiques Centrum voor Onderzoek in Diergeneeskunde en Agrochemie Veterinary and Agrochemical Research Centre Groeselenberg 99 B-1180 Bruxelles
[F12Malta:	National Veterinary Laboratory Marsa Malta**]**
Netherlands:	Instituut voor Dierhouderij en Diergezondheid, ID-DLO Lelystad Edelhertweg 15 Postbus 658200 AB Lelystad Netherlands
[F12Poland:	Laboratorium Zakładu Wirusologii Państwowego Instytutu Weterynaryjnego Al. Partyzantów 57 PL-24-100 Puławy**]**
Portugal:	Laboratório Nacional de Investigação Veterinária Estrada de Benfica, 701 P-1500 Lisboa
[F12Slovakia:	Neuroimunologický ústav SAV Dúbravská cesta 9 SK-942 45 Bratislava
Slovenia:	Nacionalni veterinarski inštitut Gerbičeva 60 SI-1000 Ljubljana**]**
Spain:	Laboratorio de la Facultad de Veterinaria Departamento de Patología Animal (Anatomía Patológica) Zaragoza Spain (BSE and scrapie, methods other than rapid tests) Laboratorio Central de Veterinaria de Algete Madrid Spain (rapid tests)

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

	Centro de Investigacion en Sanidad Anímal (CISA) Crta, De Algete al Casar de Talamanca 28130 Valdeolmos (Madrid) Spain (TSEs other than BSE or scrapie)
Sweden:	National Veterinary Institute S-751 89 Uppsala
United Kingdom	Veterinary Laboratories Agency Woodham Lane New Haw Addlestone Surrey KT15 3NB United Kingdom**]**

Textual Amendments

F12 Inserted by Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded.

F13 Substituted by Commission Regulation (EC) No 1053/2003 of 19 June 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards rapid tests (Text with EEA relevance).

Textual Amendments

F11 Substituted by Commission Regulation (EC) No 1248/2001 of 22 June 2001 amending Annexes III, X and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemio-surveillance and testing of transmissible spongiform encephalopathies.

CHAPTER B

Community reference laboratory

1. The Community reference laboratory for TSEs is:

The Veterinary Laboratories Agency

Woodham Lane

New Haw

Addlestone

Surrey KT15 3NB

United Kingdom

2. The functions and duties of the Community reference laboratory are:

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(a) to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing BSE, specifically by:

- storing and supplying corresponding tissues containing the agent, for the development or production of the relevant diagnostic tests or for typing strains of the agent;
- supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in the Member States;
- building up and retaining a collection of corresponding tissues containing the agents and strains of TSEs;
- organising periodic comparative tests of diagnostic procedures at Community level;
- collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;
- characterising isolates of the TSE agent by the most up-to-date methods to allow greater understanding of the epidemiology of the disease;
- keeping abreast of trends in surveillance, epidemiology and prevention of TSEs throughout the world;
- maintaining expertise on prion diseases to enable rapid differential diagnosis;
- acquiring a thorough knowledge of the preparation and use of diagnostic methods used to control and eradicate TSEs;

(b) to assist actively in the diagnosis of outbreaks of TSEs in Member States by studying samples from TSE-infected animals sent for confirmatory diagnosis, characterisation and epidemiological studies;

(c) to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonisation of diagnostic techniques throughout the Community.

[F5CHAPTER C

Sampling and laboratory testing

1. Sampling

Any samples intended to be examined for the presence of a TSE shall be collected using the methods and protocols laid down in the latest edition of the Manual for diagnostic tests and vaccines for Terrestrial Animals of the International Office for Epizooties (IOE/OIE) (‘the Manual’). In the absence of OIE methods and protocols, and to ensure that sufficient material is available, the competent authority shall ensure the use of sampling methods and protocols in accordance with guidelines issued by the Community Reference Laboratory. In particular the competent authority shall try to collect part of the cerebellum and the whole brain stem of small ruminants and shall keep at least half of the collected tissues fresh but not frozen until the result of the rapid or confirmatory test is negative.

The samples shall be correctly marked as to the identity of the sampled animal.

2. Laboratories

Any laboratory examination for TSE shall be carried out in laboratories approved for that purpose by the competent authority.

