



COMMISSION OF THE EUROPEAN COMMUNITIES

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**Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL REGULATION**

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

**Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE**

amending Council Directive 91/68/EEC as regards scrapie

(presented by the Commission)



EXPLANATORY MEMORANDUM

On 20 October 1997 the Commission promised, in its final consolidated report to the Temporary Committee of the European Parliament on the Follow up of the Recommendations on BSE, to present a proposal for an effective surveillance of transmissible spongiform encephalopathies (TSEs) based on Article 100A to the European Parliament and the Council.

On 31 March 1998, in adopting the decision postponing until 1 January 1999 the entry into force of Commission Decision 97/534/EC on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathy of 30 July 1997, the Council invited the Commission to submit as soon as possible, after the plenary session of the OIE in May 1998, an appropriate proposal in this field.

In response the Commission stated to maintain its intention to come forward with a larger proposal based on Article 100A of the Treaty, which would involve both the European Parliament and the Council.

The proposal at hand fulfils with respect to the production of food and feed both above commitments of the Commission.

The main objective of the proposal is to create the legal base for the control and prevention of all animal TSEs and for all products, including those not covered by Annex II of the Treaty. The articles of the proposal provide the necessary instruments to reach this goal, in the Annexes the details are worked out as far as possible according to current knowledge. Implementing rules are foreseen where future action can be expected.

The provisions are based on the OIE recommendations on BSE and the various scientific opinions available in order to ensure a very high level of protection. In addition to the amendments to the Code adopted by the OIE in May '98, the amendments proposed in September 1998 by the OIE Code Commission have been taken into account. These latter amendments, filling in all missing elements of the '98 Code on BSE, follow the recommendations of the scientific Ad hoc Group on the epidemiology of BSE which met in June 1998.

Pour parfaitement fonctionner, toute démarche en matière de sécurité alimentaire doit s'appuyer sur trois éléments majeurs : les avis scientifiques, l'analyse de risque et le contrôle. Ces éléments doivent constituer une base solide permettant aux actions proposées dans le domaine législatif de s'appuyer sur des résultats, qu'il s'agisse d'avis scientifiques, d'analyse de risque ou de missions de contrôle. D'une manière générale, les avis scientifiques sont une étape préalable d'une importance primordiale lors de l'élaboration de propositions ou de mesures législatives susceptibles d'avoir un impact sur la sécurité des denrées alimentaires et la protection du consommateur. Chaque décision doit être prise en pleine considération des meilleures données scientifiques disponibles. Cependant, et sans pour autant porter atteinte au rôle essentiel qui leur revient, il est en même temps nécessaire de reconnaître que les avis scientifiques ont des limites inéluctables à leur fonction. Dans certains cas, il peut apparaître justifié d'aller au-delà des évidences scientifiques ou bien de les pondérer en fonction de la tolérance de la société vis-à-vis des risques identifiés. Dans d'autres cas encore, il peut s'avérer que les avis scientifiques ne sont pas suffisamment probants ou exhaustifs pour permettre pas de tirer des conclusions définitives. C'est pourquoi, dans le domaine de la protection de la santé des consommateurs, l'analyse de risque, qui intègre les différentes étapes

d'évaluation des risques (évaluation scientifique des dangers et de leur probabilité d'apparition dans un contexte donné), de gestion du risque et de communication du risque, doit permettre de jouer un rôle d'interface entre le monde scientifique et celui de la politique et des autres composantes de la société civile. En effet, le rôle essentiel de la gestion du risque est de maintenir ou de réduire le niveau de risque identifié par l'étape d'évaluation de façon à atteindre un niveau de protection approprié. Dans cette approche, il est utile de rappeler que le concept de « risque zéro » n'existe pas, et que l'information sur le niveau de risque toléré, et par conséquent le niveau de protection, est essentielle pour le consommateur.

Where international standards or scientific advice are absent, for example for the eradication of BSE, current Community standards are proposed.

