L.N. 58 of 2004

VETERINARY SERVICES ACT, 2001
(ACT NO. XXIII OF 2001)

Prevention, Control and Eradication of Certain Transmissible Spongiform Encephalopathies Regulations, 2004

IN exercise of the powers conferred by articles 4, 6, 7, 8, 10, 11 and 12 of the Veterinary Services Act, 2001, to the Minister for Rural Affairs and the Environment has made the following regulations:-

CHAPTER I
GENERAL PROVISIONS

Title, scope and application

1. (1) The title to these regulations is the Prevention, Control and Eradication of Certain Transmissible Spongiform Encephalopathies Regulations, 2004.

(2) The scope of these regulations is the implementation of European Parliament and European Union Council Regulation (EC) No. 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. These regulations provide 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.

(3) These regulations 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.

Separation of live animals and products of animal origin to avoid cross-contamination or substitution

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 regulation 1 (2) and the products of animal origin referred to in regulation 1 (3) (a), (b) and (c), or the live animals referred to in regulation 1 (3) (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 regulation shall be adopted in accordance with the procedure referred to in regulation 24 (2) and also the rules found under article 4 of the Veterinary Services Act shall apply.

Definitions

3. (1) For the purposes of these regulations the following definitions shall apply -

(a) "animal suspected of being infected by a TSE" means 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;

(b) "alternative test" means the tests referred to in regulation 8(2) which are used as an alternative to the withdrawal of specified risk material;

(c) "category" means one of the classification categories referred to in Chapter C of Schedule II;

(d) "competent authority" means the central authority of a Member State, competent to ensure compliance with the requirements of these regulations or any authority to which that central authority has delegated that competence, in particular for the control of feedingstuffs; it shall also include, where appropriate, the corresponding authority of a third country; for the territory of Malta the Veterinary Services are the competent authority;

(e) "fertilisers" means any substance containing products of animal origin utilised on land to enhance growth of vegetation; it may include digestion residues from biogas production or composting;

(f) "holding" means any place in which animals covered by these regulations are held, kept, bred, handled or shown to the public;

(g) "placing on the market" means any operation the purpose of which is to sell live animals or products of animal origin covered by these regulations to a third party in the European 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;

(h) "products of animal origin" means any product derived from or containing a product derived from any animal covered by the provisions of European Union Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market or European Union Council Directive 90/425/EEC 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;

(i) "rapid tests" means the analysis methods referred to in Schedule X, Chapter C, point 4, and for which the results are known within 24 hours;

(j) "sampling" means 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) "specified risk material" means the tissues specified in Schedule V; unless otherwise indicated, it does not include products containing or derived from those tissues;

(l) "starting materials" means raw materials or any other product of animal origin out of which, or with the help of which, the products referred to in regulation 1 (3) (a) and (b) are produced;

(m) "trading partner" in the meaning of article 2 of the Veterinary Services Act, shall mean –

(i) Member States of the European Community;

(ii) Third Countries to the European Community;

where relevant;

(n) "TSEs" means all transmissible spongiform encephalopathies with the exception of those occurring in humans;

(2) The specific definitions set out in Schedule I shall also apply.

(3) Where the terms in these regulations are not defined in sub-regulation (1) or Schedule I, the relevant definitions given in European Union Parliament and Council Regulation (EC) No 1760/2000 and those given in or pursuant to European Union Council Directives 64/432/EEC, 89/662/EEC, 90/425/EEC and 91/68/EEC shall apply insofar as reference is made to them in this text.

Safeguard measures

4. (1) With regard to the implementation of safeguard measures, the principles and provisions set out in article 9 of European Union Council Directive 89/662/EEC, article 10 of European Union Council Directive 90/425/EEC, article 18 of European Union Council Directive 91/496/EEC and article 22 of European Union Council Directive 97/78/EC shall apply.

(2) The safeguard measures shall be adopted in accordance with the procedure referred to in regulation 24 (2) and the rules found under article 4 of the Veterinary

Services Act shall apply. These measures shall be notified at the same time to the European Parliament, stating the reasons

CHAPTER II
DETERMINATION OF BSE STATUS

Classification

5. (1) The BSE status of the territory of Malta, a Member State, of a third country, or of one of their regions (hereinafter referred to as "countries or regions") may be determined only on the basis of the criteria set out in Schedule II, Chapter A, and the outcome of a risk analysis on the basis of all the potential factors for the appearance of bovine spongiform encephalopathy as defined in Schedule II, Chapter B, and their development over time. The territory of Malta, Member States and third countries wishing to be retained on the list of third countries approved for the export to the European Community of the live animals or of the products covered by these regulations, shall submit to the European Commission an application for their BSE status to be determined, accompanied by the relevant information on the criteria set out in Schedule II, Chapter A, and on the potential risk factors specified in Schedule II, Chapter B, and their development over time.

(2) A decision on each application, placing the territory of Malta, 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 Schedule II, Chapter C, shall be adopted, taking account of the criteria and potential risk factors set out in sub-regulation (1), in accordance with the procedure referred to in regulation 24 (2).

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

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

(3) If the European Commission finds that the information submitted by a Member State or a third country pursuant to Schedule II, Chapters A and B, is insufficient or unclear, it may, in accordance with the procedure referred to in regulation 24 (2), determine the BSE status of the territory of Malta, another 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 European 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 regulation 24 (2) and entered on a list set out in Schedule 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 European Commission in accordance with the procedure laid down in regulation 24 (2).

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

(4) The Veterinary Services shall notify the European 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 regulation 6.

(5) The retention of a third country on one of the lists provided for by European Community rules for the purpose of being allowed to export to the European Community live animals and products of animal origin for which these regulations provides specific rules shall be decided upon under the procedure laid down in regulation 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 sub-regulation (1) being supplied. In the event of refusal to supply the said information within three months of the date of the European Commission's request, the relevant European Community legislation provisions shall apply until this information has been submitted and evaluated in accordance with sub-regulations (2) or (3).

The eligibility of third countries to export to the European Community live animals, or products of animal origin for which these regulations provide specific rules, under conditions based on their category as established by the European 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.

(6) A decision may be taken, under the procedure laid down in regulation 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 regulation 21.

(7) The decisions referred to in sub-regulations (2), (3), (5) and (6) shall be based on a risk assessment, taking into consideration the recommended criteria set out in Schedule II, Chapters A and B.

CHAPTER III
PREVENTION OF TSE

Monitoring system

6. (1) The Veterinaary Services shall carry out an annual programme for monitoring BSE and scrapie in accordance with Schedule III, Chapter A. This 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 regulation 24 (2) and listed in Schedule X, Chapter C, point 4 and also in accordance with article 4 of the Veterinary Services Act.