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

3. Methods and protocols

3.1. Laboratory testing for the presence of BSE in bovine animals

(a) Suspect cases

Samples from bovine animals sent for laboratory testing pursuant to the provisions of Article 12(2) shall be subject to a histopathological examination as laid down in the latest edition of the Manual, except where the material is autolysed. Where the result of the histopathological examination is inconclusive or negative or where the material is autolysed, the tissues shall be subjected to an examination by one of the other diagnostic methods laid down in the Manual (immunocytochemistry, immuno-blotting or demonstration of characteristic fibrils by electron microscopy). However, rapid tests cannot be used for this purpose.

If the result of one of those examinations is positive, the animals shall be regarded a positive BSE case.

(b) BSE monitoring

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

When the result of the rapid test is inconclusive or positive, the sample shall immediately be subject to confirmatory examinations in an official laboratory. The confirmatory examination shall start by a histopathological examination of the brainstem as laid down in the latest edition of the Manual, except where the material is autolysed or otherwise not suitable for examination by histopathology. Where the result of the histopathological examination is inconclusive or negative or where the material is autolysed, the sample shall be subjected to an examination by one of the other diagnostic methods referred to in (a).

An animal shall be regarded a positive BSE case, if the result of the rapid test is positive or inconclusive, and either

— the result of the subsequent histopathological examination is positive, or

— the result of another diagnostic method referred to in (a) is positive.

3.2. Laboratory testing for the presence of TSE in ovine and caprine animals

(a) Suspect cases

Samples from ovine and caprine animals sent for laboratory testing pursuant to the provisions of Article 12(2) shall be subject to a histopathological examination as laid down in the latest edition of the Manual, except where the material is autolysed. Where the result of the histopathological examination is inconclusive or negative or where the material is autolysed, the sample shall be subjected to an examination by immunocytochemistry, immuno-blotting or demonstration of characteristic fibrils by electron microscopy, as laid down in the Manual. However, rapid tests cannot be used for this purpose.

If the result of one of those examinations is positive, the animal shall be regarded a positive scrapie case.

(b) Scrapie monitoring

Samples from ovine and caprine animals sent for laboratory testing pursuant to the provisions of Annex III, Chapter A, Part II (Monitoring in ovine and caprine animals) shall be examined by a rapid test.

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

When the result of the rapid test is inconclusive or positive, the brainstem shall immediately be sent to an official laboratory for confirmatory examinations by immunocytochemistry, immuno-blotting or demonstration of characteristic fibrils by electron microscopy, as referred to in (a). If the result of the confirmatory examination is negative or inconclusive, additional confirmatory testing shall be carried out according the guidelines of the Community Reference Laboratory.

If the result of one of the confirmatory examination is positive, the animal shall be regarded a positive scrapie case.

(c) Further examination of positive scrapie cases

(i) Primary molecular testing with a discriminatory immuno-blotting

Samples from clinical suspect cases and from animals tested in accordance with Annex III, Chapter A, Part II, points 2 and 3 which are regarded as positive scrapie cases following the examinations referred to in points (a) or (b), or which display characteristics which are deemed by the testing laboratory to merit investigation, shall be forwarded for further examination by a primary molecular typing method to:

— Agence Française de Sécurité Sanitaire des Aliments, Laboratoire de pathologie bovine, 31, avenue Tony Garnier, BP 7033, F-69342, Lyon Cedex, France, or

— Veterinary Laboratories Agency, Woodham Lane, New Haw, Addlestone, Surrey KT15 3NB, United Kingdom, or

— to a laboratory, appointed by the competent authority, which has participated successfully in proficiency testing organised by the Community Reference Laboratory for the use of a molecular typing method, or

— on a provisional basis until 1 May 2005, the laboratories approved for this purpose by the CRL panel of experts.

(ii) Ring trial with additional molecular testing methods

Samples from scrapie cases in which the presence of BSE cannot be excluded according to the guidelines issued by the Community Reference Laboratory by the primary molecular testing referred to in (i), shall be forwarded immediately to the laboratories listed in point (d) after consultation with the Community Reference Laboratory, and with all the relevant information available. They shall be submitted to a ring trial with at least:

— a second discriminatory immuno-blotting,

— a discriminatory immunocytochemistry, and

— a discriminatory ELISA (Enzyme linked ImmunoSorbent Assay)

carried out in the laboratories approved for the relevant method as listed in point (d). Where samples are unsuitable for immunocytochemistry, the Community Reference Laboratory will direct appropriate alternative testing within the ring trial.