In principle the prevention and control of all animal TSEs with respect to food and feed is covered.

Industrial, cosmetic and medicinal products, medical devices and products destined for research, exhibitions or teaching are not included, because there is either no inherent risk for human or animal health or the provisions are covered by sectoral legislation. A general provision to ensure that those products, which are not covered by the Regulation, can not enter the food and feed chains provides the necessary protection during the production process.

An important exception to the above is the exclusion of the animal waste legislation, despite the fact that the predominant motivation for this legislation is protection against TSEs. For technical reasons it was considered beneficial to keep the animal waste legislation separate as a coherent independent set of legislation. The elements of this legislation such as waste processing standards, validation of processes, approval of establishments, placing on the market of rendered products, etc. are strongly interdependent and form a coherent entity. Moreover, they are primarily based on general hygiene standards.

It is proposed to treat national trade, intra-Community trade, import and export in an equivalent manner. As a consequence, Community rules for export are introduced and the dual standard for consumers in high-risk areas, i.e. the United Kingdom, is abolished. This approach is consistent with our international obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

The successful experimental infection of sheep by feeding them BSE contaminated material, and the ensuing clinical expression of the disease which is indistinguishable from scrapie, the fact that exposure to contaminated feed of sheep in the field can not be excluded and, finally, the hypothesis that in the past scrapie could have evolved into BSE and caused the BSE epidemic, lay at the root of the policy of the Commission to address all TSEs and all ruminants in its preventive measures to protect against TSEs. The feed ban prohibits the use of mammalian protein in all ruminant rations. The SRM ban requires removal and incineration of SRMs from bovine, ovine and caprine animals. The TSE surveillance addresses all TSEs and in particular BSE and scrapie.

This policy is continued in the current proposal. All existing Community rules on TSEs are incorporated in the proposal, including the preventive measures mentioned above.

A legal base is created for eradication of all TSEs, including scrapie and BSE in sheep, and for trade requirements preventing the spread of BSE by movements of live bovine, ovine and caprine animals. In the absence of scientific advice and international standards on the eradication of scrapie, or on trade rules to prevent the spread of BSE through sheep, no detailed rules are proposed in these areas. The same would apply to eradication of BSE in sheep but following the precautionary principle and the serious consequences of the possible establishment of a BSE reservoir in sheep, detailed rules for BSE eradication in sheep are proposed nevertheless.

Community rules for the movement of live breeding sheep and goats related to scrapie already exist. These have been transposed to this proposal, with the exception of the current option for Member States to demand additional guarantees on the basis of a Community approved scrapie control programme. In the past a policy decision was taken not to proceed with the approval of national programmes and the subsequent granting of additional guarantees beyond the limited list of diseases for which programmes had already been approved. It was felt that the accumulation of national programmes and additional guarantees would constitute an unjustified barrier to trade and disrupt the internal market. The aforementioned list does not include scrapie. Since the proposal at hand has as its objective to harmonise all trade rules relating to TSEs, including scrapie, and offers the legal base for eradication of scrapie there is no longer a need for national programmes for scrapie control.

For implementing rules the management procedure is proposed; for new rules, and amendment of the Annexes, the Regulatory procedure is proposed. This is considered appropriate to give the Commission the necessary tools to "manage" the BSE crisis. The management procedure is also the main procedure in the Agenda 2000 proposals.

**Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL REGULATION**

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

(Text with EEA relevance)

98/ 0323(COD)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a* thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 189b of the Treaty³,