(2) The Veterinary Services shall inform the European 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 Schedule III, Chapter B.

(4) The Veterinary Services shall submit an annual report to the European Commission covering at least the information referred to in Schedule 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 European Commission shall present a summary of the national reports covering at least the information referred to in Schedule III, Chapter B, Part II, to the Standing Veterinary Committee within three months of the receipt of the said reports.

Prohibitions concerning animal feeding

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

(2) Furthermore, the prohibition referred to in sub-regulation (1) shall be extended to animals and products of animal origin in accordance with point 1 of Schedule IV.

(3) Sub-regulations (1) and (2) shall apply without prejudice to the provisions set out in point 2 of Schedule IV.

(4) (i) Member States, or regions thereof, in category 5 shall not be permitted to export or store feed intended for farmed animals which contains protein derived from mammals or feed intended for mammals, except for dogs and cats, which contains processed protein derived from mammals.

(ii) Third countries, or regions thereof, in category 5 shall not be permitted to export to the European Community feed intended for livestock which contains protein derived from mammals or feed intended for mammals, except for dogs and cats, which contains processed protein derived from mammals.

(5) Detailed rules for the implementation of this regulation, in particular rules on the prevention of cross-contamination and on the methods of sampling and

analysis required to check compliance with this regulation, shall be adopted in accordance with the procedure referred to in regulation 24 (2) and in accordance with the provisions of the Veterinary Services Act.

Specified risk material

8. (1) The specified risk material shall be removed and destroyed in accordance with points 2, 3, 4 and 8 of Schedule V. That specified risk material or the material processed therefrom may be placed on the market or, if need be, exported only for final destruction in accordance with points 3 and 4 or as appropriate 7 (c) or 8 of Schedule V. It may not be imported into the territory of Malta. Transit of specified risk material through the European Community territory must take place in accordance with the requirements of article 3 of European Union Council Directive 91/496/EEC.

(2) Sub-regulation (1) shall not apply to tissues from animals which have undergone an alternative test approved for that distinct purpose in accordance with rules found under the Veterinary Services Act and the procedure referred to in regulation 24 (2) and listed in Schedule X, Chapter C, point 5, and applied under the conditions listed in point 5 of Schedule V and where the results of the test were negative. When the Veterinary Services will authorise that alternative test must inform the other Member States and the European Commission.

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

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

(5) With regard to the date of effective enforcement of regulation 7(1) or, as appropriate, in the third countries, the date of banning the use of mammalian protein in feed for ruminants in each country or region placed in category 3 or 4, in order to limit the application of this regulation to animals born before that date in those countries or regions, derogation from paragraph 1 to 4, may be adopted –

(a) concerning the territory of Malta, in accordance with the procedure referred to in article 11 of the Veterinary Services Act;

(b) concerning third countries in accordance with the procedure referred to in article 12 of the Veterinary Services Act.

Similarly, by way of derogation from sub-regulation (1) to (4), after consultation of the appropriate scientific committee and on the basis of an assessment of the incident, propagation and human exposure risk, a decision may be adopted in accordance with the procedure referred to in regulation 24 (2) and the relevant rules found under the Veterinary Services Act to allow the use for food, feed and fertilisers of vertebral

column and dorsal root ganglia from bovine animals in or coming from each country or region thereof placed in category 5.

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

(a) where the rules concern the territory of Malta, in accordance with the procedure referred to in article 11 of the Veterinary Services Act,

(b) concerning third countries in accordance with the procedure referred to in article 12 of the Veterinary Services Act.

Products of animal origin derived from or containing ruminant material

9. (1) In the territory of Malta the products of animal origin listed in Schedule VI shall not be produced from ruminant material from countries or regions thereof which are placed in category 5 unless they are produced in accordance with the production processes approved in accordance with the procedure referred to in regulation 24 (2) and in accordance with article 11 of the Veterinary Services Act.

(2) Bones of the head and vertebral columns of bovine, ovine and caprine animals from countries, or regions thereof, which are placed in categories 2, 3, 4 or 5, shall not be used for the production of mechanically recovered meat.

(3) Sub-regulations (1) and (2) shall not apply, in the light of the criteria set out in point 5 of Schedule V, to ruminants which have undergone an alternative test which has been recognised in accordance with the rules found under the Veterinary Services Act and the procedure referred to in regulation 24 (2), where the results of the test were negative.

(4) Rules for the implementation of this regulation shall be adopted in accordance with the procedure referred to in regulation 24 (2) and if the rules –

(a) concern the territory of Malta the procedure referred to in article 11 of the Veterinary Services Act shall apply;

(b) concern third countries in accordance with the procedure referred to in article 12 of the Veterinary Services Act.

Education programmes

10. (1) The territory of Malta shall ensure that staff of the Veterinary Services, 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 sub-regulation (1), financial assistance from the European Community may be granted. The amount of such assistance shall be determined in accordance with the procedure referred to in regulation 24 (2).

CHAPTER IV
CONTROL AND ERADICATION OF TSEs

Notification

11. Without prejudice to European Union Council Directive 82/894/EEC, the territory of Malta shall ensure that any animal suspected of being infected by a TSE is notified immediately to the Veterinary Services. Member States shall regularly inform each other and the European Commission of the cases of TSE notified. The Veterinary Services shall without delay take the measures laid down in regulation 12 of these regulations, together with any other necessary measures.

Measures with respect to suspect animals

12. (1) Any animal suspected of being infected by a TSE shall be placed under an official movement restriction until the results of a clinical and epidemiological examination carried out by the competent authority are known, or killed for laboratory examination under official control. If BSE is suspected in a bovine animal at a holding in the territory of Malta, all other bovine animals from that holding shall be placed under an official movement restriction until the results of the examination are available.

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

If there is evidence that the holding where the animal was present when BSE was suspected is not likely to be the holding where the animal could have been exposed to BSE, the Veterinary Services may decide that only the animal suspected of being infected shall be placed under an official movement restriction. If considered necessary, the Veterinary Services may also decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

Under the procedure referred to in regulation 24 (2) and by way of derogation from the requirements of the second, third and fourth subparagraphs of this sub-regulation, a Member State may be exempted from the application of official restrictions on the movement of animals if it applies measures offering equivalent safeguards.

(2) Where the Veterinary Services 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 Veterinary Services may determine shall be removed and sent to an officially approved laboratory, the national reference laboratory provided for in regulation 19 (1) or the European Community reference laboratory provided for in regulation 19 (2), for examination in accordance with the testing methods laid down in regulation 20.