The results shall be interpreted by the Community Reference Laboratory assisted by a panel of experts including a representative of the relevant National Reference Laboratory. The Commission shall be informed immediately about the outcome of that interpretation. Samples indicative for BSE by three different methods and samples inconclusive in the ring trial shall be further analysed by a mouse bioassay for final confirmation.

Further testing of samples taken from infected flocks on the same holding in accordance with the provisions of Annex III, Chapter A, Part II, point 5, shall be carried out in accordance with the advice of the Community Reference Laboratory, after consultation with the relevant National Reference Laboratory.

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(d) Laboratories approved for performing further examination by molecular typing methods

The laboratories approved for further molecular typing are:

Agence Française de Sécurité Sanitaire des Aliments

Laboratoire de pathologie bovine

31, avenue Tony Garnier

BP 7033

F-69342 Lyon Cedex

Centre CEA Fontenay-aux-Roses, BP 6

F-92265 Fontenay-aux-Roses Cedex

Service de Pharmacologie et d'Immunologie

Centre CEA Saclay, bâtiment 136

F-91191 Gif-sur-Yvette Cedex

Veterinary Laboratories Agency

Woodham Lane

New Haw

Addlestone

Surrey KT15 3NB

United Kingdom

3.3. Laboratory testing for the presence of TSEs in species other than those referred to in points 3.1. and 3.2.

Where methods and protocols are established for tests carried out to confirm the suspected presence of a TSE in a species other than bovine, ovine and caprine, they shall include at least a histopathological examination of brain tissue. The competent authority may also require laboratory tests such as immunocytochemistry, immuno-blotting, demonstration of characteristic fibrils by electron microscopy or other methods designed to detect the disease associated form of the prion protein. In any case at least one other laboratory examination shall be carried out if the initial histopathological examination is negative or inconclusive. At least three different examinations shall be carried out in the event of the first appearance of the disease.

In particular, where BSE is suspected in a species other than bovine animals, samples shall be submitted for strain-typing, where possible.

[**F14**4. Rapid tests

For the purposes of carrying out the rapid tests in accordance with Article 5(3) and Article 6(1), the following methods shall be used as rapid tests for the monitoring of BSE in bovine animals:

— immuno-blotting test based on a Western blotting procedure for the detection of the protease-resistant fragment PrP^{Res} (Prionics-Check Western test),

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

— chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer test & Enfer TSE Kit version 2.0, automated sample preparation),

— sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad TeSeE test),

— microplate based immunoassay (ELISA) which detects protease resistant PrP^{Res} with monoclonal antibodies (Prionics-Check LIA test),

— automated conformation-dependent immunoassay comparing the reactivity of a detection antibody to the protease sensitive and protease resistant forms of PrP^{Sc} (some fraction of the protease resistant PrP^{Sc} is equivalent to PrP^{Res}) and to PrP^{C} (InPro CDI-5 test),

— chemiluminescent ELISA for qualitative determination of PrP^{Sc} (CediTect BSE test),

— immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA),

— microplate based chemiluminiscent immunoassay for the detection of PrP^{Sc} in bovine tissues (Institut Pourquier Speed'it BSE),

— lateral flow immunoassay using two different monoclonal antibodies to detect Proteinase K resistant PrP fractions (Prionics Check PrioSTRIP),

— two-sided immunoassay using two different monoclonal antibodies directed against two epitopes presented in a highly unfolded state of bovine PrP^{Sc} (Roboscreen Beta Prion BSE EIA Test Kit),

— sandwich ELISA for the detection of Proteinase K (PK) resistant PrP^{Sc} (Roche Applied Science PrionScreen).

For the purposes of carrying out the rapid tests in accordance with Article 5(3) and Article 6(1), the following methods shall be used as rapid tests for the monitoring of TSE in small ruminants:

— immuno-blotting test based on a Western blotting procedure for the detection of the protease-resistant fragment PrP^{Res} (Prionics-Check Western test),

— chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer test),

— sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad TeSeE test, the former Bio-Rad Platelia test),

— microplate based immunoassay (ELISA) which detects protease resistant PrP^{Res} with monoclonal antibodies (Prionics-Check LIA test),

— automated conformation-dependent immunoassay comparing the reactivity of a detection antibody to the protease sensitive and protease resistant forms of PrP^{Sc} (some fraction of the protease resistant PrP^{Sc} is equivalent to PrP^{Res}) and to PrP^{C} (InPro CDI-5 test).

