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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)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Regulation (EC) No 1248/2001 of 22 June 2001	L 173	12	27.6.2001
► <u>M2</u>	Commission Regulation (EC) No 1326/2001 of 29 June 2001	L 177	60	30.6.2001
► <u>M3</u>	Commission Regulation (EC) No 270/2002 of 14 February 2002	L 45	4	15.2.2002
► <u>M4</u>	Commission Regulation (EC) No 1494/2002 of 21 August 2002	L 225	3	22.8.2002
► <u>M5</u>	Commission Regulation (EC) No 260/2003 of 12 February 2003	L 37	7	13.2.2003
► <u>M6</u>	Commission Regulation (EC) No 650/2003 of 10 April 2003	L 95	15	11.4.2003
► <u>M7</u>	Commission Regulation (EC) No 1053/2003 of 19 June 2003	L 152	8	20.6.2003
► <u>M8</u>	Regulation (EC) No 1128/2003 of the European Parliament and of the Council of 16 June 2003	L 160	1	28.6.2003
► <u>M9</u>	Commission Regulation (EC) No 1139/2003 of 27 June 2003	L 160	22	28.6.2003
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► <u>M21</u>	Regulation (EC) No 932/2005 of the European Parliament and of the Council of 8 June 2005	L 163	1	23.6.2005
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► <u>M23</u>	Commission Regulation (EC) No 1974/2005 of 2 December 2005	L 317	4	3.12.2005
► <u>M24</u>	Commission Regulation (EC) No 253/2006 of 14 February 2006	L 44	9	15.2.2006
► <u>M25</u>	Commission Regulation (EC) No 339/2006 of 24 February 2006	L 55	5	25.2.2006
► <u>M26</u>	Commission Regulation (EC) No 657/2006 of 10 April 2006	L 116	9	29.4.2006
► <u>M27</u>	Commission Regulation (EC) No 688/2006 of 4 May 2006	L 120	10	5.5.2006
► <u>M28</u>	Commission Regulation (EC) No 1041/2006 of 7 July 2006	L 187	10	8.7.2006
► <u>M29</u>	Council Regulation (EC) No 1791/2006 of 20 November 2006	L 363	1	20.12.2006
► <u>M30</u>	Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006	L 404	1	30.12.2006

▶ <u>M31</u>	Commission Regulation (EC) No 722/2007 of 25 June 2007	L 164	7	26.6.2007
▶ <u>M32</u>	Commission Regulation (EC) No 727/2007 of 26 June 2007	L 165	8	27.6.2007
▶ <u>M33</u>	Commission Regulation (EC) No 1275/2007 of 29 October 2007	L 284	8	30.10.2007
▶ <u>M34</u>	Commission Regulation (EC) No 1428/2007 of 4 December 2007	L 317	61	5.12.2007
▶ <u>M35</u>	Commission Regulation (EC) No 21/2008 of 11 January 2008	L 9	3	12.1.2008
▶ <u>M36</u>	Commission Regulation (EC) No 315/2008 of 4 April 2008	L 94	3	5.4.2008
▶ <u>M37</u>	Commission Regulation (EC) No 357/2008 of 22 April 2008	L 111	3	23.4.2008
▶ <u>M38</u>	Commission Regulation (EC) No 571/2008 of 19 June 2008	L 161	4	20.6.2008

Amended by:

▶ <u>A1</u>	Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded	L 236	33	23.9.2003
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**REGULATION (EC) No 999/2001 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL**

of 22 May 2001

**laying down rules for the prevention, control and eradication of
certain transmissible spongiform encephalopathies**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

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

Having regard to the proposal from the Commission ⁽¹⁾,

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

Having consulted the Committee of the Regions,

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

Whereas:

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

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

- (6) Provision should be made for safeguard measures to be taken by the Commission in cases where a risk from a TSE has not been adequately addressed by the competent authority of a Member State or third country.
- (7) A procedure should be established for the determination of the epidemiological status of a Member State, a third country and of one of their regions, hereinafter referred to as 'countries or regions' with respect to BSE, on the basis of the incident propagation and human exposure risk, using information available. Member States and third countries which choose not to apply for their status to be determined should be classified in a category by the Commission on the basis of all the information available to it.
- (8) Member States should institute education programmes for those involved in the prevention and control of TSEs, as well as for veterinarians, farmers and workers involved in the transportation, marketing and slaughter of farm animals.

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- (8a) The feeding to non-ruminants of certain processed animal proteins originating from non-ruminants should be allowed taking into account the prohibition on intra-species recycling as laid down in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption⁽¹⁾ and the control aspects in particular linked to the differentiation of processed animal proteins specific to certain species as laid down in the Communication on the TSE Road map adopted by the Commission on 15 July 2005.

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- (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 cate-

⁽¹⁾ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p. 25).

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gories 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.

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- (11a) In its resolution of 28 October 2004 ⁽¹⁾, the European Parliament expressed concerns about feeding animal proteins to ruminants as they do not form part of the natural nutrition of adult cattle. In the wake of the BSE crisis and the foot-and-mouth disease crisis it has increasingly become accepted that the best way to ensure human and animal health is to keep and nourish animals in a way that respects the particularities of each species. Pursuant to the precautionary principle and in keeping with the natural diet and living conditions of ruminants, it is therefore necessary to maintain the prohibition on the feeding of animal proteins to ruminants in forms not normally constituting part of their natural diet.
- (11b) Mechanically separated meat is obtained by removing meat from bones in such a way that the muscle fibre structure is destroyed or modified. It can contain parts of the bones and the periosteum (bone skin). Thus, mechanically separated meat is not comparable with regular meat. Consequently its use for human consumption should be reviewed.

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- (12) The suspected presence of any TSE in any animal should be notified to the competent authority, which should immediately take all appropriate measures, including placing the suspect animal under movement restrictions while awaiting the results of the investigation or having it slaughtered under official supervision. If the competent authority cannot exclude the possibility of a TSE, it should have the appropriate investigations carried out and should keep the carcasse under official supervision until a diagnosis has been made.
- (13) In the event of official confirmation of the presence of a TSE, the competent authority should take all the necessary measures, including having the carcasse destroyed, carrying out an investigation in order to identify all animals at risk and placing movement restrictions on the animals and the products of animal origin identified as such. Owners should be compensated, as soon as possible, for the loss of animals and products of animal origin destroyed pursuant to this Regulation.
- (14) Member States should draw up contingency plans for the national measures to be implemented in the event of an outbreak of BSE. Those plans should be approved by the Commission. Provision should be made for extending this provision to TSEs other than BSE.
- (15) Provisions should be laid down covering the placing on the market of certain live animals and products of animal origin. Existing Community rules on the identification and registration of bovine animals provide for a system enabling the animals to be traced back to the dam and herd of origin in accordance with international standards. Equivalent guarantees should be provided for bovine animals imported from third countries. The animals and products of animal origin covered by Community rules, moving in intra-Community trade or imported from third countries, should be accompanied by the certificates required by the said rules, supplemented as appropriate in accordance with this Regulation.
- (16) The placing on the market of certain products of animal origin derived from bovine animals in high risk regions should be prohibited. However, that prohibition should not apply to

⁽¹⁾ OJ C 174 E, 14.7.2005, p. 178.;

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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.
- (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,

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

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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;

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

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

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

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

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2. The specific definitions set out in Annex I shall also apply.
3. Where the terms in this Regulation are not defined in paragraph 1 or Annex I, the relevant definitions given in Regulation (EC) No 1760/2000 ⁽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****▼M30**

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

⁽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 121 29.7.1964, p. 1977/64). Directive as last amended by Directive 2000/20/EC of the European Parliament and of the Council (OJ L 163, 4.7.2000, p. 35).

⁽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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- negligible BSE risk as defined in Annex II,
- controlled BSE risk as defined in Annex II,
- undetermined BSE risk as defined in Annex II.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAPTER III

PREVENTION OF TSE

*Article 6***Monitoring system****▼M30**

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

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

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

- (a) all bovine animals above 24 months of age sent for emergency slaughter or with observations at ante mortem inspections;
- (b) all bovine animals above 30 months of age slaughtered normally for human consumption;

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

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

1b. After consultation of the appropriate scientific committee, the age laid down in paragraph 1a(a) and (c) may be adapted according to scientific progress in accordance with the procedure referred to in Article 24(3).

At the request of a Member State which can demonstrate the improvement of the epidemiological situation of the country, according to certain criteria to be laid down in accordance with the procedure referred to in Article 24(3), the annual monitoring programmes for that particular Member State may be revised.

The Member State concerned shall provide proof of its capability to determine the effectiveness of the measures in place and ensure protection of human and animal health based on a comprehensive risk analysis. In particular, the Member State shall demonstrate:

- (a) a clearly declining or consistently low BSE prevalence, based on up-to-date testing results;
- (b) that it has implemented and enforced for at least six years a full BSE testing scheme (Community legislation on traceability and identification of live animals and BSE surveillance);
- (c) that it has implemented and enforced for at least six years Community legislation on total feed ban for farmed animals.

▼ B

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.

▼ M30

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

*Article 6a***Breeding Programmes**

1. Member States may introduce breeding programmes to select for resistance to TSEs in their ovine populations. Those programmes shall include a framework to recognise the TSE-resistant status of certain flocks and may be extended to include other animal species based on scientific evidence corroborating the resistance to TSE of particular genotypes of those species.

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

▼M30

3. Member States which introduce breeding programmes shall submit regular reports to the Commission in order to enable the programmes to be scientifically evaluated, in particular with regard to their impact on the incidence of TSEs but also on genetic diversity and variability and on the maintenance of old or rare ovine breeds or of those that are well-adapted to a particular region. The scientific results and overall consequences of the breeding programmes shall be evaluated regularly, and where necessary, those programmes shall be amended accordingly.

▼B*Article 7***Prohibitions concerning animal feeding****▼M30**

1. The feeding to ruminants of protein derived from animals shall be prohibited.
2. The prohibition provided for in paragraph 1 shall be extended to animals other than ruminants and restricted, as regards the feeding of those animals with products of animal origin, in accordance with Annex IV.
3. Paragraphs 1 and 2 shall apply without prejudice to the provisions laid down in Annex IV setting out the derogations from the prohibition contained in those paragraphs.

The Commission may decide in accordance with the procedure referred to in Article 24(3), based on a scientific assessment of the dietary needs of young ruminants and subject to the rules adopted for the implementation of this Article provided for in paragraph 5 of this Article, and following an assessment of the control aspects of this derogation, to allow the feeding of young animals of ruminant species with proteins derived from fish.

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

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

At the request of a Member State or third country a decision in accordance with the procedure referred to in Article 24(2) may be taken, following detailed criteria to be laid down in accordance with the procedure referred to in Article 24(3), to grant individual exemptions from the restrictions in this paragraph. Any exemption shall take account of the provisions provided for in paragraph 3 of this Article.

4a. Based on a favourable risk assessment taking into account at least the amount and possible source of contamination and the final destination of the consignment, a decision may be taken in accordance with the procedure referred to in Article 24(3) to introduce a tolerance level for insignificant amounts of animal proteins in feedingstuffs caused through adventitious and technically unavoidable contamination.

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

▼B*Article 8***Specified risk material****▼M30**

1. The specified risk material shall be removed and disposed of in accordance with Annex V to this Regulation and with Regulation (EC) No 1774/2002. It shall not be imported into the Community. The list of specified risk material referred to in Annex V shall include at least the brain, spinal cord, eyes and tonsils of bovine animals aged over 12 months and the vertebral column of bovine animals above an age to be determined in accordance with the procedure referred to in Article 24(3). Taking into account the different risk categories laid down in the first subparagraph of Article 5(1) and the requirements of Article 6(1a) and (1b) (b), the list of specified risk material in Annex V shall be amended accordingly.

2. Paragraph 1 of this Article 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(3) provided that this test is listed in Annex X, is applied under the conditions provided for in Annex V and the test results are negative.

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

3. In Member States, or regions thereof, with a controlled or undetermined BSE risk, the laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injection into the cranial cavity in connection with stunning, shall not be used on bovine, ovine or caprine animals whose meat is intended for human or animal consumption.