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

(4) Rules for the implementation of this regulation shall be adopted in accordance with the procedure referred to in regulation 24 (2) and in accordance with article 4 of the Veterinary Services Act.

Measures following confirmation of the presence of a TSE

13. (1) When the presence of a TSE has been officially confirmed, the following measures shall be applied as soon as possible -

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

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

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

By way of derogation from this sub-regulation, the territory of Malta may apply other measures offering an equivalent level of protection if those measures have been approved in accordance with the procedure referred to in regulation 24 (2).

(2) Pending the implementation of the measures referred to in sub-regulation (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 Veterinary Services, 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 Veterinary Services may decide that both holdings or only the holding of exposure shall be placed under official control.

(3) In the case where the territory of Malta would decide to implement a substitute scheme offering equivalent safeguards provided for in the fifth subparagraph of regulation 12 (1) may, by way of derogation from the requirements of sub-regulation (1) (b) and (c), be exempted in accordance with the procedure referred to in regulation 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 regulation 12 (2) and sub-regulation (1) (a) and (c) of this regulation.

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

(6) Rules for the implementation of this regulation shall be adopted in accordance with the procedure referred to in regulation 24 (2). Moreover the provisions of article 4 of the Veterinary Services Act shall apply.

Contingency plan

14. (1) The territory of Malta following the rules found under article 4 of the Veterinary Services Act and in accordance with the general criteria of European Community rules on the control of animal diseases shall draw up guidelines specifying the national measures to be implemented and indicating competences and responsibilities where cases of TSE are confirmed.

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

CHAPTER V
PLACING ON THE MARKET AND EXPORT

Live animals, their semen, embryos and ova

15. (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 Schedule VIII, or, in the case of imports, to the conditions laid down in Schedule IX. The live animals and their embryos and ova shall be accompanied by the appropriate animal health certificates as required by European Community legislation, in accordance with regulation 17 or, in the case of imports, regulation 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 Schedule VIII, Chapter B.

(3) Rules for the implementation of this regulation shall be adopted in accordance with the procedure referred to in regulation 24 (2) and in accordance with article 7 of the Veterinary Services Act.

Placing on the market of products of animal origin

16. (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 regulation, to Schedule VIII, Chapters C and D, and to Schedule IX, Chapters A, C, F and G -

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

(b) (i) raw milk within the meaning of European Union Council Directive 92/46/EEC;

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

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

(iv) dicalcium phosphate (without any trace of protein or fat);

(v) hides and skins within the meaning of European Union Council Directive 92/118/EEC;

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

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

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

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

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

or

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

Furthermore, products of animal origin shall not be despatched from a Member State or a region of a Member State classified in category 5 to another Member State or be imported from a third country classified in category 5. That prohibition shall not apply to products of animal origin listed in Schedule VIII, Chapter C, and fulfilling the requirements of Schedule 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 these regulations.

(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 regulation lays down specific rules shall be accompanied by the appropriate animal health certificates or commercial documents as required by European Community legislation in accordance with regulations 17 and 18 or, if such certificates or documents are not provided for in European Community legislation, by a health certificate or commercial document the specimens of which shall be established in accordance with the procedure referred to in regulation 24(2) and according to article 10 of the Veterinary Services Act.

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

(7) In accordance with article 10 and 12 of the Veterinary Services Act and the procedure referred to in regulation 24 (2), the provisions of sub-regulations (1) to (6) may be extended to other products of animal origin. Rules for the implementation of this regulation shall be adopted by the same procedure.

Health certificates

17. In accordance with article 7 of the Veterinary Services Act and under the procedure referred to in regulation 24 (2), the health certificates referred to in Annex F to European Union Council Directive 64/432/EEC, Models II and III in Annex E to European Union Council Directive 91/68/EEC and the appropriate health certificates laid down by European 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 regulation 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 European Commission in accordance with regulation 5.

Appropriate health certificates relating to imports

18. The appropriate health certificates relating to imports provided for by European Community legislation shall, in accordance with article 8 and article 12(2)(c) of the Veterinary Services Act and under the procedure referred to in regulation 24 (2), be supplemented in respect of third countries classified in a category pursuant to regulation 5 by the specific requirements laid down in Schedule IX, as soon as that classification decision has been taken.

CHAPTER VI
REFERENCE LABORATORIES, SAMPLING, TESTING AND CONTROLS

Reference laboratories

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

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

Sampling and laboratory methods

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

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

Community controls

21. (1) Experts from the European Commission may make on-the-spot checks in co-operation with the Veterinary Services of the territory of Malta, insofar as is necessary for the uniform application of these regulations. The Veterinary Services shall provide the experts with all the assistance necessary for carrying out their duties. The European Commission shall inform the Veterinary Services of the results of the checks made.

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

(2) European Community checks concerning third countries shall be made in accordance with articles 20 and 21 of European Union Council Directive 97/78/EC.

CHAPTER VII
TRANSITIONAL AND FINAL PROVISIONS

Transitional measures concerning specified risk material

22. (1) The provisions of Schedule XI, Part A shall cease to apply immediately following the date of adoption of a decision in accordance with regulation 5 (2) or (4), on which date regulation 8 shall enter into force.

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

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

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

Amendment of the Schedules and transitional measures

23. After consultation of the appropriate scientific committee on any question which could have an impact on public health, the Schedules shall be amended or supplemented and any appropriate transitional measures shall be adopted in

accordance with the rules found under the Veterinary Services Act and the procedure referred to in regulation 24 (2).

Committees

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

(2) Where reference is made to this sub-regulation, regulations 5 and 7 of European Union Decision 1999/468/EC shall apply, in compliance with regulation 8 thereof.

The period referred to in article 5 (6) of that Decision shall be three months and, in the case of safeguard measures referred to in regulation 4 (2) of these regulations, 15 days.

(3) Each Committee shall adopt its rules of procedure.

Consultation of the scientific committees

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

SCHEDULE I
SPECIFIC DEFINITIONS

1. For the purpose of these regulations, the following definitions set out in European Union Parliament and Council Regulation (EC) No 1774/2002 (OJ L 273, 10.10.2002), European Union Parliament and Council Regulation (EC) No 178/2002 (OJ L 31, 1.2.2002) and European Union Council Directive 79/373/EEC (OJ L 86, 6.4.1979) shall apply -

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

(i) "farmed animal" in article 2(1)(t);

(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 European Union Parliament and Council Regulation (EC) No 178/2002;

(c) the definition of "complete feedingstuff" in article 2(d) of European Union Council Directive 79/373/EEC.

2. For the purpose of these regulations, 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 were -

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

(ii) reared together with the affected bovine animal at any time during the first year of their life and which may have consumed the same feed as that which the affected a bovine animal consumed during the first year of its life.