The producer of the rapid tests must have a quality assurance system in place agreed by the Community reference laboratory, which ensures that the test performance does not change. The producer must provide the test protocol to the Community reference laboratory.

Modifications to rapid tests or to test protocols may only be made following advance notification to the Community reference laboratory, and provided that the Community reference laboratory finds that the modification does not reduce the sensitivity, specificity or reliability of the rapid

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

test. That finding shall be communicated to the Commission and to the national reference laboratories.**]**

Textual Amendments

F14 Substituted by Commission Regulation (EC) No 260/2005 of 16 February 2005 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards rapid tests (Text with EEA relevance).

5. Alternative tests

(To be defined)**]**

[[F15]ANNEX XI

TRANSITIONAL MEASURES REFERRED TO IN ARTICLES 22 AND 23

Textual Amendments

F15 Substituted by Commission Regulation (EC) No 1139/2003 of 27 June 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring programmes and specified risk material.

A.Concerning specified risk material, mechanically recovered meat and slaughtering techniques

[[F16]1.

(a) The following tissues are designated as specified risk material:

(i) **[**[F3]the skull excluding the mandible and including the brain and eyes, the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, and the spinal cord of bovine animals aged over 12 months, and the tonsils, the intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages;**]**

(ii) the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum, and the spleen and ileum of ovine and caprine animals of all ages.

The age specified in (i) for the removal of the bovine vertebral column may be adjusted by amending this Regulation in the light of the statistical probability of the occurrence of BSE in the relevant age groups of the Community's bovine population, based on the results of BSE monitoring as established by Chapter A.I of Annex III.

(b) In addition to the specified risk material listed in (a), the following tissues must be designated as specified risk material in the United Kingdom of Great Britain and Northern Ireland: the entire head excluding the tongue, including the brain, eyes and trigeminal ganglia; the thymus, the spleen and the spinal cord of bovine animals aged over six months.

Textual Amendments

F16 Substituted by Commission Regulation (EC) No 1993/2004 of 19 November 2004 amending Regulation (EC) 999/2001 of the European Parliament and of the Council as regards Portugal (Text with EEA relevance).

2. By way of derogation from point 1(a)(i), a decision may be taken in accordance with the procedure referred to in Article 24(2) to allow the use of the vertebral column and dorsal root ganglia from bovine animals:

(a) born, continuously reared and slaughtered in Member States for which a scientific evaluation established that the occurrence of BSE in native bovine animals is highly unlikely, or unlikely but not excluded; or

(b) born after the date of effective enforcement of the prohibition on the feeding of mammalian protein to ruminants in Member States with reported BSE in native animals or for which a scientific evaluation established that the occurrence of BSE in native bovine animals is likely.

The United Kingdom and Sweden may benefit from this derogation on the basis of previously submitted and evaluated evidence. Other Member States may apply for this derogation by submitting conclusive supporting evidence to the Commission regarding point (a) or (b), as appropriate.

Member States benefiting from this derogation shall, in addition to the requirements laid down in Annex III, Chapter A, Section I, ensure that one of the approved rapid tests listed in Annex X, Chapter C, point 4, is applied to all bovine animals over 30 months of age which:

(i) have died on the farm or in transport, but which have not been slaughtered for human consumption, with the exception of those dead animals in remote areas with a low animal density situated in Member States where the occurrence of BSE is unlikely;

(ii) were subject to normal slaughter for human consumption.

This derogation shall not be granted to allow the use of vertebral column and dorsal root ganglia from bovine animals aged over 30 months from the United Kingdom.

Experts from the Commission may carry out on-the-spot checks to further verify the submitted evidence in accordance with Article 21.**]**

3. Bones of bovine, ovine and caprine animals shall not be used for the production of mechanically recovered meat.

4. Laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity after stunning shall not be carried out on bovine, ovine or caprine animals whose meat is intended for human or animal consumption.

5. Specified risk material shall be removed at:

(a) slaughterhouses, or, as appropriate, other places of slaughter;

(b) cutting plants, in the case of vertebral column of bovine animals;

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(c) where appropriate, in intermediate plants referred to in Regulation (EC) No 1774/2002 of the European Parliament and of the Council[32], Article 10 or users and collection centres authorised and registered pursuant to Regulation (EC) No 1774/2002, Article 23(2)(c)(iv), (vi) and (vii).

The above provisions shall not apply to category 1 material for feeding of necrophagous birds in accordance with Article 23(2)(d) of Regulation (EC) No 1774/2002.