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

5. Rules providing for exemptions from paragraphs 1 to 4 of this Article may be adopted in accordance with the procedure referred to in Article 24(3), with regard to the date of the effective enforcement of the feeding prohibition provided for in Article 7(1) or, as appropriate for third countries or regions thereof with a controlled BSE risk, with regard to the date of the effective enforcement of the ban of mammalian protein in feed for ruminants with a view to limiting the requirements to remove and destroy specified risk material to animals born before that date in the countries or regions concerned.

▼B

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****▼M30**

1. The products of animal origin listed in Annex VI shall be produced using production processes approved in accordance with the procedure referred to in Article 24(3).

2. Bones of bovine, ovine and caprine animals from countries or regions with a controlled or undetermined BSE risk shall not be used for the production of mechanically separated meat (MSM). Before

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1 July 2008, the Member States shall submit a report to the Commission on the use and the production method of MSM in their territory. This report shall include a statement as to whether the Member State intends to continue with the production of MSM.

The Commission shall thereupon present a communication to the European Parliament and the Council on the future necessity and use of MSM in the Community, including the information policy towards consumers.

▼B

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

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

*Article 10***Education programmes**

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

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

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.

⁽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).

▼ B*Article 12***Measures with respect to suspect animals****▼ M30**

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

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

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

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

In accordance with the procedure referred to in Article 24(2) and by way of derogation from the official movement restrictions provided for in this paragraph, a Member State may be exempted from implementing such restrictions if it applies measures offering equivalent safeguards based on an appropriate assessment of the possible risks for human and animal health.

▼ B

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.

▼ M30

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

▼ B

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:

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

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

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

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

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

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

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

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

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

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

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

*Article 14***Contingency plan**

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

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

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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.

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

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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;

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- (b) milk and dairy products, hides and skins, and gelatine and collagen derived from hides and skins.
2. Products of animal origin imported from a third country with a controlled or undetermined BSE risk shall come from healthy bovine, ovine and caprine animals which have not been subjected to a laceration of the central nervous tissue or gas injection into the cranial cavity as referred to in Article 8(3).
3. Food products of animal origin containing material obtained from bovine animals originating in a country or region with an undetermined BSE risk shall not be placed on the market unless they come from animals which:
 - (a) were born eight years after the date from which the prohibition on the feeding to ruminants of animal protein derived from mammals was effectively enforced; and
 - (b) were born, raised and have stayed in herds with a certified history of freedom from BSE for at least seven years.

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

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This prohibition shall not apply to products of animal origin listed in Annex VIII, Chapter C, and fulfilling the requirements of Annex VIII, Chapter C.

They must be accompanied by an animal health certificate issued by an official veterinarian certifying that they have been produced in conformity with this Regulation.

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

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

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

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

Article 17

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

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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).

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

▼M30*Article 23a*

The following measures which are designed to amend non-essential elements of this Regulation, including by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(3):

- (a) approval of the rapid tests referred to in Article 6(1) and Article 8(2),
- (b) adaptation of the age referred to in Article 6(1b),
- (c) criteria to demonstrate improvement of the epidemiological situation referred to in Article 6(1b),
- (d) decision to allow feeding of young animals of ruminant species with proteins derived from fish as referred to in Article 7(3),
- (e) criteria for granting exemptions from the restrictions referred to in Article 7(4),
- (f) decision to introduce a tolerance level as referred to in Article 7(4a),
- (g) decision on age as referred to in Article 8(1),
- (h) rules providing for exemptions from the requirement to remove and destroy specified risk material as referred to in Article 8(5),
- (i) approval of production processes referred to in Article 9(1),
- (j) decision to extend certain provisions to other animal species as referred to in Article 15(3).

*Article 24***Committees**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health. However, the Standing Committee on Zootechnics shall also be consulted by the Commission with regard to Article 6a.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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The time-limits 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. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 24a

Decisions to be adopted in accordance with one of the procedures referred to in Article 24 shall be based on an appropriate assessment of the possible risks for human and animal health and shall, taking into account existing scientific evidence, maintain, or if scientifically justified increase, the level of protection of human and animal health ensured in the Community.

▼B*Article 25***Consultation of the scientific committees**

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

*Article 26***Entry into force**

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

It shall apply from 1 July 2001.

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

▼ **M10**

ANNEX I

SPECIFIC DEFINITIONS

1. For the purpose of this Regulation, the following definitions set out in Regulation (EC) No 1774/2002 of the European Parliament and of the Council ⁽¹⁾, Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽²⁾ and Council Directive 79/373/EEC ⁽³⁾ shall apply:
 - (a) Regulation (EC) No 1774/2002:
 - (i) ‘farmed animal’ in Article 2(1)(f);
 - (ii) ‘petfood’ in point 41 of Annex I;
 - (iii) ‘processed animal protein’ in point 42 of Annex I;
 - (iv) ‘gelatine’ in point 26 of Annex I;
 - (v) ‘blood products’ in point 4 of Annex I;
 - (vi) ‘bloodmeal’ in point 6 of Annex I; and
 - (vii) ‘fishmeal’ in point 24 of Annex I.
 - (b) the definition of ‘feedingstuff’ in Article 3(4) of Regulation (EC) No 178/2002;
 - (c) the definition of ‘complete feedingstuff’ in Article 2(d) of Directive 79/373/EEC.

▼ **M32**

2. For the purpose of this Regulation, the following definitions shall also apply:
 - (a) ‘indigenous case of BSE’ means a case of bovine spongiform encephalopathy which has not been clearly demonstrated to be due to infection prior to importation as a live animal;
 - (b) ‘discrete adipose tissue’ means internal and external body fat removed during the slaughter and cutting process, in particular fresh fat from the heart, caul and kidney of bovine animals, and fat from cutting rooms;
 - (c) ‘cohort’ means a group of bovine animals which includes both:
 - (i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal; and
 - (ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life;
 - (d) ‘index case’ means the first animal on a holding, or in an epidemiologically defined group, in which a TSE infection is confirmed;
 - (e) ‘TSE in Small Ruminants’ means a transmissible spongiform encephalopathy case detected in an ovine or caprine animal following a confirmatory test for abnormal PrP protein;
 - (f) ‘scrapie case’ means a transmissible spongiform encephalopathy confirmed case in an ovine or caprine animal where a diagnosis of BSE has been excluded in accordance with the criteria laid down in the Community reference laboratory’s technical handbook on TSE strain characterisation in small ruminants ⁽⁴⁾;
 - (g) ‘classical scrapie case’ means a scrapie confirmed case classified as classical in accordance with the criteria laid down in the Community reference laboratory’s technical handbook on TSE strain characterisation in small ruminants;
 - (h) ‘atypical scrapie case’ means a scrapie confirmed case which is distinguishable from classical Scrapie in accordance with the criteria laid down in the Community reference laboratory’s technical handbook on TSE strain characterisation in small ruminants.

⁽¹⁾ OJ L 273, 10.10.2002, p. 1.

⁽²⁾ OJ L 31, 1.2.2002, p. 1.

⁽³⁾ OJ L 86, 6.4.1979, p. 30.

⁽⁴⁾ <http://www.defra.gov.uk/corporate/vla/science/science-tse-rl-confirm.htm>

▼ **M31***ANNEX II***DETERMINATION OF BSE STATUS**

CHAPTER A

Criteria

The BSE status of Member States or third countries or regions thereof (hereinafter referred to as countries or regions), shall be determined on the basis of the criteria set out in points (a) to (e).

In the country or region:

- (a) a risk analysis in accordance with the provisions of Chapter B, identifying all the potential factors for BSE occurrence and their historic perspective in the country or region, is carried out;
- (b) a system of continuous surveillance and monitoring of BSE relating in particular to the risks described in Chapter B and complying with the minimal surveillance requirements laid down in Chapter D is in place;
- (c) an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of bovine animals, to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Chapter D of this Annex is in place;
- (d) an obligation to notify and investigate all bovine animals showing clinical signs consistent with BSE is in force;
- (e) the examination of brain or other tissues collected within the framework of the surveillance and monitoring system referred to in point (b) is carried out in an approved laboratory.

CHAPTER B

Risk analysis**1. Structure of the risk analysis**

The risk analyses shall comprise a release assessment and an exposure assessment.

2. Release assessment (external challenge)

- 2.1. The release assessment shall consist of assessing the likelihood that the BSE agent has either been introduced into the country or region via commodities potentially contaminated with a BSE agent, or is already present in the country or region.

The following risk factors shall be taken into account:

- (a) the presence or absence of the BSE agent in the country or region and, if the agent is present, its prevalence based on the outcome of surveillance activities;
 - (b) the production of meat-and-bone meal or greaves from the BSE indigenous ruminant population;
 - (c) imported meat-and-bone meal or greaves;
 - (d) imported bovine and ovine and caprine animals;
 - (e) imported animal feed and feed ingredients;
 - (f) imported products of ruminant origin for human consumption, which may have contained tissues listed in point 1 of Annex V and may have been fed to bovine animals;
 - (g) imported products of ruminant origin for *in vivo* use in bovine animals.
- 2.2. Special eradication schemes, surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the bovine animals population) relevant to the risk factors listed in point 2.1 should be taken into account in carrying out the release assessment.

3. Exposure assessment

The exposure assessment shall consist of assessing the likelihood of exposure of bovine animals to the BSE agent, through a consideration of the following:

▼ **M31**

- (a) recycling and amplification of the BSE agent through consumption by bovine animals of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;
- (b) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- (c) the feeding or not of ruminants with meat-and-bone meal and greaves derived from ruminants, including measures to prevent cross-contamination of animal feed;
- (d) the level of surveillance for BSE conducted on the bovine animals population to that time and the results of that surveillance.

CHAPTER C

Definition of categories

I. COUNTRY OR REGION WITH A NEGLIGIBLE BSE RISK

A country or region:

- (1) where a risk analysis in accordance with Chapter B has been conducted in order to identify the historical and existing risk factors;
- (2) which has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
- (3) which has demonstrated that Type B surveillance, in accordance with Chapter D, is in place, and the relevant points target, in accordance with Table 2 thereof, has been met; and
- (4) which is:
 - (a) either in the following situation:
 - (i) in the country or region there has been no case of BSE, or, any case of BSE has been demonstrated to have been imported and has been completely destroyed;
 - (ii) the criteria in points (c), (d) and (e) of Chapter A of this Annex have been complied with for at least seven years; and
 - (iii) it has been demonstrated through an appropriate level of control and audit that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;
 - (b) or in the following situation:
 - (i) there has been one or more BSE indigenous cases in the country or region but every BSE indigenous case was born more than 11 years ago;
 - (ii) the criteria in points (c), (d) and (e) of Chapter A have been complied with for at least seven years;
 - (iii) it has been demonstrated through an appropriate level of control and audit that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;
 - (iv) the following animals, if alive in the country or region, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed:
 - all BSE cases,
 - all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - if the results of the investigation referred to in the second indent are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases.

▼M31**II. COUNTRY OR REGION WITH A CONTROLLED BSE RISK**

A country or region

- (1) where a risk analysis based on the information laid down in Chapter B has been conducted in order to identify the historical and existing risk factors;
- (2) which has demonstrated that appropriate measures are been taken to manage all identified risks, but those measures have not been taken for the relevant period of time;
- (3) which has demonstrated that Type A surveillance, in accordance with Chapter D, is in place and the relevant points target, in accordance with Table 2, has been met. Type B surveillance may replace Type A surveillance once the relevant points target is met; and
- (4) which is:
 - (a) either in the following situation:
 - (i) in the country or region there has been no case of BSE, or, any case of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points (c), (d) and (e) of Chapter A are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;
 - (ii) the criteria in points (c), (d) and (e) of Chapter A have been complied with for a period shorter than seven years; and/or
 - (iii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for eight years;
 - (b) or in the following situation:
 - (i) in the country or region there has been a BSE indigenous case, the criteria in points (c), (d) and (e) of Chapter A are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;
 - (ii) the criteria in points (c) to (e) of Chapter A of this Annex have been complied with for a period shorter than seven years; and/or
 - (iii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for at least eight years;
 - (iv) the following animals, if alive in the country or region, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed: and
 - all BSE cases, and
 - all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - if the results of the investigation referred to in the second indent are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases.