SCHEDULE II
DETERMINATION OF BSE STATUS

CHAPTER A

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

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

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

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

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

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

CHAPTER B

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

- the consumption by bovine animals of meat and bone meal or greaves derived from ruminants;

- the importation of meat and bone meal or greaves potentially contaminated by a TSE or animal feed containing meat and bone meal or greaves;

- the importation of animals or ova, embryos potentially infected by a TSE;

- the epidemiological status of the country or region in regard to animal TSEs;

- the extent of knowledge about the structure of the bovine, ovine and caprine population in the country or region;

- the source of animal waste, the parameters of the processes for treating such waste and the methods of producing animal feed.

CHAPTER C

Definition of categories

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

A. CATEGORY 1 -

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

1. EITHER no BSE case has been recorded and -

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

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

2. OR where all cases of BSE have been clearly demonstrated to originate directly from the importation of live bovine animals or bovine embryos, ova, and all the affected bovine

animals as well as, if these are females, their last progeny born within two years prior to, or after, the first clinical signs of onset of the disease, if alive in the country or region, have been killed and completely destroyed and, either -

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

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

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

B. CATEGORY 2 -

BSE provisionally free country or region where no indigenous case has been reported country or region where a risk analysis as described in Chapter B has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified, and -

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

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

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

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

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

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

C. CATEGORY 3 -

BSE provisionally free country or region where at least one indigenous case has been reported. Any country or region where a risk analysis based on the information referred to in Chapter B has been conducted which demonstrates that appropriate measures have been taken for the relevant period of time to manage any risk identified and -

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

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

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

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

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

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

(iii) the affected bovine animals as well as -

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

- all bovine animals from the cohort, are killed and completely destroyed if they are still alive in the country or region concerned.

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

D. CATEGORY 4 -

Country or region with low incidence of BSE -

Any country or region where -

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

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

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

- all bovine animals from the cohort,

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

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

Countries or regions where the BSE incidence rate, calculated over the past 12 months, has been less than one indigenous case per million within the cattle population over 24 months of age in the country or region, but where a risk analysis as described in Chapter A has been conducted which demonstrates that at least one of the criteria enabling the country or region to be classified in category 2 or 3 is not complied with, must be regarded as countries or regions belonging to category 4.

E. CATEGORY 5 -

Country or region with high incidence of BSE -

Any country or region where -

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

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

SCHEDULE 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 Schedule 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 European Union Council Directive 64/433/EEC, or

- slaughtered in accordance with Annex I, Chapter VI, point 28(c), to European Union Council 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.

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 European Union Commission Regulation (EC) No 716/96,

- 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 European Commission thereof, and submit a list of the derogated areas. The derogation shall not cover more than 10 % of the bovine population in the Member State.

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

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

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

4.3. A random sample comprising at least 10000 animals annually of animals not covered by points 4.1 or 4.2 shall be tested for BSE.

5. Monitoring in other animals

In addition to the testing referred to in points 2 to 4, Member States may on a voluntary basis decide to test other bovine animals on their territory, in particular where those animals originate from countries with indigenous BSE, have consumed potentially contaminated 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 European Union Council Directive 64/433/EEC shall not be carried out on the carcass of that animal until a negative result to the rapid test has been obtained.

6.2. Member States may derogate from the provisions of point 6.1 where an official system is in place in the slaughterhouse ensuring that no parts of examined animals bearing the health mark leave the slaughterhouse until a negative result to the rapid test has been obtained.

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

6.4. All parts of the body of an animal found positive to the rapid test including the hide shall be destroyed in accordance with Schedule V, point 3 or 4, apart from material to be retained in conjunction with the records provided for in Chapter B, section III.

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

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

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 Schedule X, Chapter C, point 3.2(b).

2. Monitoring in animals slaughtered for human consumption

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

Member State	Minimum annual sample size (1)
	Slaughtered animals
Belgium	3, 750
Denmark	3, 000
Germany	60, 000
Greece	60, 000
Spain	60, 000
France	60, 000
Ireland	60, 000
Italy	60, 000
Luxembourg	250
Netherlands	39, 000
Austria	8, 200
Portugal	22, 500

Finland
1, 900

Sweden
5, 250

United Kingdom
60, 000

(1) The sample size has been calculated to detect a prevalence of 0,005 % with a 95 % confidence in slaughtered animals in Member States which slaughter a large number of adult sheep. In those Member States which slaughter a smaller number of adult sheep, the sample size is calculated as 25 % of the estimated or recorded number of cull ewes slaughtered in 2000.

A Member State may test a number of animals less than that indicated in the table if the most recent official slaughter statistics indicate that this number is equivalent to 25 % of cull ewes slaughtered annually in the Member State.

3. Monitoring in animals not slaughtered for human consumption

Animals over 18 months of age or which have more than two permanent incisors erupted through the gum which have died or been killed, but which were not -

- killed in the framework of a disease eradication campaign,

- slaughtered for human consumption,

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

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

Member State

Minimum annual sample size (1)

Dead animals

Belgium
450

Denmark
400

Germany
6, 000

Greece
6, 000

Spain
6, 000

France
6, 000

Ireland
6, 000

Italy
6, 000

Luxembourg
30

Netherlands
5, 000

Austria
1, 100

Portugal
6, 000

Finland
250

Sweden
800

United Kingdom
6, 000

(1) The sample size has been calculated to detect a prevalence of 0,05 % with a 95 % confidence in dead animals in Member States with a large sheep population. In those Member States with a smaller sheep population, the sample size is calculated as 50 % of the estimated number of dead animals (estimated mortality 1%).

4. Monitoring in infected flocks

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

Number of culled animals over 12 months in the herd or flock

Minimum sample size (1)

70 or less
68

80
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

(1) The sample size is calculated to be 95 % certain of including at least one positive if the disease is present at a minimum prevalence of 2 % in the test population.

5. Monitoring in other animals

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

- animals used for dairy production,

- animals originating from countries with indigenous TSEs,

- animals which have consumed potentially contaminated feedingstuffs,

- animals born or derived from TSE infected dams,

- animals from flocks infected with TSE.

6. Measures following testing of ovine and caprine animals

6.1. Where an animal slaughtered for human consumption has been selected for testing for TSE, the health marking provided for in Chapter XI of Annex I to European Union Council Directive 64/433/EEC shall not be carried out on the carcass 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 a tested animal including the hide shall be retained under official control until a negative result to the rapid test has been obtained, unless they are destroyed in accordance with Schedule V, point 3 or 4.

