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► **B** 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

(OJ L 147, 31.5.2001, p. 1)

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REGULATION (EC) No 999/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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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

⁽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.

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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 carcase 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 carcase 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.

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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⁽¹⁾.
- (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.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

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- (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.

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;

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- (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 ⁽¹⁾ or Directive 90/425/EEC ⁽²⁾;
- (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 feeding-stuffs; 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.

⁽¹⁾ 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).

⁽²⁾ 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.

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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⁽¹⁾ and those given in or pursuant to Directives 64/432/EEC⁽²⁾, 89/662/EEC, 90/425/EEC and 91/68/EEC⁽³⁾ 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⁽⁴⁾ and Article 22 of Directive 97/78/EC⁽⁵⁾ 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).

⁽¹⁾ 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).

⁽²⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 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).

⁽³⁾ 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).

⁽⁴⁾ 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).

⁽⁵⁾ 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).

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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 reassessment 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.

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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

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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).

CHAPTER IV

CONTROL AND ERADICATION OF TSEs*Article 11***Notification**

Without prejudice to Directive 82/894/EEC ⁽¹⁾, 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

⁽¹⁾ 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).

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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.

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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⁽¹⁾;
 - (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);

⁽¹⁾ 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 (OJ L 23.5.1996, p. 10).

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- (v) hides and skins within the meaning of Directive 92/118/EEC ⁽¹⁾;
- (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

⁽¹⁾ 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).

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laid down by Community legislation relating to trade in the semen, embryos and ova of bovine, ovine or caprine animals 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.

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).

In accordance with that procedure, transitional measures shall be adopted for a maximum period of two years to permit the change-over from the current arrangements to the arrangements established by this Regulation.

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*.

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It shall apply from 1 July 2001.

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

▼B*ANNEX I***SPECIFIC DEFINITIONS**

For the purpose of this Regulation:

- (a) 'indigenous case of BSE' means a case of bovine spongiform encephalitis which has not been clearly demonstrated to be due to infection prior to importation as a live animal, embryo or ovum;
- (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, kidneys and mesentery of bovine animals, and fat from cutting rooms;
- (c) 'cohort' means a group of bovine animals which were either born in the same herd as, and within 12 months preceding or following the birth of, the affected cattle or reared together with the affected animal at any time during the first year of their life and which may have consumed the same feed as that which the affected animal consumed during the first year of its life;
- (d) 'landfill site' means a waste disposal site as defined by Directive 1999/31/EC⁽¹⁾.

⁽¹⁾ Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182, 16.7.1999, p. 1).



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.

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

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- (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:
 - (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:
 - (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.

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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 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.

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ANNEX III

MONITORING SYSTEM

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 ⁽¹⁾, or
- slaughtered in accordance with Annex I, Chapter VI, point 28(c), to Directive 64/433/EEC,

shall be tested for BSE.

2.2. All bovine animals over 30 months of age subject to normal slaughter for human consumption 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 their territory, Austria, Finland and 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**

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 716/962 ⁽²⁾,
- killed in the framework of an epidemic, such as foot-and-mouth disease,
- slaughtered for human consumption,

shall be tested for BSE at random. The number of samples shall not be less than the sample size indicated in the table. The sampling must be representative for each region and continuous.

Total population over 24 months	Sample size (*)
100 000	950
200 000	1 550
300 000	1 890
400 000	2 110
500 000	2 250
600 000	2 360
700 000	2 440
800 000	2 500
900 000	2 550
1 000 000	2 590
1 500 000	3 000
2 000 000	3 500
2 500 000	4 000
3 000 000	4 500
3 500 000	5 000
4 000 000	5 500

⁽¹⁾ OJ L21, 29.7.1964, p. 2012/64.

⁽²⁾ OJ L 99, 20.4.1996, p. 14.