III. COUNTRY OR REGION WITH UNDETERMINED BSE RISK

A country or region for which the determination of BSE status has not been concluded, or which does not meet the conditions to be fulfilled by the country or region to be classified in one of the other categories.

CHAPTER D**Minimal surveillance requirements****1. Surveillance types**

For the purpose of this Annex, the following definitions shall apply:

▼M31**(a) Type A surveillance**

The application of Type A surveillance will allow the detection of BSE at a design prevalence⁽¹⁾ of at least one case per 100 000 in the adult bovine animals population in the country or region of concern, at a confidence level of 95 %;

(b) Type B surveillance

The application of Type B surveillance will allow the detection of BSE at a design prevalence of at least one case per 50 000 in the adult bovine animals population in the country or region of concern, at a confidence level of 95 %.

Type B surveillance may be carried out by countries or region of negligible BSE risk status to confirm the conclusions of the risk analysis, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by countries or regions of controlled BSE risk status, following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

For the purpose of this Annex, the following four sub-populations of bovine animals have been identified for surveillance purposes:

- (a) bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);
- (b) bovine animals over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; bovine animals over 30 months of age sent for emergency slaughter or with abnormal observations at ante-mortem inspection (casualty or emergency slaughter);
- (c) bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock);
- (d) bovine animals over 36 months of age at routine slaughter.

2. Surveillance strategy

- 2.1. The surveillance strategy shall be designed to ensure that samples are representative of the herd of the country or region, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made shall be fully documented, and the documentation retained for seven years.
- 2.2. In order to implement the surveillance strategy for BSE, a country shall use documented records or reliable estimates of the age distribution of the adult bovine animals population and the number of bovine animals tested for BSE stratified by age and by sub-population within the country or region.

3. Points values and point targets

Surveillance samples must meet the point targets set out in Table 2, on the basis of 'point values' fixed in Table 1. All clinical suspects shall be investigated, regardless of the number of points accumulated. A country shall sample at least three out of the four sub-populations. The total points for samples collected shall be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points. The total points accumulation shall be periodically compared to the target number of points for a country or region.

⁽¹⁾ Design prevalence is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

▼ **M31**

Table 1

Surveillance point values for samples collected from animals in the given sub-population and age category

Surveillance sub-population			
Routine slaughter ⁽¹⁾	Fallen stock ⁽²⁾	Casualty slaughter ⁽³⁾	Clinical suspect ⁽⁴⁾
Age ≥ 1 year and < 2 years			
0,01	0,2	0,4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0,1	0,2	0,4	260
Age ≥ 4 years and < 7 years (middle adult)			
0,2	0,9	1,6	750
Age ≥ 7 years and < 9 years (older adult)			
0,1	0,4	0,7	220
Age ≥ 9 years (aged)			
0,0	0,1	0,2	45

⁽¹⁾ Bovine animals over 36 months of age at routine slaughter.

⁽²⁾ Bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock).

⁽³⁾ Bovine animals over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; bovine animals over 30 months of age sent for emergency slaughter or with abnormal observations at ante-mortem inspection (casualty or emergency slaughter).

⁽⁴⁾ Bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects).

Table 2

Points targets for different adult bovine animals population sizes in a country or region

Points targets for countries or regions		
Adult bovine animals population size (24 months and older)	Type A surveillance	Type B surveillance
≥ 1 000 000	300 000	150 000
800 000-1 000 000	240 000	120 000
600 000-800 000	180 000	90 000
400 000-600 000	120 000	60 000
200 000-400 000	60 000	30 000
100 000-200 000	30 000	15 000
50 000-100 000	15 000	7 500
25 000-50 000	7 500	3 750

4. Specific targeting

Within each of the sub-populations above in a country or region, a country may target bovine animals identifiable as imported from countries or regions where BSE has been detected and bovine animals which have consumed potentially contaminated feedstuffs from countries or regions where BSE has been detected.

▼M31**5. BSE surveillance model**

A country may choose to use the full BSurvE model or an alternative method based on the BSurvE model to estimate its BSE presence/prevalence.

6. Maintenance surveillance

Once the points target has been achieved, and in order to continue to designate the status of a country or region as controlled BSE risk or negligible risk, surveillance can be reduced to Type B surveillance (provided all other indicators remain positive). However, to continue to comply with the requirements laid down in this Chapter, ongoing annual surveillance must continue to include at least three of the four prescribed sub-populations. In addition all bovine animals clinically suspected of being infected with BSE shall be investigated regardless of the number of points accumulated. The annual surveillance in a country or region following the achievement of the required points target, shall be no less than the amount required for one-seventh of its total Type B surveillance target.

▼ **M13***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, except animals without clinical signs of disease slaughtered in the context of a disease eradication campaign,

shall be tested for BSE.

2.2. All bovine animals over 30 months of age:

- subject to normal slaughter for human consumption, or
- slaughtered in the context of a disease eradication campaign in accordance with Annex I, Chapter VI, point 28(c), to Directive 64/433/EEC, but showing no clinical signs of disease,

shall be tested for BSE.

▼ **M27**▼ **M13**3. **Monitoring in animals not slaughtered for human consumption**

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

- killed for destruction pursuant to Commission Regulation (EC) No 716/96 ⁽²⁾,
- killed in the framework of an epidemic, such as foot-and-mouth disease,
- slaughtered for human consumption,

shall be tested for BSE.

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

▼ **M26**4. **Monitoring in animals purchased for destruction pursuant to Regulation (EC) No 716/96**

All animals born between 1 August 1995 and 1 August 1996 killed for destruction pursuant Regulation (EC) No 716/96 shall be tested for BSE.

▼ **M13**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

⁽¹⁾ OJ 121, 29.7.1964, p. 2012/64.

⁽²⁾ OJ L 99, 20.4.1996, p. 14.

▼ M13

animals on their territory, in particular where those animals originate from countries with indigenous BSE, have consumed potentially contaminated feedingstuffs or were born or derived from BSE infected dams.

6. Measures following testing

- 6.1. Where an animal slaughtered for human consumption has been selected for testing for BSE, the health marking provided for in Chapter XI of Annex I to Directive 64/433/EEC shall not be carried out on the carcase of that animal until a negative result to the rapid test has been obtained.
- 6.2. Member States may derogate from the provisions of point 6.1 where an official system is in place in the slaughterhouse ensuring that no parts of examined animals bearing the health mark leave the slaughterhouse until a negative result to the rapid test has been obtained.
- 6.3. All parts of the body of an animal tested for BSE including the hide shall be retained under official control until a negative result to the rapid test has been obtained, unless they are disposed of in accordance with Article 4(2)(a) and (b) of Regulation (EC) No 1774/2002 of the European Parliament and of the Council ⁽¹⁾.

▼ M32

- 6.4. All parts of the body of an animal found positive or inconclusive to the rapid test including the hide shall be disposed of in accordance with Article 4(2)(a) and (b) of Regulation (EC) No 1774/2002, apart from material to be retained in conjunction with the records provided for in Chapter B(III).
- 6.5. Where an animal slaughtered for human consumption is found positive or inconclusive to the rapid test, at least the carcase immediately preceding and the two carcasses immediately following the tested positive or inconclusive animal on the same slaughter line shall be destroyed in accordance with point 6.4. By way of derogation, Member States may decide to destroy the aforementioned carcasses only if the result of the rapid test is confirmed to be positive or inconclusive by confirmatory examinations referred to in Annex X, Chapter C, point 3.1(b).

▼ M13

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

▼ M38**7. Revision of the annual monitoring programmes concerning BSE (BSE monitoring programmes), as provided for in Article 6(1b)****7.1. Member States' applications**

Applications submitted to the Commission by Member States for revision of their annual BSE monitoring programme shall include at least the following:

- (a) information on the annual BSE monitoring system in place during the previous six-year period within the territory of the Member State, including detailed documentation proving compliance with the epidemiological criteria set out in point 7.2;
- (b) information on the bovine identification and traceability system, as referred to in point (b) of the third subparagraph of Article 6(1b), in place during the previous six-year period within the territory of the Member State, including a detailed description of the functioning of the computerised database as referred to in Article 5 of Regulation (EC) No 1760/2000 of the European Parliament and of the Council ⁽²⁾
- (c) information on prohibitions concerning animal feeding during the previous six-year period within the territory of the Member

⁽¹⁾ OJ L 273, 10.10.2002, p. 1.

⁽²⁾ OJ L 204, 11.8.2000, p. 1.

▼ M38

State, including a detailed description of the enforcement of the feed ban for farmed animals, as referred to in point (c) of the third subparagraph of Article 6(1b), including the sampling plan and the number and type of infringements found and the follow-up results;

- (d) a detailed description of the proposed revised BSE monitoring programme that includes the geographical area in which the programme is to be implemented and a description of subpopulations of bovine animals to be covered by the BSE revised monitoring programme, including indications of the age limits and the sample sizes for testing;
- (e) the result of a comprehensive risk analysis showing that the revised BSE monitoring programme will ensure the protection of human and animal health. This risk analysis shall include a birth cohort analysis or other relevant studies aiming to demonstrate that the TSE risk reducing measures, including the feeding prohibitions as referred to in point (c) of the third subparagraph of Article 6(1b), have been implemented in an efficient way.

7.2. Epidemiological criteria

Applications for revision of a BSE monitoring programme may only be accepted if the Member State concerned can demonstrate that, in addition to the requirements laid down in points (a), (b) and (c) of the third subparagraph of Article 6(1b), the following epidemiological criteria are met within its territory:

- (a) for a period of at least six consecutive years following the date of implementation of the Community BSE testing scheme as referred to in point (b) of the third subparagraph of Article 6(1b):

either

- (i) the average decrease of the annual BSE incidence rate observed within the adult bovine animal population (over 24 months of age) was superior to 20 %, and the total number of BSE affected cattle born after the implementation of the Community total feed ban for farmed animals, as referred to in point (c) of the third subparagraph of Article 6(1b), did not exceed 5 % of the total number of confirmed BSE cases;

or

- (ii) the annual observed BSE incidence rate within the adult bovine animal population (over 24 months of age) remained consistently less than 1/100 000;

or

- (iii) as a further option for a Member State with an adult bovine animal population (over 24 months of age) of less than 1 000 000 animals, the cumulated number of confirmed BSE cases remained under five;

- (b) following the six-year period referred to in point (a), there is no evidence that the BSE epidemiological situation is deteriorating.

▼ M32

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 ovine and caprine animals slaughtered for human consumption**

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

▼ **M32**

- (b) Member States in which the population of goats which have already kidded and goats mated exceeds 750 000 animals shall test in accordance with the sampling rules set out in point 4 a minimum annual sample of 10 000 caprine animals slaughtered for human consumption;
- (c) Where a Member State experiences difficulty in collecting sufficient numbers of healthy slaughtered ovine or caprine animals to reach its allotted minimum sample size established in points (a) and (b), it may choose to replace a maximum of 50 % of its minimum sample size by testing dead ovine or caprine animals over the age of 18 months at the ratio of one to one and in addition to the minimum sample size set out in point 3. In addition a Member State may choose to replace a maximum of 10 % of its minimum sample size by testing ovine or caprine animals killed in the framework of a disease eradication campaign over the age of 18 months at the ratio of one to one.
- 3. Monitoring in ovine and caprine animals not slaughtered for human consumption**

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

- killed in the framework of a disease eradication campaign, or
- slaughtered for human consumption.

Table A

Member State population of ewes and ewe lambs put to the ram	Minimum sample size of dead ovine animals ⁽¹⁾
> 750 000	10 000
100 000-750 000	1 500
40 000-100 000	100 % up to 500
< 40 000	100 % up to 100

- ⁽¹⁾ Minimum sample sizes are set to take account of the size of the ovine populations in the individual Member States and are intended to provide achievable targets.

Table B

Member State population of goats which have already kidded and goats mated	Minimum sample size of dead caprine animals ⁽¹⁾
> 750 000	10 000
250 000-750 000	1 500
40 000-250 000	100 % up to 500
< 40 000	100 % up to 100

- ⁽¹⁾ Minimum sample sizes are set to take account of the size of the caprine population in the individual Member States and are intended to provide achievable targets.