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

7. Genotyping

7.1. The prion protein genotype shall be determined for each positive TSE case in sheep. TSE cases found in resistant genotypes (sheep of genotypes which encode alanin on both alleles at codon 136, arginin on both alleles at codon 154 and arginin on both alleles at codon 171) shall immediately be reported to the European Commission. Where possible, such cases shall be submitted for strain-typing. Where strain-typing of such cases is not possible, the herd of origin and all other herds where the animal has been shall be subjected to enhanced monitoring with a view to find other TSE cases for strain-typing.

7.2. In addition to the animals genotyped under the provisions of point 7.1, the prion protein genotype of a random subsample of the ovine animals tested under the provisions of Chapter A, Section II, point 2 shall be determined. This subsample shall represent at least one per cent of the total sample for each Member State, and shall not be less than 100 animals per Member State. By derogation, Member States may choose to genotype an equivalent number of live animals of a similar age.

III. MONITORING IN OTHER ANIMAL SPECIES

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

CHAPTER B

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

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

2. The number of suspected cases per animal species subject to laboratory examination in accordance with regulation 12(2) and the outcome of the examination.

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

4. The estimated size of each subpopulation referred to in Chapter A, Section I, points 3 and 4.

5. The number of bovine animals tested within each subpopulation referred to in Chapter A, Section I, point 2 to 5, the method for sample selection and the outcome of the tests.

6. The estimated size of those subpopulations referred to in Chapter A, Section II, points 2 and 3 which have been selected for sampling.

7. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, Section II, points 2 to 5, the method for sample selection and the outcome of the tests.

8. Number, age distribution and geographical distribution of positive cases of BSE and scrapie. The country of origin, if not the same as the reporting country, of positive cases of BSE and scrapie. Number and geographical distribution of scrapie positive flocks. The year and, where possible, month of birth should be given for each BSE case.

9. Positive TSE cases confirmed in animals other than bovine, ovine and caprine animals.

10. The genotype and where possible breed of each animal sampled within each subpopulation referred to in Chapter A, part II, points 7.1 and 7.2.

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 regulation 12(1),

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

- the number and outcome of laboratory examinations as referred to in regulation 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.

SCHEDULE IV
ANIMAL FEEDING

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

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

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

(a) processed animal protein;

(b) gelatine of ruminant origin;

(c) blood products;

(d) hydrolysed protein;

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

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

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

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

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

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

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

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

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

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

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

(ii) eggs and egg products;

(iii) gelatine derived from non-ruminants;

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

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

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

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

However, by way of derogation from that condition -

(i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing fishmeal is not required for home compounders -

- registered by the competent authority,

- keeping only non-ruminants,

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

- provided that the feedingstuffs containing fishmeal used in the production contain less than 50 % crude protein;

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

- bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing fishmeal are manufactured,

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

- records detailing the purchases and uses of fishmeal and the sales of feedingstuffs containing fishmeal are kept available to the competent authority for at least five years, and

- routine tests are carried out on feedingstuffs destined to ruminants to ensure that prohibited proteins including fishmeal are not present.

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

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

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

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

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

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

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

However, by way of derogation from that condition -

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

- registered by the competent authority,

- keeping only non-ruminants,

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

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

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

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

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

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

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

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

(e) The use and storage of feedingstuffs containing hydrolysed proteins 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 hydrolysed proteins in farms where ruminants are kept, if they are satisfied that on-farm measures are implemented to prevent the feeding of feedingstuffs containing hydrolysed proteins to ruminants.

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

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

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

However, by way of derogation from that condition -

(i) a specific authorisation for the production of complete feedingstuffs from feedingstuffs containing dicalcium phosphate or tricalcium phosphate is not required for home compounders -

- registered by the competent authority,

- keeping only non-ruminants,

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

- provided that the feedingstuffs containing dicalcium phosphate or tricalcium phosphate used in the production contain less than 10 % total phosphorus;

(ii) the production of feedingstuffs for ruminants in establishments which also produce feedingstuffs containing dicalcium phosphate or tricalcium phosphate for other animal species may be authorised by the competent authority subject to the following conditions -

- bulk and packaged feedingstuffs destined for ruminants are manufactured in facilities physically separate from facilities where feedingstuffs containing dicalcium phosphate or tricalcium phosphate are manufactured,

- bulk feedingstuffs destined for ruminants are kept in facilities physically separated from facilities where bulk dicalcium phosphate and bulk tricalcium phosphate and bulk feedingstuffs containing dicalcium phosphate and tricalcium phosphate are kept during storage, transport and packaging,

- records detailing the purchases and uses of dicalcium phosphate or tricalcium phosphate and the sales of feedingstuff containing dicalcium phosphate or tricalcium phosphate are kept available to the competent authority for at least five years.

(c) The label and accompanying document of the feedingstuffs containing dicalcium phosphate or tricalcium phosphate shall clearly indicate the words **"contains dicalcium, tricalcium phosphate of animal origin - cannot be fed to ruminants"**.

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

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

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

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

(a) the blood shall be derived from EU approved slaughterhouses not slaughtering ruminants which are registered as not slaughtering ruminants and shall be transported

directly to the processing plant in vehicles dedicated exclusively to the transport of non-ruminant blood. If the vehicle was used for the transport of ruminant blood, it shall be, following cleaning, inspected by the competent authority before the transport of non-ruminant blood.

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

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

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

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

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

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

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

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

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

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

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

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

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

3. II. General implementing conditions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- they are destined for uses not prohibited by article 7,

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

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

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

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

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

SCHEDULE V
SPECIFIED RISK MATERIAL

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

CATEGORIES 1 AND 2

None.

CATEGORIES 3 AND 4

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

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

CATEGORY 5

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

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

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

2. Specified risk material must be removed at -

(a) slaughterhouses;

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

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

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

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

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

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

(i) in accordance with the systems described in Chapters I to IV, VI and VII of the Annex to European Union Decision 92/562/EEC -

- by incineration;

- by coincineration;

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

4. Member States may derogate from the provisions of points 2 and 3 to allow the incineration or burial of specified risk material or entire bodies, without prior staining, or, as appropriate, removal of the specified risk materials, in the circumstances set out in article 3 (2) of European Union Council Directive 90/667/EEC and by a method which precludes all risk of transmission of a TSE and is authorised and supervised by the competent authority, in particular where animals have died or have been killed in the context of disease control measures and without prejudice to articles 12 and 13.

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

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

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

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

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

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

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

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

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

8. Member States may send specified risk material or the material processed therefrom to other Member States for incineration only under the conditions laid down in article 4 (2) of European Union Decision 97/735/EC, where applicable. These points may be amended at the request of a Member State to allow the dispatch of specified risk material or the material processed therefrom to third countries for incineration. The conditions governing export shall be adopted at the same time, by the same procedure.