- (1) Whereas several distinct transmissible spongiform encephalopathies (TSEs) have been recognised for many years to occur separately in humans and animals; whereas bovine spongiform encephalopathy (BSE) was first recognised in bovine animals in 1986 and in following years was recognised to occur in other species of animals; whereas a new variant of Creutzfeldt-Jakob Disease (nv-CJD) was described in 1996; whereas evidence is accumulating that the agent causing BSE is identical to that causing nv-CJD;
- (2) Whereas since 1990 the Community has adopted a series of measures to protect human and animal health from the risk of BSE; whereas those measures have been based on the safeguard provisions of Council Directives on veterinary control measures; whereas it is appropriate, in view of the magnitude of the risk posed to human and animal health by certain TSEs, to adopt specific rules in the form of a Regulation for their prevention and control;
- (3) Whereas this regulation directly concerns public health and is relevant to the functioning of the internal market; whereas it covers products which are included in Annex II to the Treaty as well as products which are not; whereas, therefore, it is appropriate to choose Article 100a of the Treaty as the legal basis;
- (4) Whereas the Commission has obtained scientific opinions, in particular from the Scientific Steering Committee and the Scientific Committee on Veterinary Measures related to Public Health, on several aspects of TSEs; whereas those opinions include advice on measures to reduce the potential risk for humans and animals resulting from exposure to infected animal products;

* At the moment at which the Amsterdam Treaty comes into force, please read Article 152.

1 O J C

2 O J C

3 O J C

- (5) Whereas the rules should apply to the production and placing on the market of live animals and products of animal origin; whereas, however, they should not apply to cosmetic, or medicinal products, medical devices or their starting materials or intermediate products, for which other specific rules apply; whereas they should also not apply to products of animal origin which do not pose a risk to animal or human health since they are intended for purposes other than human food, animal feed or fertiliser; whereas it is appropriate to ensure that products of animal origin excluded from the scope of this Regulation are kept separate from those covered by it unless they meet at least the same health standards as the latter;
- (6) Whereas provision should be made for safeguard measures to be taken by the Commission in cases where a risk from a TSE has not been adequately addressed by the competent authority of a Member State or third country;
- (7) Whereas a procedure should be established for the determination of the epidemiological status, with respect to BSE, of countries or regions, on the basis of the assessment of the incident, propagation and human exposure risk using information supplied to the Commission; whereas Member States and third countries which choose not to apply for their status to be determined should be placed in a category by the Commission on the basis of all information available to the Commission;
- (8) Whereas Member States should institute education programmes for those involved in the prevention and control of TSEs, as well as for veterinarians, farmers and workers involved in the transportation, marketing and slaughter of farm animals;
- (9) Whereas Member States should carry out an annual programme of monitoring for BSE and scrapie and should inform the Commission and the other Member States of the results of the programme each year, and of the emergence of any other TSE;
- (10) Whereas certain ruminant tissues should be designated as specified risk materials on the basis of the pathogenesis of TSEs and the epidemiological status of the country or region of origin or residence of the animal concerned; whereas the specified risk materials should be removed and disposed of in a manner which avoids any risk to human or animal health; whereas, in particular, they should not be placed on the market for human food, animal feed or fertiliser; whereas, however, provision should be made for an equivalent level of health protection to be achieved by means of a test for TSEs carried out on individual animals; whereas slaughter techniques presenting a risk of causing brain material to contaminate other tissues should not be permitted in countries or regions other than those presenting the lowest risk of BSE;
- (11) Whereas measures should be taken to prevent the transmission of TSEs to humans or animals by prohibiting the feeding of certain categories of animal protein to certain categories of animals, and by prohibiting the use of certain ruminant materials in human food; whereas those prohibitions should be proportionate to the risks involved;