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

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

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

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

▼ **M32**

The sampling shall be representative for each region and season. Multiple sampling in the same flock shall be avoided, wherever possible. Member States shall aim their monitoring programmes to achieve, wherever possible, that in successive sampling years all officially registered holdings with more than 100 animals and where TSE cases have never been detected are subject to TSE testing.

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

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

5. Monitoring in infected flocks

Animals over 18 months of age or have more than two permanent incisors erupted through the gum, and which are killed for destruction in accordance with Annex VII, point 2.3(b)(i) or (ii) or point 5(a), shall be tested based on the selection of a simple random sample, in accordance with the sample size indicated in the following table.

Number of animals over 18 months of age or which have more than two permanent incisors erupted through the gum, killed for destruction in the herd or flock	Minimum sample size
70 or less	All eligible animals
80	68
90	73
100	78
120	86
140	92
160	97
180	101
200	105
250	112
300	117
350	121
400	124
450	127
500 or more	150

6. Monitoring in other animals

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

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

▼ M32**7. Measures following testing of ovine and caprine animals**

- 7.1. Where an ovine or caprine animal slaughtered for human consumption has been selected for TSE testing in accordance with point 2, its carcase shall not be marked with the health marking provided for in Section I, Chapter III of Annex I to Regulation (EC) No 854/2004 until a negative result to the rapid test has been obtained.
- 7.2. Member States may derogate from point 7.1. where a system approved by the competent authority is in place in the slaughterhouse ensuring that all parts of an animal can be traced and that no parts of the animals tested bearing the health mark can leave the slaughterhouse until a negative result to the rapid test has been obtained.
- 7.3. All parts of the body of a tested animal, including the hide, shall be retained under official control until a negative result has been obtained to the rapid test, except for animal by-products directly disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.
- 7.4. Except for the material to be retained in conjunction with the records provided for in Chapter B, Part III of this Annex, all parts of the body of an animal found positive to the rapid test, including the hide, shall be directly disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

8. Genotyping

- 8.1. The prion protein genotype for the codons 136, 154 and 171 shall be determined for each positive TSE case in sheep. TSE cases found in sheep of genotypes which encode alanine on both alleles at codon 136, arginine on both alleles at codon 154 and arginine on both alleles at codon 171 shall immediately be reported to the Commission. Where the positive TSE case is an atypical scrapie case the prion protein genotype for the codon 141 shall be determined.
- 8.2. In addition to the animals genotyped in accordance with point 8.1, the prion protein genotype for the codons 136, 141, 154 and 171 of a minimum sample of ovine animals shall be determined. In the case of Member States with an adult sheep population of more than 750 000 animals, this minimum sample shall consist of at least 600 animals. In the case of other Member States the minimum sample shall consist of at least 100 animals. The samples may be chosen from animals slaughtered for human consumption, from animals dead-on-farm or from live animals. The sampling should be representative of the entire ovine population.

▼ M18**III. MONITORING IN OTHER ANIMAL SPECIES**

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

CHAPTER B**REPORTING AND RECORDING REQUIREMENTS****I. REQUIREMENTS ON MEMBER STATES****A. Information to be presented by Member States in their annual report as provided for in Article 6(4)**

1. The number of suspected cases placed under official movement restrictions in accordance with Article 12(1), per animal species.
2. The number of suspected cases subject to laboratory examination in accordance with Article 12(2), per animal species, including the results of the rapid and confirmatory tests (number of positives and negatives) and, with regard to bovine animals, an estimation of the age distribution of all tested animals. The age distribution should be grouped whenever possible as follows: 'below 24 months', distribution per 12 months between 24 and 155 months, and 'above 155 months' of age.

▼ M18

3. The number of flocks where suspected cases in ovine and caprine animals have been reported and investigated pursuant to Article 12(1) and (2).
4. The number of bovine animals tested within each subpopulation referred to in Chapter A, Part (I), points 2.1., 2.2., 2.3., 3.1., 4.1., 4.2., 4.3. and 5. The method for the sample selection, the results of the rapid and confirmatory tests and an estimation of the age distribution of the tested animals grouped as set out in point 2 shall be provided.
5. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, Part II, points 2, 3 and 5 together with the method for sample selection and the results of the rapid and confirmatory tests.
6. The geographical distribution, including the country of origin if not the same as the reporting country, of positive cases of BSE and scrapie. The year, and where possible the month of birth shall be given for each TSE case in bovine, ovine and caprine animals. TSE cases which have been considered atypical and the reasons why shall be indicated. For scrapie cases, the results of the primary molecular testing with a discriminatory immuno-blotting, referred to in Annex X, Chapter C, point 3.2.(c)(i), shall be reported.
7. In animals other than bovine, ovine and caprine, the number of samples and confirmed TSE cases per species.
8. The genotype, and where possible the breed, of each ovine animal either found positive to TSE or sampled in accordance with Chapter A, Part II, points 8.1. and 8.2.

B. Reporting periods

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

▼ M13**II. INFORMATION TO BE PRESENTED BY THE COMMISSION IN ITS SUMMARY**

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

III. RECORDS

1. The competent authority shall keep, for seven years, records of:
 - the number and types of animals placed under movement restrictions as referred to in Article 12(1),
 - the number and outcome of clinical and epidemiological investigations as referred to in Article 12(1),
 - the number and outcome of laboratory examinations as referred to in Article 12(2),
 - the number, identity and origin of animals sampled in the framework of the monitoring programmes as referred to in Chapter A and, where possible, age, breed and anamnestic information,
 - the prion protein genotype of positive TSE cases in sheep.
2. The investigating laboratory shall keep, for seven years, all records of testing, in particular laboratory workbooks and, where appropriate, paraffin blocks and photographs of western blots.

▼ **M22***ANNEX IV***ANIMAL FEEDING****I. Extension of the prohibition provided for in Article 7(1)**

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

- (a) to farmed animals, with the exception of the feeding to carnivorous fur producing animals, of:
 - (i) processed animal protein;
 - (ii) gelatine of ruminant origin;
 - (iii) blood products;
 - (iv) hydrolysed protein;
 - (v) dicalcium phosphate and tricalcium phosphate of animal origin (dicalcium phosphate and tricalcium phosphate);
 - (vi) feedingstuffs containing the proteins listed in points (i) to (v).
- (b) to ruminants, of animal protein and feedingstuffs containing such protein.

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

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

- (a) the feeding to farmed animals of the proteins referred to in points (i), (ii), (iii) and (iv) and of feedingstuffs derived from such proteins:
 - (i) milk, milk-based products and colostrum;
 - (ii) eggs and egg products;
 - (iii) gelatine derived from non-ruminants;
 - (iv) hydrolysed proteins derived from parts of non-ruminants and from ruminant hides and skins;
- (b) the feeding to non-ruminant farmed animals of the proteins referred to in points (i), (ii) and (iii), and of products derived from such proteins:
 - (i) fishmeal, in accordance with the conditions laid down in point B;
 - (ii) dicalcium phosphate and tricalcium phosphate, in accordance with the conditions laid down in point C;
 - (iii) blood products derived from non-ruminants in accordance with the conditions laid down in point D;
- (c) the feeding to fish of blood meal derived from non-ruminants in accordance with the conditions laid down in point D;
- (d) the feeding to farmed animals of tuber and root crops and feedingstuffs containing such products following the detection of bone spicules may be permitted by the Member States if there has been a favourable risk assessment. The risk assessment shall take into account at least the amount and possible source of contamination and the final destination of the consignment.

B. The following conditions shall apply for the use of fishmeal referred to in point A(b)(i) and feedingstuffs containing fishmeal in the feeding of non-ruminant farmed animals (not applicable to the feeding of carnivorous fur producing animals):

- (a) the fishmeal shall be produced in processing plants dedicated exclusively to the production of fish derived products;
- (b) before release for free circulation in the Community, each consignment of imported fishmeal shall be analysed by microscopy in accordance with Directive 2003/126/EC;
- (c) feedingstuffs containing fishmeal shall be produced in establishments which do not produce feedingstuffs for ruminants and which are authorised for this purpose by the competent authority.

▼ M22

By way of derogation from point (c):

- (i) a specific authorisation for the production of complete feeding-stuffs from feedingstuffs containing fishmeal shall not be required for home compounders:
 - registered by the competent authority,
 - keeping only non-ruminants,
 - producing complete feedingstuffs for use only in the same holding, and
 - provided that the feedingstuffs containing fishmeal used in the production contain less than 50 % crude protein;
- (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing fishmeal for other animal species may be authorised by the competent authority subject to the following conditions:
 - bulk and packaged feedingstuffs destined for ruminants are kept in facilities physically separate from those for bulk fishmeal and bulk feedingstuffs containing fishmeal during storage, transport and packaging,
 - feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feeding-stuffs containing fishmeal are manufactured,
 - records detailing the purchases and uses of fishmeal and the sales of feedingstuffs containing fishmeal are kept available to the competent authority for at least five years, and
 - routine tests are carried out on feedingstuffs destined for ruminants to ensure that prohibited proteins including fishmeal are not present.
- (d) The label and accompanying document of feedingstuffs containing fishmeal shall clearly indicate the words contains fishmeal — shall not be fed to ruminants.
- (e) Bulk feedingstuffs containing fishmeal shall be transported by means of vehicles which do not at the same time transport feedingstuffs for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure approved by the competent authority to avoid cross-contamination.
- (f) The use and storage of feedingstuffs containing fishmeal shall be prohibited in farms where ruminants are kept.

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

C. The following conditions shall apply for the use of dicalcium phosphate and tricalcium phosphate referred to in point A(b)(ii) and feedingstuffs containing such proteins in the feeding of non-ruminant farmed animals (not applicable to the feeding of carnivorous fur producing animals):

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

By way of derogation from that condition:

- (i) a specific authorisation for the production of complete feeding-stuffs from feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall not be required for home compounders:
 - registered by the competent authority,
 - keeping only non-ruminants,

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- producing complete feedingstuffs for use only in the same holding, and
 - provided that the feedingstuffs containing dicalcium phosphate or tricalcium phosphate used in the production contain less than 10 % total phosphorus;
- (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing dicalcium phosphate or tricalcium phosphate for other animal species may be authorised by the competent authority subject to the following conditions:
- bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from those where feedingstuffs containing dicalcium phosphate or tricalcium phosphate are manufactured,
 - bulk feedingstuffs destined for ruminants are during storage, transport and packaging kept in facilities physically separate from those for bulk dicalcium phosphate, bulk tricalcium phosphate and bulk feedingstuffs containing dicalcium phosphate or tricalcium phosphate,
 - records detailing the purchases and uses of dicalcium phosphate or tricalcium phosphate and the sales of feedingstuff containing dicalcium phosphate or tricalcium phosphate are kept available to the competent authority for at least five years.

- (b) The label and accompanying document of the feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall clearly indicate the words 'contains dicalcium/tricalcium phosphate of animal origin – shall not be fed to ruminants'.
- (c) Bulk feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be transported by means of vehicles which do not at the same time transport feedingstuffs for ruminants. If the vehicle is subsequently used for the transport of feedingstuffs intended for ruminants, it shall be thoroughly cleaned in accordance with a procedure approved by the competent authority to avoid cross-contamination.
- (d) The use and storage of feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall be prohibited in farms where ruminants are kept.

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

- D. The following conditions shall apply for the use of blood products referred to in point A(b)(iii) and blood meal referred to in point A(c) and of feedingstuffs containing such proteins, in the feeding of respectively non-ruminant farmed animals and fish:

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

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

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

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- keeping collection, storage, transport and packaging facilities for blood of ruminant origin physically separate from those for blood of non-ruminant origin, and
- regular sampling and analysis of blood of non-ruminant origin to detect the presence of ruminant proteins

- (b) The blood products and blood meal shall be produced in an establishment exclusively processing non-ruminant blood.

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

- processing of non-ruminant blood in a closed system physically separate from the processing of ruminant blood,
- keeping of bulk raw material and bulk finished products of ruminant origin during storage, transport and packaging in facilities physically separate from those for bulk raw material and bulk finished products of non-ruminant origin, and
- regular sampling and analysis of non-ruminant blood products and blood meal to detect the presence of ruminant proteins.