6. Tongues of bovine animals of all ages intended for human or animal consumption shall be harvested at the slaughterhouse by a transverse cut rostral to the lingual process of the basihyoid bone.

7. Head meat of bovine animals above 12 months of age shall be harvested at slaughterhouses, in accordance with a control system, recognised by the competent authority, to ensure the prevention of possible contamination of head meat with central nervous system tissue. The system shall include at least the following provisions:

— harvesting shall take place in a dedicated area, physically separated from the other parts of the slaughterline,

— where the heads are removed from the conveyor or hooks before harvesting the head meat, the frontal shot hole and *foramen magnum* shall be sealed with an impermeable and durable stopper. Where the brainstem is sampled for laboratory testing for BSE, the *foramen magnum* shall be sealed immediately after that sampling,

— head meat shall not be harvested from heads where the eyes are damaged or lost immediately prior to, or after slaughter, or which are otherwise damaged in a way which might result in contamination of the head with central nervous tissue,

— head meat shall not be harvested from heads which have not been properly sealed in accordance with the second indent,

— without prejudice to general rules on hygiene, specific working instructions shall be in place to prevent contamination of the head meat during the harvesting, in particular in the case when the seal referred to in the second indent is lost or the eyes damaged during the activity,

— a sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented.

8. By way of derogation from the requirements of point 7, Member States may decide to apply at the slaughterhouse an alternative control system for the harvesting of bovine head meat, leading to an equivalent reduction in the level of contamination of head meat with central nervous system tissue. A sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented. Member States using this derogation shall inform the Commission and the other Member States in the framework of the Standing Committee of the Food Chain and Animal Health of their control system and the results of the sampling.

9. The provisions of point 7 and 8 shall not apply to the harvesting of the tongue in accordance with point 6 nor to the harvesting of cheek meat in the slaughterhouse if performed without removing the bovine head from the conveyor or hooks.

10. By way of derogation from point 5 and 7, Member States may decide to allow:

(a) removal of spinal cord of ovine and caprine animals in cutting plants specifically authorised for this purpose;

(b) removal of vertebral column from carcases or parts of carcases in butcher shops specifically authorised, monitored and registered for this purpose;

(c) harvesting of head meat from bovine in cutting plants specifically authorised for this purpose in accordance with the following provisions:

bovine heads intended for transport to cutting plants specifically authorised for the harvesting of head meat, shall comply with the following provisions:

— the heads shall be suspended on a rack during the storing period and the transport from the slaughterhouse to the specifically authorised cutting plant,

— the frontal shot hole and the *foramen magnum* shall be properly sealed with an impermeable and durable stopper before being moved from the conveyor or hooks to the racks. Where the brainstem is sampled for laboratory testing for BSE, the *foramen magnum* shall be sealed immediately after that sampling,

— the heads which have not been properly sealed in accordance with the second indent, where the eyes are damaged or lost immediately prior to or after slaughter or which were otherwise damaged in a way which might result in contamination of the head meat with central nervous tissue shall be excluded from transport to the specifically authorised cutting plants,

— a sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify the proper implementation of the measures to reduce contamination;

the harvesting of head meat from bovine heads in cutting plants specifically authorised for this purpose shall be in accordance with a control system, recognised by the competent authority, to ensure the prevention of possible contamination of head meat. The system shall include at least:

— all heads shall be visually controlled for signs of contamination or damage and proper sealing before the commencement of the harvesting of the head meat,

— head meat shall not be harvested from heads which have not been properly sealed, where the eyes are damaged or which were otherwise damaged in a way which might result in contamination of the head meat with central nervous tissue. Head meat shall also not be harvested from any head where contamination from such heads is suspected,

— without prejudice to general rules on hygiene, specific working instructions shall be in place to prevent contamination of the head meat during transport and harvesting, in particular where the seal is lost or the eyes damaged during the activity,

— a sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented.

11. All specified risk material shall be stained with a dye or, as appropriate, marked immediately on removal, and disposed of in accordance with the provisions laid down in Regulation (EC) No 1774/2002, and in particular Article 4(2).

12. Member States shall carry out frequent official inspections to verify the correct application of this part and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants or other places where

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specified risk material is removed, such as butcher shops or establishments referred in point 5(c).