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Total population over 24 months	Sample size (*)
4 500 000	6 000
5 000 000	6 500
5 500 000	7 000
6 000 000	7 500
6 500 000	8 000
7 000 000	8 500
7 500 000	9 000
8 000 000	9 500
8 500 000	10 000
9 000 000	10 500
9 500 000	11 000
10 000 000	11 500
10 500 000	12 000
11 000 000	12 500
11 500 000	13 000
12 000 000	13 500

(*) The sample size has been calculated to detect a prevalence of 0,1 % with a 95 % confidence in the subpopulation referred to in point 3, based on the assumption that the proportion of this subpopulation in the total population of bovine animals over 24 months of age is 1 %. Where the size of the total population of bovine animals over 24 months of age is 1 500 animals or more, the sample size has been increased by 500 samples per 500 000 animals as a proportionality adjustment, to take account of the larger likelihood of variation in risk for BSE within the population.

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 born between 1 August 1996 and 1 August 1997 shall be tested for BSE.
- 4.3. A random sample comprising at least 50 000 animals annually of animals not covered by points 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 feeding-stuffs or were born or derived from BSE infected dams.

6. **Measures following testing**

- 6.1. Where an animal slaughtered for human consumption is tested 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 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 destroyed in accordance with Annex V, point 3 or 4.
- 6.4. All parts of the body of an animal found positive to the rapid test including the hide shall be destroyed in accordance with Annex V, point 3 or 4, apart from material to be retained in conjunction with the records provided for in Chapter B, Section III.

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

II. 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).

2. Monitoring in animals slaughtered for human consumption

Animals over 18 months of age slaughtered for human consumption shall be tested in accordance with the sample size indicated in the table. The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, species, age, breed, production type or any other characteristic. The age of the animals shall be estimated based on dentition, obvious signs of maturity or other reliable information. Multiple sampling in the same flock shall be avoided, where possible.

Total number of slaughtered animals over 18 months of age	Minimum sample size, slaughtered animals (*)
5 000	4 750
10 000	7 760
15 000	9 470
20 000	10 540
25 000	11 270
30 000	11 790
40 000	12 490
50 000	12 940
60 000	13 260
70 000	13 490
80 000	13 660
90 000	13 800
100 000	13 910
150 000	14 250
200 000	14 430
250 000	14 540
300 000	14 610
350 000	14 660
400 000	14 700
450 000	14 730
500 000	14 760
600 000	14 790
700 000	14 820
800 000	14 840
900 000	14 850
1 000 000	14 870
1 100 000	14 880
1 200 000	14 890
1 300 000	14 890

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Total number of slaughtered animals over 18 months of age	Minimum sample size, slaughtered animals (*)
1 400 000	14 900
1 500 000	14 900
1 600 000	14 910
1 700 000	14 910
1 800 000	14 920
1 900 000	14 920
2 000 000	14 920
2 100 000	14 920
2 200 000 or more	14 930

(*) The sample size has been calculated to detect a prevalence of 0,02 % with a 95 % confidence in slaughtered animals.

3. Monitoring in animals not slaughtered for human consumption

Animals over 18 months of age which have died or been killed, but which were not:

- killed in the framework of an epidemic, such as foot-and-mouth disease,
- slaughtered for human consumption,

shall be tested in accordance with the sample size indicated in the table. The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, species, age, breed, production type or any other characteristic. The age of the animal shall be estimated based on dentition, obvious signs of maturity or other reliable information. Multiple sampling in the same flock shall be avoided, where possible.

Total number of animals over 18 months of age (*)	Minimum sample size, dead animals (**)
100 000	950
200 000	1 550
300 000	1 890
400 000	2 110
500 000	2 250
600 000	2 360
700 000	2 440
800 000	2 500
900 000	2 550
1 000 000	2 590
1 500 000 or more	3 000

(*) Where the total number of ovine and caprine animals over 18 months of age is not known, the total number of 'ewes and ewe-lambs put to the ram' and 'goats which have already kidded and goats mated' shall be used instead.

(**) The sample size has been calculated to detect a prevalence of 0,1 % with a 95 % confidence in dead animals, based on the assumption that the proportion of dead animals in the total population of ovine and caprine animals over 18 months of age is 1 %.