- (c) Feedingstuffs containing blood products or blood meal shall be produced in establishments which do not prepare feedingstuffs for respectively ruminants or farmed animals other than fish and which are authorised for this purpose by the competent authority.

By way of derogation from that condition:

- (i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing blood products or blood meal shall not be required for home compounders:

- registered by the competent authority,
- keeping only non-ruminants in case blood products are used, or only fish in case blood meal is used,
- producing complete feedingstuffs for use only in the same holding, and
- provided that the feedingstuffs containing blood products or blood meal used in the production contain less than 50 % total protein.

- (ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing blood products or blood meal for respectively non-ruminant farmed animals or fish may be authorised by the competent authority subject to the following conditions:

- bulk and packaged feedingstuffs destined for ruminants or farmed animals other than fish are manufactured in facilities physically separate from those where feedingstuffs containing respectively blood products or blood meal are manufactured,
- bulk feedingstuffs kept, during storage transport and packaging, in physically separate facilities as follow:
 - (a) feedingstuff destined for ruminants is kept separate from blood products and from feedingstuffs containing blood products;
 - (b) feedingstuff destined for farmed animals other than fish is kept separate from blood meal and feedingstuffs containing blood meal,
- records detailing the purchases and uses of blood products and blood meal, and the sales of feedingstuffs containing such products, are kept available to the competent authority for at least five years.

- (d) The label, accompanying commercial document or health certificate, as appropriate, of the feedingstuffs containing blood products or

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blood meal shall clearly indicate the words ‘contains blood products – shall not be fed to ruminants’ or ‘contains blood meal – shall only be fed to fish’ as appropriate.

- (e) Bulk feedingstuffs containing blood products shall be transported by means of vehicles which do not transport at the same time feedingstuffs for ruminants and bulk feedingstuffs containing blood meal by means of vehicles which do not transport at the same time feedingstuffs for farmed animals other than fish. If the vehicle is subsequently used for the transport of feedingstuffs intended for respectively ruminants or farmed animals other than fish, it shall be thoroughly cleaned in accordance with a procedure to avoid cross-contamination approved by the competent authority.
- (f) The use and storage of feedingstuffs containing blood products shall be prohibited in farms where ruminants are kept, and that of feedingstuffs containing blood meal shall be prohibited in farms where farmed animals other than fish are kept.

By way of derogation, the competent authority may permit the use and storage of feedingstuffs containing respectively blood products or blood meal in farms where respectively ruminants or farmed animals other than fish are kept, if it is satisfied that on-farm measures are implemented to prevent that feedingstuffs containing respectively blood products or blood meal are fed to respectively ruminants or species other than fish.

III. General implementing conditions

- A. This Annex shall apply without prejudice to the provisions in Regulation (EC) No 1774/2002.
- B. Member States shall keep up-to-date lists of:
 - (a) slaughterhouses approved for the collection of blood in accordance with point D(a) of Part II;
 - (b) approved processing plants producing dicalcium phosphate, tricalcium phosphate, blood products or blood meal, and
 - (c) establishments, with the exception of home compounders, authorised for manufacturing feedingstuffs containing fishmeal and the proteins referred to in point (b) which operate in accordance with the conditions laid down in points B(c), C(a) and D(c) of Part II.
- C. (a) Bulk processed animal protein, with the exception of fishmeal, and bulk products, including feedingstuffs, organic fertilisers and soil improvers, containing such proteins, shall be stored and transported in dedicated facilities. The store or vehicle may only be used for other purposes, following cleaning, and after having been inspected by the competent authority.
- (b) Bulk fishmeal referred to in point A(b)(i) of Part II, bulk dicalcium phosphate and bulk tricalcium phosphate referred to in point A(b)(ii) of Part II, blood products referred to in point A(b)(iii) of Part II and blood meal referred to in point A(c) of Part II shall be stored and transported in stores and vehicles dedicated to that purpose.
- (c) By way of derogation from point (b):
 - (i) stores or vehicles may be used for the storage and transport of feedingstuffs containing the same protein;
 - (ii) stores or vehicles, following cleaning, may be used for other purposes after having been inspected by the competent authority; and
 - (iii) stores and vehicles transporting fishmeal may be used for other purposes if the company has a control system in place, recognised by the competent authority, to prevent cross-contamination. The control system shall at least include:
 - records on material transported and cleaning of the vehicle, and
 - regular sampling and analysis of feedingstuffs transported to detect the presence of fishmeal.

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The competent authority shall carry out frequent on-the-spot checks to verify the correct application of the above control system.

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

Bulk feedingstuffs, including petfood, which contain blood products of ruminant origin or processed animal proteins, other than fishmeal, shall during storage, transport and packaging be kept in facilities physically separate from facilities for bulk feedingstuffs for farmed animals, with the exception of feedingstuffs for carnivorous fur producing animals.

Petfood and feedingstuffs intended for carnivorous fur producing animals containing dicalcium phosphate or tricalcium phosphate referred to in point A(b)(ii) of Part II, and blood products referred to in point A(b)(iii) of Part II shall be manufactured and transported in accordance with points C(a) and (c) and points D(c) and (e), respectively of Part II.

- E. 1. The export to third countries of processed animal proteins derived from ruminants, and of products containing such processed animal proteins, shall be prohibited.
2. The export of processed animal proteins derived from non-ruminants and of products containing such proteins shall only be permitted by the competent authority subject to the following conditions:
- they are destined for uses not prohibited by Article 7,
 - a written agreement with the third country is made prior to exportation, which includes an undertaking from the third country to respect the final use and not to re-export the processed animal protein or products containing such proteins for uses prohibited by Article 7.
3. Member States which permit exports in accordance with point 2 shall for the effective implementation of this Regulation inform the Commission and the other Member States of all terms and conditions as agreed with the third country concerned, in the context of the Standing Committee on the Food Chain and Animal Health.

Points 2 and 3 shall not apply to:

- exports of fishmeal, provided it fulfils the conditions set out in point B of Part II,
- products containing fishmeal,
- petfood.

- F. The competent authority shall carry out documentary and physical checks, including tests on feedingstuffs, throughout the production and distribution chain in accordance with Directive 95/53/EC to control compliance with its provisions and with the provisions of this Regulation. Where any presence of prohibited animal protein is detected, Directive 95/53/EC shall apply. The competent authority shall verify on a regular basis the competence of laboratories carrying out analyses for such official controls, in particular by evaluating the results of ring trials. If the competence is considered unsatisfactory, a re-training of the laboratory staff shall be undertaken as the minimal corrective measure.

▼M31*ANNEX V***SPECIFIED RISK MATERIAL****1. Definition of specified risk material**

The following tissues shall be designated as specified risk material if they come from animals whose origin is in a Member State or third country or of one of their region with a controlled or undetermined BSE risk:

- (a) as regards bovine animals:
 - (i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months;

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- (ii) the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months; and

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- (iii) the tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages.

- (b) as regards ovine and caprine animals

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

2. Derogation for Member States

By way of derogation from point 1, tissues listed in that point whose origin is in Member States with a negligible BSE risk shall continue to be considered as specified risk material.

3. Marking and disposal

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

4. Removal of specified risk material**4.1. Specified risk material shall be removed at:**

- (a) slaughterhouses, or, as appropriate, other places of slaughter;
- (b) cutting plants, in the case of vertebral column of bovine animals;
- (c) where appropriate, in intermediate plants referred to in Article 10 of Regulation (EC) No 1774/2002 or users and collection centres authorised and registered pursuant to Article 23(2)(c)(iv), (vi) and (vii) of Regulation (EC) No 1774/2002.

4.2. By way of derogation from point 4.1, 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.

4.3. By way of derogation from point 4.1, Member States may decide to allow:

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- (a) the removal of spinal cord of ovine and caprine animals in cutting plants specifically authorised for this purpose;
 - (b) the removal of bovine vertebral column from carcasses or parts of carcasses in butcher shops specifically authorised, monitored and registered for this purpose;
 - (c) the harvesting of head meat from bovine animals in cutting plants specifically authorised for this purpose in accordance with the provisions laid down in point 9.
- 4.4. The rules on removal of specified risk material laid down in this Chapter shall not apply to Category 1 material as defined in Regulation (EC) No 1774/2002 used under the supervision of competent authorities for feeding of endangered and protected species of necrophagous birds.
5. **Measures concerning mechanically separated meat**
- Notwithstanding the individual decisions referred to in Article 5(2), and by way of derogation from Article 9(3), it shall be prohibited in all Member States to use bones or bone-in cuts of bovine, ovine and caprine animals for the production of mechanically separated meat.
6. **Measures concerning laceration of tissues**
- Notwithstanding the individual decisions referred to in Article 5(2), and by way of derogation from Article 8(3), in all Member States, until all Member States are classified as countries with negligible BSE risk, laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity after stunning shall be prohibited in bovine, ovine or caprine animals whose meat is intended for human or animal consumption.
7. **Harvesting of tongues from bovine animals**
- Tongues of bovine animals of all ages intended for human or animal consumption shall be harvested at the slaughterhouse by a transverse cut rostral to the lingual process of the basihyoid bone.
8. **Harvesting of bovine head meat**
- 8.1. Head meat of bovine animals above 12 months of age shall be harvested at slaughterhouses, in accordance with a control system, recognised by the competent authority, to ensure the prevention of possible contamination of head meat with central nervous system tissue. The system shall include at least the following provisions:
- (a) harvesting shall take place in a dedicated area, physically separated from the other parts of the slaughterline;
 - (b) where the heads are removed from the conveyor or hooks before harvesting the head meat, the frontal shot hole and foramen magnum shall be sealed with an impermeable and durable stopper. Where the brainstem is sampled for laboratory testing for BSE, the foramen magnum shall be sealed immediately after that sampling;
 - (c) head meat shall not be harvested from heads where the eyes are damaged or lost immediately prior to, or after slaughter, or which are otherwise damaged in a way which might result in contamination of the head with central nervous tissue;
 - (d) head meat shall not be harvested from heads which have not been properly sealed in accordance with the second indent;
 - (e) without prejudice to general rules on hygiene, specific working instructions shall be in place to prevent contamination of the head meat during the harvesting, in particular in the case when the seal referred to in the second indent is lost or the eyes damaged during the activity;
 - (f) a sampling plan using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented.
- 8.2. By way of derogation from the requirements of point 8.1, Member States may decide to apply at the slaughterhouse an alternative control system for the harvesting of bovine head meat, leading to an equivalent reduction in the level of contamination of head meat with central nervous system tissue. A sampling plan using an appropriate laboratory test to detect central

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nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented. Member States using this derogation shall inform the Commission and the other Member States in the framework of the Standing Committee of the Food Chain and Animal Health of their control system and the results of the sampling.

- 8.3. If the harvesting is performed without removing the bovine head from the conveyor or hooks, points 8.1 and 8.2 shall not apply.

9. Harvesting of bovine head meat in authorised cutting plants

By way of derogation from point 8, Member States may decide to allow the harvesting of head meat from bovine in cutting plants specifically authorised for this purpose and provided that the following conditions are complied with:

- (a) the heads intended for transport to the cutting plant shall be suspended on a rack during the storing period and the transport from the slaughterhouse to the cutting plant;
- (b) the frontal shot hole and the foramen magnum shall be properly sealed with an impermeable and durable stopper before being moved from the conveyor or hooks to the racks. Where the brainstem is sampled for laboratory testing for BSE, the foramen magnum shall be sealed immediately after that sampling;
- (c) the heads which have not been properly sealed in accordance with point (b), where the eyes are damaged or lost immediately prior to or after slaughter or which were otherwise damaged in a way which might result in contamination of the head meat with central nervous tissue shall be excluded from transport to the specifically authorised cutting plants;
- (d) a sampling plan for the slaughterhouse using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify the proper implementation of the measures to reduce contamination;
- (e) the harvesting of head meat shall be carried out in accordance with a control system, recognized by the competent authority, to ensure the prevention of possible contamination of head meat. The system shall include at least:
 - (i) all heads shall be visually checked for signs of contamination or damage and proper sealing before the harvesting of the head meat begins;
 - (ii) head meat shall not be harvested from heads which have not been properly sealed, where the eyes are damaged or which were otherwise damaged in a way which might result in contamination of the head meat with central nervous tissue. Head meat shall also not be harvested from any head where contamination from such heads is suspected;
 - (iii) without prejudice to general rules on hygiene, specific working instructions shall be in place to prevent contamination of the head meat during transport and harvesting, in particular where the seal is lost or the eyes damaged during the activity;
- (f) a sampling plan for the cutting plant using an appropriate laboratory test to detect central nervous system tissue shall be in place to verify that the measures to reduce contamination are properly implemented.