Member States shall in particular set up a system to ensure and check that:

(a) specified risk material used for purposes authorised pursuant to Article 1(2) and to Regulation (EC) No 1774/2002 are used solely for authorised purposes;

(b) specified risk material is disposed of in accordance with Regulation (EC) No 1774/2002.

13. Member States may decide to allow dispatch of heads or carcases containing specified risk material to another Member State after that other Member State has agreed to receive the material and has approved the specific conditions applicable to such transport.

However, carcases, half carcases or half carcases cut into no more than three wholesale cuts, and quarters containing no specified risk material other than vertebral column, including dorsal root ganglia, may be imported into a Member State, or dispatched to another Member State without the latter's prior agreement

14. A control system shall be put in place for the removal of the vertebral column as specified in point 1(a)(i). The system shall include at least the following measures:

(a) when removal of the vertebral column is not required, carcases or wholesale cuts of carcases of bovine animals containing vertebral column, shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000;

(b) a specific indication of the number of bovine carcases or wholesale cuts of carcases, from which removal of the vertebral column is required and from which removal of the vertebral column is not required, shall be added to the commercial document referred to in Article 3(1)(A)(f)(ii) of Directive 64/433/EEC or to the document referred to in Article 1(2) of Commission Decision 93/13/EEC[(33)], as applicable;

(c) butcher shops shall keep, for at least one year, the commercial documents referred to in (b).

15.

(a) The products of animal origin listed below shall be subject to the conditions laid down in (b) on import into the Community:

— the specified risk material referred to in point 1(a),
— fresh meat: the meat defined by Directive 64/433/EEC,
— minced meat and meat preparations: the minced meat and meat preparations defined by Directive 94/65/EC[(34)],
— meat products: the meat products defined by Directive 77/99/EEC[(35)],
— other products of animal origin: other products of animal origin as defined by Directive 77/99/EEC,
— rendered fats as referred to in Regulation (EC) No 1774/2002,
— gelatine as referred to by Directive 92/118/EEC and Regulation (EC) No 1774/2002,
— pet food as referred to in Regulation (EC) No 1774/2002,
— blood products as referred to in Regulation (EC) No 1774/2002
— the processed animal protein referred to in Regulation (EC) No 1774/2002,

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— bones and bone products as referred to in Regulation (EC) No 774/2002,
— category 3 material as referred to in Regulation (EC) No 1774/2002.

Any reference to 'products of animal origin' designates products of animal origin listed in this point and does not concern other products of animal origin containing or derived from those products of animal origin.

(b) When the abovementioned products of animal origin, containing material from bovine, ovine or caprine animals are imported into the Community from third countries or regions thereof, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

This product does not contain and is not derived from:

either[36]

specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

Carcases, half carcases and quarter carcases may contain vertebral column on import;

or ([1])

bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in the following countries:

— [F17Argentina
— Australia
— Botswana
— Brazil
— Chile
— El Salvador
— Iceland
— Namibia
— Territoire français de la Nouvelle Calédonie
— New Zealand
— Nicaragua
— Panama
— Paraguay
— Singapore
— Swaziland
— Uruguay
— Vanuatu.]]

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

Textual Amendments

F17 Substituted by Commission Regulation (EC) No 1809/2003 of 15 October 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards rules for importation of live bovine animals and products of bovine, ovine and caprine origin from Costa Rica and New Caledonia (Text with EEA relevance).

F18B. Concerning statistical surveys

1. . . . . .

2. . . . . .

Textual Amendments

F18 Deleted by Commission Regulation (EC) No 1494/2002 of 21 August 2002 amending Annexes III, VII and XI to Regulation (EC) No 999/2001 of the European Parliament and the Council as regards monitoring of bovine spongiform encephalopathy, eradication of transmissible spongiform encephalopathy, removal of specified risk materials and rules for importation of live animals and products of animal origin (Text with EEA relevance).

F19C. Concerning prohibitions on animal feeding

. . . . . .

Textual Amendments

F19 Deleted by Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (Text with EEA relevance).

[F20D. Concerning placing on the market and export

1. The following provisions remain in force as transitional measures:

Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC.

Commission Decision 98/351/EC of 29 May 1998 setting the date on which dispatch from Northern Ireland of bovine products under the Export Certified Herds Scheme may commence by virtue of Article 6(5) of Council Decision 98/256/EC.

Commission Decision 1999/514/EC of 23 July 1999 setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence by virtue of Article 6(5) of Council Decision 98/256/EC.]