4. Monitoring in Member States with a small ovine and caprine population

Member States, where the total number of ovine and caprine animals over 18 months of age is 500 000 or less may, by way of derogation from the

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sampling foreseen in points 2 and 3, decide to monitor the following combined subpopulation:

- (a) animals over 18 months of age which have died or been killed, but which were not:
 - killed in the framework of an epidemic, such as foot-and-mouth disease,
 - slaughtered for human consumption ('dead animals'); and
- (b) animals over 18 months of age whose appearance suggests a chronic wasting condition ('chronic wasting animals').

The number of samples tested annually in each Member State from the above combined subpopulation shall not be less than the sample size indicated in the table.

The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, species, age, breed, production type or any other characteristic. Where dead animals are sampled, the age of the animal shall be estimated based on dentition, obvious signs of maturity or other reliable information. Where chronic wasting animals are sampled, only animals inspected by an official veterinarian and for which the age and clinical symptoms are well documented shall be selected for sampling. Multiple sampling in the same flock shall be avoided, where possible.

Total number of ovine and caprine animals over 18 months of age (*)	Minimum sample size, dead and chronic wasting animals
10 000	100
20 000	200
30 000	300
40 000	400
50 000	500
60 000	600
70 000	700
80 000	800
90 000	900
100 000	950
200 000	1 550
300 000	1 890
400 000	2 110
500 000	2 250

(*) Where the total number of ovine and caprine animals over 18 months of age is not known, the total number of 'ewes and ewe-lambs put to the ram' and 'goats which have already kidded and goats mated' shall be used instead.

5. Monitoring in other animals

In addition to the monitoring programmes set out in points 2 to 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,
- animals from flocks infected with TSE.

6. Measures following testing of ovine and caprine animals

All parts of the body of a tested animal including the hide shall be retained under official control until a negative result to the rapid test has been obtained, unless they are destroyed in accordance with Annex V, point 3 or 4.

All parts of the body of an animal found positive to the rapid test including the hide shall be destroyed in accordance with Annex V, point

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3 or 4, apart from material to be retained in conjunction with the records provided for in Chapter B, section III.

7. Genotyping

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 alanin on both alleles at codon 136, arginin on both alleles at codon 154 and arginin 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 cases is not possible, the herd of origin and all other herds where the animal has been shall be subjected to enhanced monitoring with a view to find other TSE cases for strain-typing.

CHAPTER B

I. INFORMATION TO BE PRESENTED BY MEMBER STATES IN THEIR REPORT

1. The number of suspected cases per animal species placed under movement restrictions in accordance with Article 12(1).
2. The number of suspected cases per animal species subject to laboratory examination in accordance with Article 12(2) and the outcome of the examination.
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 estimated size of each subpopulation referred to in Chapter A, Section I, points 3 and 4.
5. The number of bovine animals tested within each subpopulation referred to in Chapter A, Section I, point 2 to 5, the method for sample selection and the outcome of the tests.
6. The estimated size of those subpopulations referred to in Chapter A, Section II, points 2 to 4, which have been selected for sampling.
7. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, Section II, points 2 to 5, the method for sample selection and the outcome of the tests.
8. Number, age distribution and geographical distribution of positive cases of BSE and scrapie. The country of origin, if not the same as the reporting country, of positive cases of BSE and scrapie. Number and geographical distribution of scrapie positive flocks. The year and, where possible, month of birth should be given for each BSE case.
9. Positive TSE cases confirmed in animals other than bovine, ovine and caprine animals.

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,
 - where chronic wasting ovine and caprine animals have been selected for sampling, the method to establish the age of and the clinical symptoms observed in each sampled animal.

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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.