10. Rules on trade and export

- 10.1. Member States may allow dispatch of heads or of un-split carcasses containing specified risk material to another Member State only after that Member State has agreed to receive the material and has approved the conditions of dispatch and transport.
- 10.2. By way of derogation from point 10.1, carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be dispatched from one Member State to another without the latter's prior agreement.
- 10.3. Exports outside the Community of heads and of fresh meat of bovine, ovine or caprine animals containing specified risk materials shall be prohibited.

▼M31**11. Controls**

- 11.1. Member States shall carry out frequent official controls to verify the correct application of this Annex and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants or other places where specified risk material is removed, such as butcher shops or establishments referred in point 4.1 (c).
- 11.2. Member States shall in particular set up a system to ensure and check that specified risk material is handled and disposed of in accordance with Regulation (EC) No 999/2001 and Regulation (EC) No 1774/2002.
- 11.3. A control system shall be put in place for the removal of the vertebral column as specified in point 1(a). The system shall include at least the following measures:
 - (a) when removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000;
 - (b) specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as the number where removal of the vertebral column is not required, shall be added on the commercial document relating to consignments of meat. When applicable, the specific information shall be added to the document referred to in Article 2(1) of Commission Regulation (EC) No 136/2004 ⁽¹⁾ in the case of imports;
 - (c) butcher shops shall keep, for at least one year, the commercial documents referred to in (b).

⁽¹⁾ OJ L 21, 28.1.2004, p. 11.

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ANNEX VI

**PRODUCTS OF ANIMAL ORIGIN DERIVED FROM OR CONTAINING
RUMINANT MATERIAL, AS REFERRED TO IN ARTICLE 9(1)**

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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.

▼ **M32***ANNEX VII***ERADICATION OF TRANSMISSIBLE SPONGIFORM
ENCEPHALOPATHY****CHAPTER A****Measures following confirmation of the presence of a TSE**

1. The inquiry referred to in Article 13(1)(b) must identify:
 - (a) in the case of bovine animals:
 - all other ruminants on the holding of the animal in which the disease was confirmed,
 - where the disease was confirmed in a female animal, its progeny born within two years prior to, or after, clinical onset of the disease,
 - all animals of the cohort of the animal in which the disease was confirmed,
 - the possible origin of the disease,
 - other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
 - the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;
 - (b) in the case of ovine and caprine animals:
 - all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,
 - in so far as they are identifiable, the parents, and in the case of females all embryos, ova and the last progeny of the female animal in which the disease was confirmed,
 - all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those referred to in the second indent,
 - 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 TSE agent to or from the holding in question.
2. The measures laid down in Article 13(1)(c) shall comprise at least:
 - 2.1. In the case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in the second and third indents of point 1(a); however, the Member State may decide:
 - not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,
 - to defer the killing and destruction of animals in the cohort referred to in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death.
 - 2.2. If a TSE is suspected in an ovine or caprine animal on a holding in a Member State, all other ovine and caprine animals from that holding shall be placed under official movement restriction until the results of the examination are available. If there is evidence that the holding where the animal was present when the TSE was suspected is not likely to be the holding where the animal could have been exposed to a TSE, the competent authority may decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

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2.3. In the case of confirmation of TSE in an ovine or caprine animal:

- (a) if BSE cannot be excluded after the results of a ring trial carried out in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b);
- (b) if BSE is excluded in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), pursuant to the decision of the competent authority:

either

- (i) the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). The conditions set out in point 3 shall apply to the holding;

or

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

- breeding rams of the ARR/ARR genotype,
- breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,
- sheep carrying at least one ARR allele which are intended solely for slaughter,
- if the competent authority so decides, sheep and goats less than three months old which are intended solely for slaughter.

The conditions set out in point 3 shall apply to the holding;

or

- (iii) a Member State may decide not to kill and destroy the animals, identified by the inquiry referred to in the second and third indents of point 1(b) where it is difficult to obtain replacement ovine animals of a known genotype or where the frequency of the ARR allele within the breed or holding is low, or where it is deemed necessary in order to avoid inbreeding, or based on a reasoned consideration of all the epidemiological factors. The conditions set out in point 4 shall apply to the holding;

- (c) by way of derogation from the measures set out in point (b), and only where the TSE case confirmed on a holding is an atypical scrapie case, the Member State may decide to apply the measures laid down in point 5.

(d) Member States may decide:

- (i) to replace the killing and complete destruction of all animals referred to in b(i) by slaughtering for human consumption;
- (ii) to replace the killing and complete destruction of animals referred to in b(ii) by slaughtering for human consumption;

provided that:

- the animals are slaughtered within the territory of the concerned Member State,
- all animals which are over 18 months of age or have more than two permanent incisors erupted through the gum and are slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2(b);

- (e) the prion protein genotype of ovine animals, up to a maximum of 50, killed and destroyed or slaughtered for human consumption in accordance with points (b)(i) and (iii) shall be determined;

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- (f) Where the frequency of the ARR allele within the breed or holding is low, or where it is deemed necessary in order to avoid inbreeding, a Member State may decide to delay the destruction of animals as referred to in point 2.3 (b)(i) and (ii) for up to five breeding years.

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- 2.4. If the infected animal has been introduced from another holding, a Member State may decide, based on the history of the case, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed; in the case of land used for common grazing by more than one flock, Member States may decide to limit the application of those measures to a single flock, based on a reasoned consideration of all the epidemiological factors; where more than one flock is kept on a single holding, Member States may decide to limit the application of the measures to the flock in which the TSE has been confirmed, provided it has been verified that the flocks have been kept isolated from each other and that the spread of infection between the flocks through either direct or indirect contact is unlikely.
3. Following the application on a holding of the measures referred to in point 2.3(a) and (b)(i) and (ii):
- 3.1. Only the following animals may be introduced to the holding(s):
- (a) male sheep of the ARR/ARR genotype;
 - (b) female sheep carrying at least one ARR allele and no VRQ allele;
 - (c) caprine animals, provided that:
 - (i) no ovine animals for breeding other than those of the genotypes referred to in points (a) and (b) are present on the holding;
 - (ii) thorough cleaning and disinfection of all animal housing on the premises has been carried out following destocking.
- 3.2. Only the following ovine germinal products may be used in the holding(s):
- (a) semen from rams of the ARR/ARR genotype;
 - (b) embryos carrying at least one ARR allele and no VRQ allele.
- 3.3. Movement of the animals from the holding shall be subject to the following conditions:
- (a) movement of ARR/ARR sheep from the holding shall not be subject to any restriction;
 - (b) sheep carrying only one ARR allele may be moved from the holding only to go directly for slaughter for human consumption or for the purposes of destruction; however,
 - ewes carrying one ARR allele and no VRQ allele may be moved to other holdings which are restricted following the application of measures in accordance with point 2.3(b)(ii) or 4,
 - if the competent authority so decides, lambs and kids may be moved to one other holding solely for the purposes of fattening prior to slaughter; the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter;
 - (c) caprine animals may be moved provided that the holding is subjected to intensified TSE monitoring, including the testing of all caprine animals which are over the age of 18 months and:
 - (i) are slaughtered for human consumption at the end of their productive lives; or
 - (ii) have died or been killed on the holding, and meet the conditions set out in Annex III, Chapter A, Part II, point 3;
 - (d) if the Member State so decides, lambs and kids less than three months old may be moved from the holding to go directly for slaughter for human consumption.
- 3.4. The restrictions set out in points 3.1, 3.2 and 3.3 shall continue to apply to the holding for a period of two years from:

▼ **M32**

- (a) the date of attainment of ARR/ARR status by all ovine animals on the holding; or
 - (b) the last date when any ovine or caprine animal was kept on the premises; or
 - (c) the date when the intensified TSE monitoring set out in 3.3(c) commenced; or
 - (d) the date when all breeding rams on the holding are of ARR/ARR genotype and all breeding ewes carry at least one ARR allele and no VRQ allele, provided that during the two-year period, negative results are obtained from TSE testing of the following animals over the age of 18 months:
 - an annual sample of ovine animals slaughtered for human consumption at the end of their productive lives in accordance with the sample size referred to in the Table in Annex III, Chapter A, Part II, point 5, and
 - all ovine animals referred to in Annex III, Chapter A, Part II, point 3 which have died or been killed on the holding.
4. Following the application on a holding of the measures set out in point 2.3(b)(iii) and for a period of two breeding years following the detection of the last TSE case:
- (a) all ovine and caprine animals on the holding shall be identified;
 - (b) all ovine and caprine animals on the holding may be moved only within the territory of the concerned Member State for slaughter for human consumption or for the purposes of destruction; all animals over the age of 18 months slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b);
 - (c) the competent authority shall ensure that embryos and ova are not dispatched from the holding;
 - (d) only the semen from rams of the ARR/ARR genotype and embryos carrying at least one ARR allele and no VRQ allele may be used in the holding;
 - (e) all ovine and caprine animals which are over the age of 18 months which have died or been killed on the holding shall be subject to TSE testing;
 - (f) only male sheep of the ARR/ARR genotype and female ovine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions set out in point 3.4 may be introduced in the holding;
 - (g) only caprine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions of point 3.4 may be introduced in the holding;
 - (h) All ovine and caprine animals in the holding shall be subject to common grazing restrictions to be determined by the competent authority, based on a reasoned consideration of all the epidemiological factors;
 - (i) by way of derogation of point (b) if the competent authority so decides, lambs and kids may be moved to another holding within the same Member State solely for the purposes of fattening prior to slaughter; provided that the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter.
5. Following the application of the derogation provided for in point 2.3(c) the following measures shall apply:
- (a) either the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). Member States may decide to determine the prion protein genotype of ovine animals which have been killed and destroyed;
 - (b) or, for a period of two breeding years following the detection of the last TSE case, at least the following measures:

▼ **M32**

- (i) all ovine and caprine animals in the holding shall be identified;
 - (ii) the holding must be subject to intensified TSE monitoring for a two years period, including the testing of all ovine and caprine animals which are over the age of 18 months and slaughtered for human consumption and all ovine and caprine animals over the age of 18 which have died or been killed on the holding;
 - (iii) the competent authority shall ensure that live ovine and caprine animals, embryos and ova from the holding are not dispatched to other Member States or third countries.
6. Member States applying the measures set out in point 2.3(b)(iii) or the derogations provided for in points 2.3(c) and (d) shall notify to the Commission an account of the conditions and criteria used for granting them. Where additional TSE cases are detected in flocks where derogations are applied, the conditions for granting such derogations shall be reassessed.

CHAPTER B

Minimum requirements for a breeding programme for resistance to TSEs in sheep in accordance with Article 6a*PART 1**General requirements*

1. The breeding programme shall concentrate on flocks of high genetic merit.
2. A database shall be established containing at least the following information:
 - (a) the identity, breed and number of animals in all flocks participating in the breeding programme;
 - (b) the identification of the individual animals sampled under the breeding programme;
 - (c) the results of any genotyping tests.
3. A system of uniform certification shall be established in which the genotype of each animal sampled under the breeding programme is certified by reference to its individual identification number.
4. A system for the identification of animals and samples, the processing of samples and the delivery of results shall be established which minimises the possibility of human error. The effectiveness of that system shall be subject to regular random checking.
5. Genotyping of blood or other tissues collected for the purposes of the breeding programme shall be carried out in laboratories that have been approved under that programme.
6. The competent authority of the Member State may assist breed societies, to establish genetic banks consisting of semen, ova and/or embryos representative of prion protein genotypes which are likely to become rare as a result of the breeding programme.
7. Breeding programmes shall be drawn up for each breed, taking account of:
 - (a) frequencies of the different alleles within the breed;
 - (b) rarity of the breed;
 - (c) avoidance of inbreeding or genetic drift.