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

The use of ruminant material for the production of the following products of animal origin is prohibited as referred to in regulation 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 European Union Council Directive 90/667/EEC.

SCHEDULE VII
ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

1. The inquiry referred to in regulation 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, all embryos, ova and the last progeny of the animal in which the disease was confirmed,

- all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those mentioned in the second 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 BSE agent to or from the holding in question.

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

(a) in case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in point 1(a), first, second and third indent. The Member State may decide not to kill and destroy all bovine animals on the holding of the animal in which the disease was confirmed as referred to in the first indent of point 1(a), depending upon the epidemiological situation and traceability of the animals on that holding;

(b) in the case of confirmation of TSE in an ovine or caprine animal, according to the decision of the competent authority -

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

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

- breeding rams of the ARR/ARR genotype,

- breeding ewes carrying at least 1 ARR allele and no VRQ allele, and,

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

(iii) if the infected animal has been introduced from another holding, a Member State may decide, based on the history of the case, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed. In the case of land used for common grazing by more than one flock, Member States may decide to limit the application of the measures to a single flock, based on a consideration of all the epidemiological factors,

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

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

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

(b) female sheep carrying at least 1 ARR allele and no VRQ allele;

(c) Caprine animals, provided that -

- no ovine animals other than those of the ARR/ARR genotype are present on the holding,

- thorough cleaning and disinfection of all animal housing on the premises has been carried out following de-stocking,

- the holding shall be subjected to intensified TSE monitoring, including the testing of all culled and dead-on-farm caprine animals over the age of 18 months.

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

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

(b) embryos carrying at least 1 ARR allele and no VRQ allele.

4. During a transitional period until 1 January 2006 at the latest, and by way of derogation from the restriction set out in point 3(b), where it is difficult to obtain replacement ovine animals of a known genotype, Member States may decide to allow non-pregnant ewe lambs of an unknown genotype to be introduced to the holdings referred to in point 2(b)(i) and (ii).

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

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

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

(c) sheep of other genotypes may only be moved from the holding for the purposes of destruction.

6. The restrictions referred to in points 3 and 5 shall continue to apply to the holding for a period of three years from -

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

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

(c) in the case of point 3.1(c), the date when the intensified TSE monitoring commenced.

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

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

(b) allow ovine animals other than those specified in point 3 to be introduced to the holdings referred to in point 2(b)(i) and (ii), provided that they do not carry a VRQ allele.

8. Members States applying the derogations referred to in points 4 and 7 shall notify to the European Commission an account of the conditions and criteria used for granting them.

SCHEDULE VIII
PLACING ON THE MARKET AND EXPORT

CHAPTER A

Conditions for intra-Community trade in live animals

I. Conditions which apply irrespective of the category of the Member State or third country of origin or residence of the animal

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

(a) ovine and caprine animals for breeding shall either -

(i) come from a holding which has satisfied the following requirements for at least three years -

- 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 culling is carried out on the holding,

- females are introduced into that holding only if they come from a holding which complies with the same requirements; or

(ii) have been continuously kept on a holding or holdings complying with the requirements laid down in point (i) since birth or for the last three years; or

(iii) be animals of the ARR/ARR prion protein genotype, as defined in Annex I of European Union Commission Decision 2002/1003/EC.

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), they shall comply with the additional guarantees, general or specific, which have been defined in accordance with the procedure referred to in regulation 24(2);

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

(i) may submit the said program to the European 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 regulation 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 regulation 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 regulation 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 European 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 regulation 24(2). Such guarantees must not exceed those which the Member State implements nationally,

(iii) the Member State concerned is to notify the European 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 regulation 24(2).

3. In Part D, point 1 of Schedule XI the following words are deleted -

"Commission Decision 92/290/EEC of 14 May 1992 concerning certain protection measures relating to bovine embryos in respect of bovine spongiform encephalopathy (BSE) in the United Kingdom."

II. Conditions which apply depending on the category of the Member State of origin or residence of the animal determined in accordance with Schedule II, Chapter C

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

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

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

CATEGORIES 3 AND 4

The animals must have -

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

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

CATEGORY 5

The animals must have -

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

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

CHAPTER B

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

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

CHAPTER C

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

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

- fresh meat;

- minced meat;

- meat preparations;

- meat products;

- petfood which is destined for domestic carnivores.

II.

DATE-BASED SCHEME

Deboned fresh meat from which all adherent tissues, including obvious nervous and lymphatic tissue, has been removed, and products of animal origin referred to in Part I deriving therefrom obtained from

eligible animals from countries or regions in category 5 may be marketed in accordance with the second subparagraph of regulation 16 (3) when they are obtained from animals born after the date from which the animal feeding standards laid down in regulation 7 (2) were effectively enforced and certified as meeting the conditions laid down in point 1 and they are produced in establishments which meet the condition laid down in point 9. The competent authority shall ensure that the conditions with respect to controls laid down in points 2 to 8 and point 10 are complied with.

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

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

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

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

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

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

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

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

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

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

6. All approved eligible carcasses must have individual numbers correlated with the ear-tag number.

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

(a) tracing and controls prior to slaughter;

(b) controls during slaughter;

(c) controls during processing of petfood;

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

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

THE ESTABLISHMENT

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

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

III.

CERTIFIED HERD SCHEME

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

The competent authority shall ensure that the conditions laid down in points 3 to 10 and 12 with respect to the computerised tracing system and the controls are complied with.

Conditions relating to herds -

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

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

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

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

and,

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

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

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

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

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

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

Conditions relating to the animal -

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

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

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

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

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

Computerised tracing system

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

Controls

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

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

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

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

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

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

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

(a) tracing and controls prior to slaughter;

(b) controls during slaughter;

(c) controls during processing of petfood;

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

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

The establishment

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

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

CHAPTER D

Conditions applicable to exports of 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 these regulations for intra-Community trade.

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

CHAPTER A

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

CHAPTER B

Imports of bovine animals

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

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

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

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

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

2. bovine animals intended for export to the European Community -

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

- were born, raised and had remained in herds in which no case of BSE had been confirmed for at least seven years;

or,

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

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

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

2. bovine animals intended for export to the European Community -

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

and

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

or

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

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

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

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

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

(b) all bovine animals from the same cohort if such animals are still alive in the country or region;

3. the animals intended for export to the European Community -

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

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

and,

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

or

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

CHAPTER C

Imports of fresh meat and products of bovine animal origin

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

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

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

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

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

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

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

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

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

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

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

4. the bovine animals from which the meat or meat products intended for export to the European Community -

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

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

and either -

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

or

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

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

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

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

(b) all bovine animals from the same cohort if they are still alive in the country or region.