*ANNEX IV***ANIMAL FEEDING**

1. In Member States or regions thereof placed in category 5, the prohibition referred to in Article 7(1) shall be extended to:
 - (a) the feeding to any farmed animal of protein derived from mammals;
 - (b) the feeding to any mammal of processed animal protein derived from mammals; this prohibition shall not apply to feeding to dogs and cats nor to the production of dog and cat food;
 - (c) the feeding to any ruminant of rendered ruminant fat.
2. The prohibition laid down in Article 7(1) and (2) shall not apply to the following products from healthy animals:
 - (a) milk and milk products;
 - (b) gelatine derived from hides and skins;
 - (c) hydrolysed proteins with a molecular weight below 10 000 daltons which:
 - (i) have been derived from hides and skins obtained from animals which have been slaughtered in a slaughterhouse and have undergone an ante mortem inspection by an official veterinarian in accordance with Chapter VI of Annex I to Directive 64/433/EEC and passed fit, as a result of such inspection, for slaughter for the purpose of that Directive,
and
 - (ii) have been produced by a production process which involves appropriate measures to minimise contamination of hides and skins, preparation of the hides and skins by brining, liming and intensive washing followed by exposure of the material to a pH of more than 11 for more than three hours at a temperature of more than 80 °C and followed by heat treatment of more than 140 °C for 30 minutes at more than 3,6 bar or by an equivalent production process approved by the Commission after consultation of the appropriate Scientific Committee in accordance with the procedure laid down in Article 24(2),
and
 - (iii) come from establishments which carry out an own checks programme (HACCP);
 - (d) dicalcium phosphate (with no trace of protein or fat);
 - (e) dried plasma and other blood products, with the exception of bovine blood products for feeding to ruminants.



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:

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⁽¹⁾, 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⁽²⁾:
 - by incineration;
 - by co-incineration;
 - (ii) in accordance with at least the standards referred to in Annex I to Decision 1999/534/EC⁽³⁾, 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

⁽¹⁾ 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.

⁽²⁾ 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.

⁽³⁾ 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).

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prior staining, 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⁽¹⁾, 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.

⁽¹⁾ 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).

▼B*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.

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ANNEX 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, all its embryos, ova and its progeny collected or 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, embryos or ova, 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, all embryos, ova and the last progeny of the animal in which the disease was confirmed,
 - all animals of the cohort, to be defined in accordance with the procedure laid down in Article 24(2), of the 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 mentioned in the second and third indents,
 - 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 case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals and the destruction of embryos and ova identified by the inquiry referred to in point 1(a), first, second and third indent. The Member State may decide not to kill and destroy all bovine animals on the holding of the animal in which the disease was confirmed as referred to in the first indent of point 1(a), depending upon the epidemiological situation and traceability of the animals on that holding;
 - (b) in 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 point 1(b), second to sixth indents.



ANNEX VIII

PLACING ON THE MARKET AND EXPORT

CHAPTER A

Conditions for intra-Community trade in live animals, embryos and ova

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

1. Dispatch to other Member States must follow the rules of Article 15(1).
2. The following conditions shall apply to the movement of bovine embryos and ova:

Bovine embryos and ova must be derived from female animals which, at the time of collection:

- were not suspected of being infected by BSE;
- themselves complied with the conditions laid down in Part II.

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

(a) Ovine and caprine animals for breeding must:

- (i) come from a holding satisfying the following requirements:
 - it is subject to regular official veterinary checks;
 - the animals are marked;
 - no case of scrapie has been confirmed for at least three years;
 - checking by sampling is carried out on the holding on old female animals intended for culling;
 - females are introduced into that holding only if they come from a holding which complies with the same requirements;
- (ii) have been continuously kept on a holding or holdings complying with the requirements laid down in point (i) since birth or for the last three years;
- (iii) 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), comply with the guarantees provided for in the programmes referred to in that point.