*PART 2**Specific rules for participating flocks*

1. The breeding programme shall be aimed at increasing the frequency of the ARR allele within the sheep flock, while reducing the prevalence of those alleles which have been shown to contribute to susceptibility to TSEs.
2. The minimum requirements for participating flocks shall be the following:
 - (a) all animals in the flock that are to be genotyped shall be individually identified using secure means;
 - (b) all rams intended for breeding within the flock shall be genotyped before being used for breeding;

▼M32

- (c) any male animal carrying the VRQ allele shall be slaughtered or castrated, within six months following the determination of its genotype; any such animal shall not leave the holding except for slaughter;
 - (d) female animals that are known to carry the VRQ allele shall not leave the holding except for slaughter;
 - (e) male animals, including semen donors used for artificial insemination, other than those certified under the breeding programme, shall not be used for breeding within the flock.
3. Member States may decide to grant derogations from the requirements set out in point 2(c) and (d) for the purposes of protection of breeds and production traits.
 4. Member States shall inform the Commission of derogations granted under point 3 and of the criteria used.

*PART 3****The framework for the recognition of the TSE-resistant status of flocks of sheep***

1. The framework shall recognise the TSE-resistant status of flocks of sheep that as a result of participation in the breeding programme as provided for in Article 6a, satisfy the criteria required in the programme.

This recognition shall be granted on at least the following two levels:

- (a) level I flocks shall be flocks composed entirely of sheep of the ARR/ARR genotype;
- (b) level II flocks shall be flocks whose progeny have been sired exclusively by rams of the ARR/ARR genotype.

Member States may decide to grant recognition on further levels to suit national requirements.

2. Regular random sampling of sheep from TSE-resistant flocks shall be carried out:
 - (a) on the farm or at the slaughterhouse to verify their genotype;
 - (b) in the case of level I flocks, in animals over 18 months of age at the slaughterhouse, for TSE testing in accordance with Annex III.

*PART 4****Reports to be provided to the Commission by the Member States***

Member States introducing national breeding programmes to select for resistance to TSE in their ovine populations shall notify to the Commission the requirements for such programmes and shall provide an annual report on their progress. The report for each calendar year shall be submitted at the latest by 31 March of the following year.

▼B*ANNEX VIII***PLACING ON THE MARKET AND EXPORT****▼M5**

CHAPTER A

▼M16**Conditions for intra-Community trade in live animals, semen and embryos****▼M31****I. CONDITIONS WHICH APPLY TO OVINE AND CAPRINE ANIMALS AND SEMEN AND EMBRYOS THEREOF****▼M5**

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

▼M14

- (a) ovine and caprine animals for breeding shall either be sheep of the ARR/ARR prion protein genotype, as defined in Annex I of Commission Decision 2002/1003/EC ⁽¹⁾, or they shall have been kept continuously since birth or for the last three years on a holding or holdings which have satisfied the following requirements for at least three years:

(i) until 30 June 2007:

- it is subject to regular official veterinary checks,
- the animals are marked,
- no case of scrapie has been confirmed,
- checking by sampling of old female animals intended for slaughter is carried out,
- females, with the exception of sheep of the ARR/ARR prion protein genotype, are introduced into the holding only if they come from a holding which complies with the same requirements.

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

- all animals referred to in Annex III, Chapter A, Part II, point 3 over the age of 18 months which have died or been killed on the holding shall be examined for scrapie in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b), and
- ovine and caprine animals, with the exception of sheep of the ARR/ARR prion protein genotype, shall be introduced into the holding only if they come from a holding which complies with the same requirements.

(ii) from 1 July 2007:

- it is subject to regular official veterinary checks,
- the animals are identified in conformity with Community legislation,
- no case of scrapie has been confirmed,
- all animals referred to in Annex III, Chapter A, Part II, point 3 over the age of 18 months which have died or been killed on the holding have been examined for scrapie in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b),
- ovine and caprine animals, with the exception of sheep of the ARR/ARR prion protein genotype, are introduced into the holding only if they come from a holding which complies with the same requirements.

If they are destined for a Member State which benefits, for all or part of its territory, from the provisions laid down in point (b) or (c), ovine and caprine animals for breeding shall comply with the additional

⁽¹⁾ OJ L 349, 24.12.2002, p. 105.

▼ M14

guarantees, general or specific, which have been defined in accordance with the procedure referred to in Article 24(2).

▼ M5

- (b) a Member State which has a compulsory or voluntary national scrapie control program for all or part of its territory:
- (i) may submit the said program to the Commission, outlining in particular:
 - the distribution of the disease in the Member State,
 - the reasons for the program, taking into consideration the importance of the disease and the cost/benefit ratio,
 - the geographical area in which the program will be implemented,
 - the status categories defined for holdings and the standards which must be attained in each such category,
 - the test procedures to be used,
 - the program monitoring procedures,
 - the action to be taken if, for any reason, a holding loses its status,
 - the measures to be taken if the results of checks carried out in accordance with the provisions of the program are positive,
 - (ii) the program referred to in point (i) may be approved if it complies with the criteria laid down in that point, in accordance with the procedure referred to in Article 24(2). The additional guarantees, general or specific, which may be required in intra-Community trade, shall be defined at the same time or at the latest three months after approval of the program in accordance with the procedure referred to in Article 24(2). Such guarantees must not exceed those which the Member State implements nationally,
 - (iii) amendments or additions to the programmes submitted by Member States may be approved in accordance with the procedure referred to in Article 24(2). Amendments to the guarantees which have been defined in accordance with point (ii) may be approved in accordance with that procedure,
- (c) where a Member State considers that its territory or part of its territory is free from scrapie:
- (i) it is to submit to the Commission appropriate supporting documentation, setting out in particular:
 - the history of the occurrence of the disease in its territory,
 - the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation,
 - the period over which the surveillance was carried out,
 - the arrangements for verifying the absence of the disease,
 - (ii) the additional guarantees, general or specific, which may be required in intra-Community trade are to be defined in accordance with the procedure 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),

▼ M16

- (d) from 1 January 2005 semen and embryos of ovine and caprine animals shall:

▼M16

- (i) be collected from animals which have been kept continuously since birth or for the last three years of their life on a holding or holdings which have satisfied the requirements of subparagraph (a)(i) or, as appropriate, (a)(ii) for three years or
- (ii) in the case of ovine semen, be collected from male animals of the ARR/ARR prion protein genotype as defined in Annex I to Commission Decision 2002/1003/EC ⁽¹⁾ or
- (iii) in the case of ovine embryos, be of the ARR/ARR prion protein genotype as defined in Annex I to Decision 2002/1003/EC.

▼M31

II. CONDITIONS WHICH APPLY TO BOVINE ANIMALS

The United Kingdom shall ensure that bovine animals born or reared on its territory before 1 August 1996 are not dispatched from its territory to other Member States or third countries.

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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.

▼M31

CHAPTER C

Conditions for intra-Community trade in certain products of animal origin*SECTION A**Products*

The following products of animal origin are exempt from the prohibition referred to in Article 16(3), provided that they are derived from bovine, ovine and caprine animals that satisfy the requirements of Section B:

- fresh meat,
- minced meat,
- meat preparations,
- meat products.

*SECTION B**Requirements*

The products referred to in Section A must satisfy the following requirements:

- (a) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;
- (b) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;
- (c) the products of bovine, ovine and caprine animal origin are not derived from:
 - (i) specified risk material as defined in Annex V;
 - (ii) nervous and lymphatic tissues exposed during the deboning process; and
 - (iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

⁽¹⁾ OJ L 349, 24.12.2002, p. 105.

▼B

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.

▼B*ANNEX IX***IMPORTATION INTO THE COMMUNITY OF LIVE ANIMALS,
EMBRYOS, OVA AND PRODUCTS OF ANIMAL ORIGIN****▼M31**

CHAPTER B

Imports of bovine animals*SECTION A****Imports from a country or a region with a negligible BSE risk***

Imports of bovine animals from a country or a region with a negligible BSE risk shall be subject to the presentation of an animal health certificate attesting that:

- (a) the animals were born and continuously reared in a country or region classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk;
- (b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, part I, point (4) (b) (iv) of Annex II; and
- (c) if there have been BSE indigenous cases in the country concerned, the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

*SECTION B****Imports from a country or a region with a controlled BSE risk***

Imports of bovine animals from a country or a region with a controlled BSE risk shall be subject to the presentation of an animal health certificate attesting that:

- (a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;
- (b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, Part II, point (4)(b)(iv) of Annex II;
- (c) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

*SECTION C****Imports from a country or a region with undetermined BSE risk***

Imports of bovine animals from a country or a region with an undetermined BSE risk shall be subject to the presentation of an animal health certificate attesting that:

- (a) the country or region has not been categorized in accordance with Article 5(2) of Regulation (EC) No 999/2001 or has been categorized as a country or region with undetermined BSE risk;
- (b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, Part II, point (4)(b)(iv) of Annex II;
- (c) the animals were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

▼ **M31**

CHAPTER C

Imports of products of animal origin from bovine, ovine or caprine animals▼ **M33**

SECTION A

Products

The following products of bovine, ovine and caprine animal origin, as defined by Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽¹⁾ shall be subject to the conditions laid down in Sections B, C and D depending on the BSE risk category of the country of origin:

- fresh meat,
- minced meat and meat preparations,
- meat products,
- treated intestines,
- rendered animal fats,
- greaves, and
- gelatine.

▼ **M31**

SECTION B

Imports from a country or a region with a negligible BSE risk

Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with a negligible BSE risk shall be subject to the presentation of an animal health certificate attesting that:

- (a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk;
- (b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country with negligible BSE risk and passed ante-mortem and post-mortem inspections;
- (c) if in the country or region there have been BSE indigenous cases:
 - (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or
 - (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

SECTION C

Imports from a country or a region with a controlled BSE risk

1. Imports of products of bovine, ovine and caprine animal origin referred to in section A from a country or a region with a controlled BSE risk shall be subject to the presentation of an animal health certificate attesting that:
 - (a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;
 - (b) the animals from which the products of bovine, ovine and caprine animal origin were derived passed ante-mortem and post-mortem inspections;
 - (c) animals from which the products of bovine, ovine and caprine animal origin destined for export were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

⁽¹⁾ OJ L 139, 30.4.2004, p. 55, as corrected by OJ L 226, 25.6.2004, p. 22.

▼ M31

- (d) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.
- 2. By way of derogation from point 1(d) carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.
- 3. When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column, shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000.
- 4. The number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as the number where removal of the vertebral column is not required shall be added to the document referred to in Article 2(1) of Regulation (EC) No 136/2004 in case of imports.

▼ M33

- 5. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the presentation of an animal health certificate attesting that:
 - (a) the country or region is classified in accordance with Article 5(2) as a country or region posing a controlled BSE risk;
 - (b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed *ante-mortem* and *post-mortem* inspections;
 - (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:
 - (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or
 - (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V.

▼ M31*SECTION D****Imports from a country or a region with an undetermined BSE risk***

- 1. Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with an undetermined BSE risk, shall be subject to the presentation of an animal health certificate attesting that:
 - (a) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;
 - (b) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;
 - (c) the products of bovine, ovine and caprine animal origin are not derived from:
 - (i) specified risk material as defined in Annex V;
 - (ii) nervous and lymphatic tissues exposed during the deboning process;
 - (iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.
- 2. By way of derogation from point 1(c), carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing

▼ M31

no specified risk material other than the vertebral column, including dorsal root ganglia, may be imported.

3. When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column, shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000.
4. Specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required and from which removal of the vertebral column is not required shall be added to the document referred to in Article 2(1) of Regulation (EC) No 136/2004 in case of imports.