CHAPTER D

Imports of bovine embryos and ova

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

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

2. the embryos, ova were collected, processed and stored in conformity with the provisions of Annexes A and B to European Union Council Directive 89/556/EC.

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

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

2. ova, embryos destined for export to the European Community are derived from females which -

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

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

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

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

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

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

2. the ova, embryos intended for export to the European Community are derived from females which -

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

(b) are not affected with BSE;

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

and

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

or

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

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

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

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

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

3. ova, embryos intended for export to the European Community are derived from females which -

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

(b) are not affected with BSE;

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

and

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

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

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

CHAPTER E

Imports of ovine and caprine animals

Ovine and caprine animals imported into the European Community 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 subparagraphs (i) and (ii) of point (a) of Chapter A(I) of Schedule VIII;

(b) or they are sheep of the ARR/ARR prion protein genotype, as defined in Annex I to European Union 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 Schedule VIII, they shall comply with the additional guarantees, general or specific, which have been defined in accordance with the Veterinary Services Act and the procedure referred to in regulation 24(2).

CHAPTER F

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

- mechanically recovered meat;

- dicalcium phosphate intended for feeding livestock;

- gelatine unless produced from hides or skins;

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

CHAPTER G

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

"The product of animal origin does not contain, and is not derived from, specified risk material as defined in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies or mechanically recovered meat obtained from bones of the head or vertebral column of bovine animals. The animals have not been slaughtered after stunning by means of a gas injected into the cranial cavity or killed instantaneously by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rodshaped instrument introduced into the cranial cavity."

SCHEDULE 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 European Community reference laboratory;

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

(c) be responsible for co-ordination 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 co-operate with the European 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 European Community reference laboratory or of national reference laboratories in other Member States.

3. The national reference laboratories are -

Austria -
Bundesanstalt für Tierseuchenbekämpfung, Mödling Robert Koch Gasse 17 A2340 Mödling

Belgium -
CERVACODAVAR Centre d'Étude et de Recherches Vétérinaires et Agrochimiques Centrum voor Onderzoek in Diergeneeskunde en Agrochemie Veterinary and Agrochemical Research Centre Groeselenberg 99 B1180 Bruxelles.

Denmark -
Danish Veterinary Laboratory Bülowsvej 27 DK1790 Copenhagen V.

Finland -
Eläinlääkintä- ja elintarvikelaitos Hämeentie 57 FIN00550 Helsinki.

France -
Agence Française de Sécurité, Sanitaire des Aliments Laboratoire de pathologie bovine 31, avenue Tony Garnier BP 7033 F69342 Lyon Cedex.

Germany -
Bundesforschungsanstalt für Viruskrankheiten der Tiere Anstaltsteil Insel Riems Boddenblick 5A D17498 Insel Riems.

Greece -
Greece Ministry of Agriculture; Veterinary Laboratory of Larisa; 7th km of Larisa — Trikala Highway GR-411 10 Larisa (rapid tests and immunological tests).

Laboratory of Gross Pathology; Faculty of Veterinary Medicine; Aristotelian University of Thessaloniki; Giannitson & Voutyra St. GR-546 27 Thessaloniki (histopathology).

Ireland -
Central Veterinary Research Laboratory, Abbotstown, Castleknock, Dublin 15, Ireland.

Italy -
Istituto Zooprofilattico Sperimentale del Piemonte Liguria e Valle d'Aosta CEA Via Bologna I14810150 Torino.

Luxembourg -
CERVACODAVAR Centre d'Étude et de Recherches Vétérinaires et Agrochimiques Centrum voor Onderzoek in Diergeneeskunde en Agrochemie Veterinary and Agrochemical Research Centre Groeselenberg 99 B1180 Bruxelles.

Netherlands -
Instituut voor Dierhouderij en Diergezondheid, IDDLO Lelystad Edelhertweg 15 Postbus 65 8200 AB Lelystad Netherlands.

Portugal -
Laboratório Nacional de Investigação Veterinária Estrada de Benfica, 701 P1500 Lisboa.

Spain -
Laboratorio de la Facultad de Veterinaría Departamento de Patología Animal (Anatom¡a Patológíca) Zaragoza Spain (BSE and scrapie, methods other than rapid tests) Laboratorio Central de Veterinaria de Algete Madrid Spain (rapid tests) Centro de Investigacion en Sanidad An¡mal (CISA) Crta, De Algete al Casar de Talamanca 28130 Valdeolmos (Madrid) Spain (TSEs other than BSE or scrapie).

Sweden -
National Veterinary Institute S751 89 Uppsala.

United Kingdom -
United Kingdom Veterinary Laboratories Agency Woodham Lane New Haw Addlestone Surrey KT15 3NB.

CHAPTER B

Community reference laboratory

1. The European 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 European Community reference laboratory are -

(a) to co-ordinate, in consultation with the European 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 European Community level;

- collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the European Community;

- characterising isolation 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 European Community.

CHAPTER C

Sampling and laboratory testing

1. Sampling

Any samples intended to be examined for the presence of a TSE shall be collected using the methods and protocols laid down in the latest edition of the Manual of standards for diagnostic tests and vaccines of the International Office for Epizooties (IOE/OIE) (hereinafter referred to as "the Manual"). In the absence of such methods and protocols, the samples shall be collected in a manner appropriate for the correct application of tests. The samples shall be correctly marked as to the identity of the sampled animal.

2. Laboratories

Any laboratory examination for TSE shall be carried out in laboratories approved for that purpose.

3. Methods and protocols

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

(a) Suspect cases

Tissues from bovine animals sent for laboratory testing pursuant to the provisions of regulation 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 (immuno-cytochemistry, immuno-blotting or demonstration of characteristic fibrils by electron microscopy). However, rapid tests cannot be used for this purpose.

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

(b) BSE monitoring

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

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

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

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

- the result of another diagnostic method mentioned under (a) is positive.

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

(a) Suspect cases

Tissues from ovine and caprine animals sent for laboratory testing pursuant to the provisions of regulation 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 immuno-cytochemistry or immuno-blotting, as laid down in the Manual. However, rapid tests cannot be used for this purpose.

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

(b) Scrapie monitoring

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

When the result of the rapid test is inconclusive or positive, the brainstem shall immediately be sent to an official laboratory for confirmatory examinations by immuno-cytochemistry or immuno-blotting, as referred to under (a).

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

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

The tests carried out to confirm the suspected presence of a TSE different from those referred to in points 3.1 and, 3.2 shall include at least a histopathological examination of brain tissue. The competent authority may also require laboratory tests such as immuno-cytochemistry, 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.