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

- (i) may submit the said programme to the Commission, outlining in particular:
 - the distribution of the disease in the Member State;
 - the reasons for the programme, taking into consideration the importance of the disease and the cost/benefit ratio;
 - the geographical area in which the programme will be implemented;
 - the status categories to be applied to the holdings, the standards which must be attained in each category and the test procedures to be used;
 - the programme 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 programme are positive;
- (ii) the programmes referred to in point (i) may be approved in compliance with the criteria laid down in that point in accordance with the procedure referred to in Article 24(2). According to the same procedure, 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 programmes. Such guarantees must not exceed those which the Member State implements nationally;
- (iii) programmes submitted by Member States may be amended or supplemented in accordance with the procedure referred to in Article 24(2). According to the same procedure, an amendment

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or an addition to a programme which has already been approved or to guarantees which have been defined in accordance with subparagraph (ii) may be approved.

- (c) Where a Member State considers that its territory or part of its territory is free from ovine 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 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).

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

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.

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:
 - (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, axillary, 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.

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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

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;
 - (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.

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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, axillary, 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.
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.

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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.

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.
- 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;

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- (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⁽¹⁾.
- 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:
 - 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;

⁽¹⁾ 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).

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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:
 - (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.

CHAPTER E

Imports of ovine and caprine animals

Ovine and caprine animals imported into the Community are to meet the requirements which provide health guarantees equivalent to those required by this Regulation or pursuant to this Regulation.

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.’

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ANNEX X

REFERENCE LABORATORIES, SAMPLING AND LABORATORY ANALYSIS METHODS

CHAPTER A

National reference laboratories

1. The designated national reference laboratory is to:
 - (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.

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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
Denmark:	Danish Veterinary Laboratory Bülowsvej 27 DK-1790 Copenhagen V
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

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Greece:	<p>Laboratory of Microbiology and Infectious Diseases Faculty of Veterinary Medicine Aristotelian University of Thessaloniki University Campus GR-54006 Thessaloniki (rapid and immunological tests)</p> <p>Laboratory of Gross Pathology (Morgue) Faculty of Veterinary Medicine Aristotelian University of Thessaloniki Giannitson & Voutyra St GR-54627 Thessaloniki (histopathology)</p>
Ireland:	<p>Central Veterinary Research Laboratory Abbotstown Castleknock Dublin 15 Ireland</p>
Italy:	<p>Istituto Zooprofilattico Sperimentale del Piemonte Liguria e Valle d'Aosta CEA Via Bologna I-148-10150 Torino</p>
Luxembourg:	<p>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</p>
Netherlands:	<p>Instituut voor Dierhouderij en Diergezondheid, ID-DLO Lelystad Edelhertweg 15 Postbus 658200 AB Lelystad Netherlands</p>
Portugal:	<p>Laboratório Nacional de Investigação Veterinária Estrada de Benfica, 701 P-1500 Lisboa</p>
Spain:	<p>Laboratorio de la Facultad de Veterinaria Departamento de Patología Animal (Anatomía Patológica) Zaragoza Spain (BSE and scrapie, methods other than rapid tests)</p> <p>Laboratorio Central de Veterinaria de Algete Madrid Spain (rapid tests)</p> <p>Centro de Investigacion en Sanidad Animal (CISA) Crta. De Algete al Casar de Talamanca 28130 Valdeolmos (Madrid) Spain (TSEs other than BSE or scrapie)</p>
Sweden:	<p>National Veterinary Institute S-751 89 Uppsala</p>
United Kingdom	<p>Veterinary Laboratories Agency Woodham Lane New Haw Addlestone Surrey KT15 3NB United Kingdom</p>

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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:
 - (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.

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CHAPTER 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 of standards for diagnostic tests and vaccines* of the International Office for Epizootics (IOE/OIE) (hereinafter referred to as 'the Manual'). In the absence of such methods and protocols, the samples shall be collected in a manner appropriate for the correct application of tests. 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.
3. **Methods and protocols**
 - 3.1. *Laboratory testing for the presence of BSE in bovine animals*
 - (a) Suspect cases

Tissues 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

▼ **M1**

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 the above examinations is positive, the animals shall be regarded a positive BSE case.

(b) BSE monitoring

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

When the result of the rapid test is inconclusive or positive, the tissues 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 tissues shall be subjected to an examination by one of the other diagnostic methods mentioned under (a).