▼ M33

5. In the case of intestines originally sourced from a country or a region with a negligible BSE risk, imports of treated intestines shall be subject to the presentation of an animal health certificate attesting that:
 - (a) the country or region is classified in accordance with Article 5(2) as a country or region posing an undetermined BSE risk;
 - (b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country or region with a negligible BSE risk and passed *ante-mortem* and *post-mortem* inspections;
 - (c) if the intestines are sourced from a country or region where there have been BSE indigenous cases:
 - (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or
 - (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V.

▼ M31

CHAPTER D

Imports of animal by-products and processed products derived therefrom from bovine, ovine and caprine animal origin*SECTION A**Animal by-products*

This Chapter shall apply to the following animal by-products and processed products derived therefrom from bovine, ovine and caprine animal origin as referred to in Regulation (EC) No 1774/2002:

- rendered fats,
- pet food,
- blood products,
- the processed animal protein,
- bones and bone products,
- category 3 material, and
- gelatine.

SECTION B

Imports of the animal by-products processed products derived therefrom from bovine, ovine and caprine animal origin referred to in Section A. shall be subject to the presentation of an animal health certificate attesting that:

- (a) the animal by-product does not contain and is not derived from specified risk material as defined in Annex V or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;
- (b) the animals from which this animal by-product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity,

▼ M31

or

- (c) the animal by-product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk.

▼ M12

CHAPTER E

Imports of ovine and caprine animals

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

- (a) either they were born in and continuously reared on holdings in which a case of scrapie has never been diagnosed, and, in the case of ovine and caprine animals for breeding, they satisfy the requirements of subparagraph (i) of point (a) of Chapter A(I) of Annex VIII;
- (b) or they are sheep of the ARR/ARR prion protein genotype, as defined in Annex I to Commission Decision 2002/1003/EC, coming from a holding where no case of scrapie has been reported in the last six months.

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

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CHAPTER F

Imports of products of animal origin from farmed and wild cervid animals

1. When fresh meat, minced meat, meat preparations and meat products as defined by Regulation (EC) No 853/2004, derived from farmed cervid animals, are imported into the Community from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

‘This product contains or is derived exclusively from meat, excluding offal and spinal cord, of farmed cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognized by the competent authority with negative results and is not derived from animals coming from a herd where chronic wasting disease has been confirmed or is officially suspected.’

2. When fresh meat, minced meat, meat preparations and meat products as defined by Regulation (EC) No 853/2004, derived from wild cervid animals, are imported into the Community from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

‘This product contains or is derived exclusively from meat, excluding offal and spinal cord, of wild cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognized by the competent authority with negative results and is not derived from animals coming from a region where chronic wasting disease has been confirmed in the last three years or is officially suspected.’

▼ M16

CHAPTER H

Import of ovine and caprine semen and embryos

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

▼B*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: Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, Institut für veterinärmedizinische Untersuchungen 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

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Bulgaria: Национален диагностичен научноизследователски ветеринарномедицински институт 'Проф. Д-р Георги Павлов'
Национална референтна лаборатория 'Трансмисивни спонгиформни енцефалопатии'
бул. 'Пенчо Славейков'
София 1606
(National Diagnostic Veterinary Research Institute 'Prof. Dr. Georgi Pavlov' National Reference Laboratory for Transmissible Spongiform Encephalopathies
15, Pencho Slaveykov Blvd.
1606 Sofia)

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Cyprus:	State Veterinary Laboratories Veterinary Services CY-1417 Athalassa Nicosia
Czech Republic:	Státní veterinární ústav Jihlava Rantířovská 93 586 05 Jihlava
Denmark:	Danmarks Fødevareforskning Bülowsvej 27 DK-1790 København V
Estonia:	Veterinaar- ja Toidulaboratoorium Kreutzwaldi 30 Tartu 51006
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 69 364 LYON CEDEX 07
Germany:	Friedrich-Loeffler-Institut, Bundesforschungsinstitut für Tiergesundheit Anstaltsteil Insel Riems Boddenblick 5A D-17498 Insel Riems
Greece:	Ministry of Agriculture — Veterinary Laboratory of Larisa 7th km of Larisa — Trikala Highway GR-411 10 Larisa
Hungary:	Országos Állategészségügyi Intézet (OÁI) Pf. 2. Tábornok u. 2. H-1581 Budapest
Ireland:	Central Veterinary Research Laboratory Young's Cross Celbridge Co. Kildare
Italy:	Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta — CEA Via Bologna, 148 I-10154 Torino
Latvia:	State Veterinary Medicine Diagnostic Centre Lejupes Str. 3 Riga LV 1076
Lithuania:	Nacionalinė veterinarijos laboratorija J. Kairiūkščio g. 10 LT-08409 Vilnius
Luxembourg:	CERVA -CODA-VAR Centre d'Étude et de Recherches Vétérinaires et Agro- chimiques Centrum voor Onderzoek in Diergeneeskunde en Agro- chemie Veterinary and Agrochemical Research Centre Groeselenberg 99 B-1180 Bruxelles
Malta:	National Veterinary Laboratory Albert Town Marsa

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Netherlands:	Centraal Instituut voor Dierziektecontrole-Lelystad Houtribweg 3g 8221 RA Lelystad Postbus 2004 8203 AA Lelystad
Poland:	Państwowy Instytut Weterynaryjny (PIWet) 24-100 Puławy al. Partyzantów 57
Portugal:	Laboratório Nacional de Investigação Veterinária Estrada de Benfica 701 P-1500 Lisboa

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Romania:	Institutul de Diagnostic și Sănătate Animală Strada Dr. Staicovici nr. 63, sector 5 codul 050557, București.
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Slovakia:	State Veterinary Institute Zvolen Pod dráhami 918 SK-960 86, Zvolen
Slovenia:	National Veterinary Institute Gerbičeva 60 1000 Ljubljana
Spain:	Laboratorio Central de Veterinaria (Algete) Ctra. de Algete km. 8 28110 Algete (Madrid)
Sweden:	National Veterinary Institute S-751 89 Uppsala
United Kingdom:	Veterinary Laboratories Agency Woodham Lane New Haw Addlestone Surrey KT15 3NB

▼ B

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;

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- 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.

▼M18

CHAPTER C

Sampling and laboratory testing**▼M32**1. *Sampling*

Any samples intended to be examined for the presence of a TSE shall be collected using the methods and protocols laid down in the latest edition of the Manual for diagnostic tests and vaccines for Terrestrial Animals of the International Office for Epizootics (IOE/OIE) (the Manual). In addition, or in the absence, of OIE methods and protocols, and to ensure that sufficient material is available, the competent authority shall ensure the use of sampling methods and protocols in accordance with guidelines issued by the Community Reference Laboratory. In particular the competent authority shall collect the appropriate tissues, according to the available scientific advice and the guidelines of the Community Reference Laboratory, in order to ensure the detection of all known strains of TSE in small ruminants and shall keep at least half of the collected tissues fresh but not frozen until the result of the rapid test is negative. Where the result is positive or inconclusive the residual tissues must be processed in accordance with the Community reference laboratory guidelines.

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

▼M182. *Laboratories*

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

3. *Methods and protocols*3.1. *Laboratory testing for the presence of BSE in bovine animals*(a) *Suspect cases*

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

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

▼ M18(b) *BSE monitoring*

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

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

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

- the result of the subsequent histopathological examination is positive, or
- the result of another diagnostic method referred to in (a) is positive.

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

(a) *Suspect cases*

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

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

▼ M32(b) *TSE monitoring*

Samples from ovine and caprine animals sent for laboratory testing pursuant to the provisions of Annex III, Chapter A, Part II (Monitoring in ovine and caprine animals) shall be examined by a rapid test using the appropriate methods and protocols, according to the available scientific advice and the guidelines of the Community Reference Laboratory, in order to ensure the detection of all known strains of TSE.

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

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

▼ M18(c) *Further examination of positive scrapie cases*(i) *Primary molecular testing with a discriminatory immuno-blotting*

Samples from clinical suspect cases and from animals tested in accordance with Annex III, Chapter A, Part II, points 2 and 3 which are regarded as positive scrapie cases following the examinations referred to in points (a) or (b), or which display characteristics which are deemed by the testing laboratory to merit inves-

▼M18

tigation, shall be forwarded for further examination by a primary molecular typing method to:

- Agence Française de Sécurité Sanitaire des Aliments, Laboratoire de pathologie bovine, 31, avenue Tony Garnier, BP 7033, F-69342, Lyon Cedex, France, or
- Veterinary Laboratories Agency, Woodham Lane, New Haw, Addlestone, Surrey KT15 3NB, United Kingdom, or
- to a laboratory, appointed by the competent authority, which has participated successfully in proficiency testing organised by the Community Reference Laboratory for the use of a molecular typing method, or
- on a provisional basis until 1 May 2005, the laboratories approved for this purpose by the CRL panel of experts.

(ii) Ring trial with additional molecular testing methods

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

- a second discriminatory immuno-blotting,
- a discriminatory immunocytochemistry, and
- a discriminatory ELISA (Enzyme linked ImmunoSorbent Assay)

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

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

▼M32

Further testing of positive TSE samples detected in infected flocks on the same holding shall be carried out at least on the first two positive TSE cases detected every year following the index case.

▼M18(d) *Laboratories approved for performing further examination by molecular typing methods*

The laboratories approved for further molecular typing are:

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

Centre CEA Fontenay-aux-Roses, BP 6
F-92265 Fontenay-aux-Roses Cedex

Service de Pharmacologie et d'Immunologie
Centre CEA Saclay, bâtiment 136
F-91191 Gif-sur-Yvette Cedex

Veterinary Laboratories Agency
Woodham Lane
New Haw
Addlestone

▼ **M18**

Surrey KT15 3NB
United Kingdom

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

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

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

▼ **M36**

4. *Rapid tests*

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

- immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K-resistant fragment PrP^{Res} (Prionics-Check Western test),
- chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer test & Enfer TSE Kit version 2.0, automated sample preparation),
- microplate-based immunoassay for the detection of PrP^{Sc} (Enfer TSE Version 3),
- sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad Te-SeE test),
- microplate-based immunoassay (ELISA) which detects Proteinase K-resistant PrP^{Res} with monoclonal antibodies (Prionics-Check LIA test),
- conformation-dependent immunoassay, BSE antigen test kit (Beckman Coulter InPro CDI kit),
- chemiluminescent ELISA for qualitative determination of PrP^{Sc} (CediTect BSE test),
- immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA),
- lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (Prionics Check PrioSTRIP),
- two-sided immunoassay using two different monoclonal antibodies directed against two epitopes presented in a highly unfolded state of bovine PrP^{Sc} (Roboscreen Beta Prion BSE EIA Test Kit),
- sandwich ELISA for the detection of Proteinase K-resistant PrP^{Sc} (Roche Applied Science PrionScreen),
- antigen-capture ELISA using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (Fujirebio FRELISA BSE post-mortem rapid BSE Test).

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

- conformation-dependent immunoassay, BSE antigen test kit (Beckman Coulter InPro CDI kit),
- sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad Te-SeE test),
- sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad Te-SeE Sheep/Goat test),
- chemiluminescent ELISA test involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer TSE Kit version 2.0),
- microplate-based immunoassay for the detection of PrP^{Sc} (Enfer TSE Version 3),
- immunoassay using a chemical polymer for selective PrP^{Sc} capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),

▼ M36

- microplate-based chemiluminiscent immunoassay for the detection of PrP^{Sc} in ovine tissues (POURQUIER'S-LIA Scrapie),
- immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K-resistant fragment PrP^{Res} (Prionics-Check Western Small Ruminant test),
- microplate-based chemiluminiscent immunoassay for the detection of Proteinase K-resistant PrP^{Sc} (Prionics Check LIA Small Ruminants).

In all tests, sample tissue on which the test must be applied must comply with the manufacturer's instructions for use.

Producers of rapid tests must have a quality assurance system in place that has been approved by the Community Reference Laboratory (CRL) and ensures that the test performance does not change. Producers must provide the CRL with the test protocols.

Changes to rapid tests and to test protocols may only be made after prior notification to the CRL and provided that the CRL finds that the change does not alter the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the Commission and to the national reference laboratories.

▼ M185. *Alternative tests*

(To be defined)

▼ M31