Textual Amendments

F21 Deleted by Commission Regulation (EC) No 260/2003 of 12 February 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos (Text with EEA relevance).

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

F22 Deleted by Commission Regulation (EC) No 1993/2004 of 19 November 2004 amending Regulation (EC) 999/2001 of the European Parliament and of the Council as regards Portugal (Text with EEA relevance).

[F20 2. Imports of bovine animals are to be subject to the presentation of an international animal health certificate attesting that:

(a) the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;

(b) the bovine animals intended for export to the Community are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspected females.

[F17 3. Point 2 shall not apply to imports of bovine animals born and continuously reared in the following countries:

— Argentina
— Australia
— Botswana
— Brazil
— Chile
— El Salvador
— Iceland
— Namibia
— Territoire français de la Nouvelle Calédonie
— New Zealand
— Nicaragua
— Panama
— Paraguay
— Singapore
— Swaziland
— Uruguay
— Vanuatu.]]

F18 4. . . . . .

[F23 4.

(a) When the farmed game meat defined by Council Directive 91/495/EEC[37], meat preparations defined by Council Directive 94/65/EC[38], and meat products defined by Council Directive 77/99/EEC[39], derived from farmed cervid animals, are imported into the Community from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

> This product contains or is derived exclusively from meat, excluding offal and spinal cord, of cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognised by the competent authority with negative results and is not derived from animals coming from a herd where chronic wasting disease has been confirmed or is officially suspected.

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(b) When game meat as defined by Council Directive 92/45/EEC[40], meat preparations defined by Council Directive 94/65/EC, and meat products defined by Council Directive 77/99/EEC, derived from wild cervid animals, is imported into the Community from Canada or the United States of America, the health certificate shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

> This product contains or is derived exclusively from meat, excluding offal and spinal cord, of cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognised by the competent authority with negative results and is not derived from animals coming from a region where chronic wasting disease has been confirmed in the last three years or is officially suspected.**]**

Textual Amendments

F23 Inserted by Commission Regulation (EC) No 1471/2004 of 18 August 2004 amending Annex XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the import of cervid products from Canada and the United States (Text with EEA relevance).

Textual Amendments

F20 Inserted by Commission Regulation (EC) No 1326/2001 of 29 June 2001 laying down transitional measures to permit the changeover to the Regulation of the European Parliament and of the Council (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, and amending Annexes VII and XI to that Regulation.

Status: *Point in time view as at 09/03/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(**1**) OJ C 45, 19.2.1999, p. 2 and
OJ C 120 E, 24.4.2001, p. 89.

(**2**) OJ C 258, 10.9.1999, p. 19.

(**3**) Opinion of the European Parliament of 17 May 2000 (OJ C 59, 23.2.2001, p. 93), Common Position of the Council of 12 February 2001 (OJ C 88, 19.3.2001, p. 1) and Decision of the European Parliament of 3 May 2001.

(**4**) OJ L 184, 17.7.1999, p. 23.

(**5**) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 395, 30.12.1989, p. 13). Directive as last amended by Council Directive 92/118/EEC (OJ L 62, 15.3.1993, p. 49).

(**6**) Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29). Directive as last amended by Council Directive 92/118/EEC.

(**7**) Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

(**8**) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121 29.7.1964, p. 1977/64). Directive as last amended by Directive 2000/20/EC of the European Parliament and of the Council (OJ L 163, 4.7.2000, p. 35).

(**9**) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Commission Decision 94/953/EC (OJ L 371, 31.12.1994, p. 14).

(**10**) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ L 268, 24.9.1991, p. 56). Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).

(**11**) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

(**12**) Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58). Directive as last amended by Commission Decision 2000/556/EC (OJ L 235, 19.9.2000, p. 27).

(**13**) Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products (OJ L 268, 14.9.1992, p. 1). Directive as last amended by Directive 96/23/EC (JO L 23.5.1996, p. 10).

(**14**) Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(1) to Directive 89/662/EEC and, as regards pathogens, in Directive 90/425/EEC (OJ L 62, 15.3.1993, p. 49). Directive as last amended by Commission Decision 1999/724/EC (OJ L 290, 12.11.1999, p. 32).