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

- the result of the subsequent histopathological examination is positive, or
- the result of another diagnostic method mentioned under (a) is positive.

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

(a) Suspect cases

Tissues 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 tissues shall be subjected to an examination by immunocytochemistry or immuno-blotting, as laid down in the Manual. However, rapid tests cannot be used for this purpose.

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

(b) Scrapie monitoring

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

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 or immuno-blotting, as referred to under (a).

An animal shall be regarded a positive scrapie case if the result of the confirmatory examination is positive.

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

The tests carried out to confirm the suspected presence of a TSE different from those referred to in points 3.1 and 3.2 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.

▼ M14. **Rapid tests**

For the purposes of carrying out the tests in accordance with Article 5(3) and Article 6(1), the following methods shall be used as rapid tests within the meaning of this Regulation:

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

5. **Alternative tests**

(To be defined)

▼ M2

ANNEX XI

A. Concerning the removal of specified risk material

1. Member States shall ensure that the specified risk material designated below is removed and destroyed in accordance with points 7 to 11.
 - (a) The following tissues are designated as specified risk material:
 - (i) the skull including the brain and eyes, the tonsils, the vertebral column excluding the vertebrae of the tail and the transverse processes of the lumbar vertebrae, but including dorsal root ganglia and spinal cord of bovine animals aged over 12 months, and the intestines from the duodenum to the rectum 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 of ovine and caprine animals of all ages.

A decision may be taken in accordance with the procedure referred to in Article 24(2) in particular with a view to adjust the age for the removal of bovine vertebral column, 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, with particular reference to testing of bovine animals, as established by 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 and in Portugal, with the exception of the Autonomous Region of the Azores:
 - 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.
2. Specified risk material or processed material derived from it may be despatched only with a view to subsequent incineration, in accordance with point 11 or, where appropriate, point 7(b).
3. Member States shall ensure that bones of bovine, ovine and caprine animals are not used for the production of mechanically recovered meat.
4. Member States shall ensure that laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity is not effected within their territory with regard to bovine, ovine or caprine animals whose meat is intended for human or animal consumption.
5. The specified risk material referred to in point 1(a) shall not be imported into the Community after 31 March 2001.

The products of animal origin listed below shall be subject to restrictions on import into the Community:

- 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⁽¹⁾;
- meat products: the meat products defined by Directive 77/99/EEC⁽²⁾,
- other products of animal origin: other products of animal origin as defined by Directive 77/99/EEC,
- rendered fats as referred to by Directive 92/118/EEC,
- gelatin as referred to by Directive 92/118/EEC,
- petfood as referred to by Directive 92/118/EEC,
- the processed animal protein referred to in Directive 92/118/EEC,
- bones and bone products as referred to by Directive 92/118/EEC,
- raw material for the manufacture of animal feedingstuffs as referred to by Directive 92/118/EEC,
- bovine intestines as referred to in Article 2(b)(v) of Directive 77/99/EEC.

⁽¹⁾ 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).

⁽²⁾ 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).

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- (a) 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:

‘The product of animal origin does not contain, and is not derived from any product referred to in Chapter F of Annex IX to Regulation (EC) No 999/2001 of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, nor from specified risk material as defined in Annex V to that Regulation, produced after 31 March 2001, or mechanically recovered meat obtained from bones of the head or vertebral column of bovine, ovine or caprine animals, produced after 31 March 2001. After 31 March 2001 the animals 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.’

- (b) 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.

6. Point 5 shall not apply to imports from:

Australia
 Argentina
 Botswana
 Brazil
 Chile
 Costa Rica
 Namibia
 New Zealand
 Nicaragua
 Paraguay
 Uruguay
 Singapore
 Swaziland.

7. Member States shall carry out frequent official inspections to verify the correct application of this Section and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants, animal waste processing plants, high-risk processing plants or premises approved 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. 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 authorised purposes;
- (b) specified risk material, especially where the removal takes place at establishments or premises other than slaughterhouses, is completely separated from other waste not intended for incineration, is collected separately and is disposed of in accordance with point 1 and points 8 to 11. Member States may decide to allow dispatch of heads or carcasses 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, carcasses, half carcasses and quarter carcasses 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.