4. Rapid tests

For the purposes of carrying out the rapid tests in accordance with regulation 5(3) and regulation 6(1), the following methods shall be used as rapid tests -

- immuno-blotting test based on a Western blotting procedure for the detection of the protease-resistant fragment PrPRes (Prionics-Check Western test),

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

- sandwich immunoassay for PrPRes carried out following denaturation and concentration steps (Bio-Rad TeSeE test, the former Bio-Rad Platelia test). However, existing stocks bearing the name 'Bio-Rad Platelia test' may be used within nine months from the date of entry into force of these Regulations,

- microplate based immunoassay (ELISA) which detects protease-resistant PrPRes with monoclonal antibodies (Prionics-Check LIA test),

- automated conformation-dependent immunoassay comparing the reactivity of a detection antibody to the protease-sensitive and protease-resistant forms of PrPSc (some fraction of the protease-resistant PrPSc is equivalent to PrPRes) and to PrPC (InPro CDI-5 test).

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

Modifications to the rapid test or to the test protocol may only be made following advance notification to the European Community reference laboratory and provided that the European Community reference laboratory finds that the modification does not reduce the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the European Commission and to the national reference laboratories.

5. Alternative tests.

SCHEDULE XI
TRANSITIONAL MEASURES REFERRED TO IN REGULATIONS 22 AND 23

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

1. (a) The following tissues are designated as specified risk material -

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

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

The age set forth above for the removal of bovine vertebral column may be adjusted by amending these regulations in the light of the statistical probability of the occurrence of BSE in the relevant age groups of the European Community's bovine population, based on the results of BSE monitoring as established by Chapter A.I of Schedule III.

(b) In addition to the specified risk material listed in (a), the following tissues must be designated as specified risk material in the United Kingdom of Great Britain and Northern Ireland and in Portugal, with the exception of the Autonomous Region of the Azores -

- the entire head excluding the tongue, including the brain, eyes and trigeminal ganglia; the thymus, the spleen and the spinal cord of bovine animals aged over 6 months.

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

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

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

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

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

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

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

This derogation shall not be granted to allow the use of vertebral column and dorsal root ganglia from bovine animals aged over 30 months from the United Kingdom or from Portugal with the exception of the Autonomous Region of the Azores.

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

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

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

5. Specified risk material shall be removed at -

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12. Member States shall carry out frequent official inspections to verify the correct application of this part and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants or other places where specified risk material is removed, such as butcher shops or establishments referred in point 5(c).

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

(a) specified risk material used for purposes authorised pursuant to regulation 1(3) and to European Union Regulation (EC) No 1774/2002 are used solely for authorised purposes;

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

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

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

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

(a) when removal of the vertebral column is not required, 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 European Union Regulation (EC) No 1760/2000;

(b) a specific indication of 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 commercial document referred to in article 3(1)(A)(f)(ii) of European Union Council Directive 64/433/EEC or to the document referred to in article 1(2) of European Union Commission Decision 93/13/EEC, as applicable;

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

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

- the specified risk material referred to in point 1(a),

- fresh meat - the meat defined by European Union Council Directive 64/433/EEC,

- minced meat and meat preparations: the minced meat and meat preparations defined by European Union Council Directive 94/65/EC,

- meat products: the meat products defined by European Union Council Directive 77/99/EEC,

- other products of animal origin: other products of animal origin as defined by European Union Council Directive 77/99/EEC,

- rendered fats as referred to in European Union Regulation (EC) No 1774/2002,

- gelatine as referred to by European Union Council Directive 92/118/EEC and European Union Regulation (EC) No 1774/2002,

- pet food as referred to in European Union Regulation (EC) No 1774/2002,

- blood products as referred to in European Union Regulation (EC) No 1774/2002,

- the processed animal protein referred to in European Union Regulation (EC) No 1774/2002,

- bones and bone products as referred to in European Union Regulation (EC) No 1774/2002,

- category 3 material as referred to in European Union Regulation (EC) No 1774/2002.

Any reference to "products of animal origin" designates products of animal origin listed in this point and does not concern other products of animal origin containing or derived from those products of animal origin.

(b) When the abovementioned products of animal origin, containing material from bovine, ovine or caprine animals are imported into the European Community from third countries or regions thereof, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows -

"This product does not contain and is not derived from -

either

specified risk material as defined in Annex XI, section A, to European Union Regulation (EC) No 999/2001 produced or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals. The bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

Carcasses, half carcasses and quarter carcasses may contain vertebral column on import;

Or

Bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in the following countries -

- Argentina

- Australia

- Botswana

- Brazil

- Chile

- El Salvador

- Iceland

- Namibia

- Territoire français de la Nouvelle Calédonie

- New Zealand

- Nicaragua

- Panama

- Paraguay

- Singapore

- Switzerland

- Uruguay

- Vanuatu."

B. Concerning statistical surveys

deleted by (EC) No. 1494/2002

C. Concerning prohibitions on animal feeding

deleted by (EC) No. 1234/2003

D. Concerning placing on the market and export

1. The following provisions remain in force as transitional measures -

European Union Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC.

European Union Commission Decision 98/351/EC of 29 May 1998 setting the date on which dispatch from Northern Ireland of bovine products under the Export Certified Herds Scheme may commence by virtue of article 6(5) of European Union Council Decision 98/256/EC.

European Union Commission Decision 1999/514/EC of 23 July 1999 setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence by virtue of article 6(5) of Council Decision 98/256/EC.

European Union Commission Decision 2000/345/EC of 22 May 2000 setting the date on which dispatch from Portugal to Germany of certain products for the purpose of incineration may commence by virtue of article 3(6) of European Union Decision 98/653/EC.

European Union Commission Decision 2000/371/EC of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to France may commence by virtue of article 3(7) of European Union Decision 98/653/EC.

European Union Commission Decision 2000/372/EC of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to Spain may commence by virtue of article 3(7) of European Union Decision 98/653/EC.

European Union Commission Decision 2001/376/EC of 18 April 2001 concerning measures made necessary by the occurrence of bovine spongiform encephalopathy in Portugal and implementing a date-based export scheme.

2. Imports of bovine animals are to be subject to the presentation of an international animal health certificate attesting that -

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

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

3. Point 2 shall not apply to imports of bovine animals born and continuously reared in the following countries -

Argentina

- Australia

- Botswana

- Brazil
- Chile
- El Salvador
- Iceland
- Namibia
- Territoire français de la Nouvelle Calédonie
- New Zealand
- Nicaragua
- Panama
- Paraguay
- Singapore
- Switzerland
- Uruguay
- Vanuatu.