(**15**) **[**[F2]OJ L 273, 10.10.2002, p. 1.**]**

(**16**) **[**[F2]OJ L 31, 1.2.2002, p. 1.**]**

(**17**) **[**[F2]OJ L 86, 6.4.1979, p. 30.**]**

(**18**) **[**[F4]OJ 121, 29.7.1964, p. 2012/64.**]**

(**19**) **[**[F4]OJ L 99, 20.4.1996, p. 14.**]**

(**20**) **[**[F4]OJ L 273, 10.10.2002, p. 1.**]**

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Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council. (See end of Document for details)*

(21) **[**[F4][F5][F6]The minimum sample size has been calculated to detect a prevalence in slaughtered animals of 0,03 % with a 95 % confidence.**]]]**

(22) **[**[F2]OJ L 318, 27.11.1998, p. 45.**]**

(23) **[**[F2]OJ L 265, 5.11.1995, p. 17.**]**

(24) Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC (OJ L 363, 27.12.1990, p. 51). Directive as last amended by the 1994 Act of Accession.

(25) Commission Decision 92/562/EEC of 17 November 1992 on the approval of alternative heat treatment systems for processing high-risk material (OJ L 359, 9.12.1992, p. 23). Decision as amended by the 1994 Act of Accession.

(26) Council Decision 1999/534/EC of 19 July 1999 on measures applying to the processing of certain animal waste to protect against transmissible spongiform encephalopathies and amending Commission Decision 97/735/EC (OJ L 204, 4.8.1999, p. 37).

(27) Commission Decision 97/735/EC of 21 October 1997 concerning certain protection measures with regard to trade in certain types of mammalian animal waste (OJ L 294, 28.10.1997, p. 7). Decision as amended by Council Decision 1999/534/EC (OJ L 204, 4.8.1999, p. 37).

(28) **[**[F3]OJ L 273, 10.10.2002, p. 1.**]**

(29) **[**[F7][F8]OJ L 349, 24.12.2002, p. 105.**]]**

(30) **[**[F7][F9]OJ L 349, 24.12.2002, p. 105.**]]**

(31) Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p. 1). Directive as last amended by Commission Decision 94/113/EC (OJ L 53, 24.2.1994, p. 23).

(32) **[**[F15]OJ L 273, 10.10.2002, p. 1.**]**

(33) **[**[F15]OJ L 9, 15.1.1993, p. 3.**]**

(34) **[**[F15]Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations (OJ L 368, 31.12.1994, p. 10).**]**

(35) **[**[F15]Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products (OJ L 26, 31.1.1977, p. 85). Directive as last amended by Council Directive 97/76/EC (OJ L 10, 16.1.1998, p. 25).**]**

(36) **[**[F15]Delete one of these as appropriate.'**]**

(37) **[**[F23]OJ L 268 24.9.1991, p. 41.**]**

(38) **[**[F23]OJ L 368, 31.12.1994, p. 10.**]**

(39) **[**[F23]OJ L 26, 31.1.1977, p. 85.**]**

(40) **[**[F23]OJ L 268, 14.9.1992, p. 35.**]**

Textual Amendments

F2 Substituted by Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (Text with EEA relevance).

F3 Substituted by Commission Regulation (EC) No 1492/2004 of 23 August 2004 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in bovine, ovine and caprine animals, the trade and

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importation of semen and embryos of ovine and caprine animals and specified risk material (Text with EEA relevance).

F4 Substituted by Commission Regulation (EC) No 2245/2003 of 19 December 2003 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine and caprine animals.

F5 Substituted by Commission Regulation (EC) No 36/2005 of 12 January 2005 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemio-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals (Text with EEA relevance).

F6 Substituted by Commission Regulation (EC) No 214/2005 of 9 February 2005 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in caprine animals (Text with EEA relevance).

F7 Substituted by Commission Regulation (EC) No 260/2003 of 12 February 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos (Text with EEA relevance).

F8 Substituted by Commission Regulation (EC) No 876/2004 of 29 April 2004 amending Annex VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards trade in ovine and caprine animals for breeding (Text with EEA relevance).

F9 Inserted by Commission Regulation (EC) No 1492/2004 of 23 August 2004 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in bovine, ovine and caprine animals, the trade and importation of semen and embryos of ovine and caprine animals and specified risk material (Text with EEA relevance).

F15 Substituted by Commission Regulation (EC) No 1139/2003 of 27 June 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring programmes and specified risk material.

F23 Inserted by Commission Regulation (EC) No 1471/2004 of 18 August 2004 amending Annex XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the import of cervid products from Canada and the United States (Text with EEA relevance).

Status:
Point in time view as at 09/03/2005.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council.