8. Member States shall ensure that specified risk material is 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, under the supervision of a designated agent appointed by the competent authority. Those establishments shall be approved for that purpose by the competent authority.

▼ **M2**

However, Member States may provide for the vertebral column to be removed at points of sale to the consumer.

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 must be treated as specified risk material.

9. Member States shall ensure that all specified risk material is stained with a dye and, as appropriate, marked immediately on removal, and completely destroyed:
 - (a) by incineration without pre-processing; or,
 - (b) provided that the dye or marking 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:
 - by incineration,
 - by co-incineration;
 - (ii) in accordance at least with the standards set out in Annex I to Decision 1999/534/EC, by burial in an approved landfill site.
10. Member States may derogate from the provisions of points 8 and 9 to allow the incineration or burial of specified risk material or entire bodies, without prior staining, or, as appropriate, without removal of the specified risk material, 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 approved and verified by the competent authority, in particular where animals have died or have been killed in the context of disease control measures.
11. Member States may despatch specified risk material or the material processed therefrom to other Member States for incineration under the conditions laid down in Article 4(2) of Decision 97/735/EC, where applicable.

This point may be amended at the request of a Member State to allow the despatch of specified risk material or the material processed therefrom to third countries for incineration, conditions governing such export having been adopted.

12. 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 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, Portugal, Finland, Sweden and Austria 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:

- (a) 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;
- (b) 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 or from Portugal with the exception of the Autonomous Region of the Azores.

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

▼M1**B. Concerning statistical surveys**

1. The statistical survey referred to in Article 22 must cover:
 - the animals sampled pursuant to the provisions of Annex III, Chapter A, Section I, points 2.1 and 4.1,
 - all the animals in the subpopulation referred to in Annex III, Chapter A, Section I, point 3, instead of a random sample.

This provision, applicable for a period of one year, may be reviewed in the light of experience gained in the first six months.
2. Austria, Finland and Sweden may decide to derogate from the provisions of point 1, second indent, in remote areas with a low animal density.

▼M2**C. Concerning prohibitions on animal feeding**

Council Decision 2000/766/EC concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein, and Commission Decision 2001/9/EC concerning control measures required for the implementation of Council Decision 2000/766/EC, remain in force.

A decision may be taken in accordance with the procedure referred to in Article 24(2) to adapt Decision 2000/766/EC to the situation of each Member State in the light of the results of Commission inspections and the incidence of BSE, based on the results of BSE monitoring, with particular reference to testing of bovine animals, as established by Annex III.

D. Concerning placing on the market and export

1. The following provisions remain in force as transitional measures:
 - Commission Decision 92/290/EEC of 14 May 1992 concerning certain protection measures relating to bovine embryos in respect of bovine spongiform encephalopathy (BSE) in the United Kingdom.
 - 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.
 - Commission Decision 2000/345/EC of 22 May 2000 setting the date on which dispatch from Portugal to Germany of certain products for the purpose of incineration may commence by virtue of Article 3(6) of Decision 98/653/EC.
 - Commission Decision 2000/371/EC of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to France may commence by virtue of Article 3(7) of Decision 98/653/EC.
 - Commission Decision 2000/372/EC of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to Spain may commence by virtue of Article 3(7) of Decision 98/653/EC.
 - Commission Decision 2001/376/EC of 18 April 2001 concerning measures made necessary by the occurrence of bovine spongiform encephalopathy in Portugal and implementing a date-based export scheme.
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.
3. Imports of bovine embryos and ova are to be subject to the presentation of an international animal health certificate attesting that the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced.

▼ M2

4. Points 2 and 3 shall not apply to imports from:

Australia
Argentina
Botswana
Brazil
Chile
Costa Rica
Namibia
New Zealand
Nicaragua
Paraguay
Uruguay
Singapore
Swaziland.