- (12) Whereas the suspected presence of any TSE in any animal should be notified to the competent authority, which should immediately take all appropriate measures, including placing the suspect animal under movement restrictions pending the outcome of an assessment or its killing under official supervision; whereas if the competent authority cannot exclude the possibility of a TSE, it should have the appropriate investigations carried out and should retain the carcase under official supervision until a diagnosis has been made;
- (13) Whereas in the event of official confirmation of the presence of a TSE, the competent authority should take all the necessary measures including the destruction of the carcase, carrying out an enquiry to identify any other animals at risk, and placing animals and products of animal origin identified as carrying a risk under movement restrictions; whereas owners should be compensated fully, without delay, for the loss of animals and products of animal origin destroyed pursuant to this Regulation;
- (14) Whereas Member States should draw up contingency plans for the national measures to be implemented in the event of an outbreak of BSE; whereas those plans should be approved by the Commission; whereas provision should be made for extending this provision to TSEs other than BSE;
- (15) Whereas provisions should be laid down covering the placing on the market of certain live animals, semen, ova and embryos; whereas existing Community rules on the identification and registration of bovine animals provide for a system enabling the animals to be traced back to the dam and herd of origin in accordance with the international standards; whereas equivalent guarantees should be provided for bovine animals imported from third countries; whereas the animals and products of animal origin covered by these provisions, moving in intra-Community trade or imported from third countries, should be accompanied by the certificates required by Community legislation, supplemented as appropriate in accordance with this Regulation; whereas those existing rules may be extended to cover other live animals, semen, ova and embryos;
- (16) Whereas the placing on the market of products of animal origin derived from bovine animals in high risk areas should be prohibited; whereas, however, that prohibition should not apply to certain products of animal origin produced under controlled conditions from animals which can be demonstrated not to pose a high risk of infection with a TSE;
- (17) Whereas it is necessary, in order to ensure that the rules concerning the prevention and control of TSEs are observed, for samples to be taken for laboratory testing; whereas in order to guarantee uniform testing procedures and results, national and Community Reference Laboratories should be established;
- (18) Whereas Community inspections should be carried out in the Member States in order to ensure uniform implementation of the requirements concerning the prevention and control of TSEs and should also include the application of audit procedures; whereas in order to ensure that guarantees concerning the prevention and control of TSEs equivalent to those applied by the Community are provided by third countries on import of live animals and products of animal origin, Community on the spot inspections and audits must be carried out in order to verify that the import conditions are met by exporting third countries;

- (19) Whereas trade measures for TSEs should be based on international standards, guidelines or recommendations, where they exist; whereas, however, scientifically justified measures resulting in a higher level of sanitary protection may be adopted if measures based on the relevant international standards, guidelines or recommendations would not achieve the appropriate level of sanitary protection;
- (20) Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Regulation; whereas to that end, procedures should be laid down establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee and the Standing Committee for Feedingstuffs;
- (21) Whereas this Regulation should be reviewed in the light of new scientific information,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs). It shall apply to the production and placing on the market of live animals and products of animal origin.
2. This Regulation shall not apply to:
 - (a) cosmetic or medicinal products or medical devices, together with their starting materials or intermediate products;
 - (b) products which are not destined for use in human food, animal feed or fertilisers together with their starting materials or intermediate products;
 - (c) products of animal origin destined for exhibition, teaching, research, special studies or analysis.

Article 2

Separation of products of animal origin

In order to avoid cross-contamination or substitution of the products of animal origin referred to in Article 1(1) by those referred to in Article 1 (2), they shall be kept separate at all stages unless the latter are produced under at least the same conditions of health protection in respect of TSEs.

Rules for the implementation of this Article shall be adopted in accordance with the procedure laid down in Article 22.

Article 3

Definitions

For the purposes of this Regulation, the following definitions and those laid down in Annex I shall apply:

- (1) *transmissible spongiform encephalopathies or TSEs*: all TSEs with the exception of those occurring in humans;
- (2) *placing on the market*: any operation the purpose of which is to supply live animals, semen, embryos, ova or products of animal origin covered by this Regulation to a third party for sale, or any other form of transfer against payment or free of charge to a third party and storage with a view to supply to a third party, regardless of whether the operation takes place within a Member State, between Member States or between a Member State and a third country or vice versa;
- (3) *products of animal origin*: any products derived from or containing a product derived from any animal;
- (4) *starting materials*: raw materials or any other product of animal origin out of which, or with the help of which, the products referred to in Article 1(2)(a) and (b) are produced;
- (5) *competent authority*: the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country;
- (6) *categories*: the categories set out in Annex II, Chapter B;
- (7) *specified risk material*: the tissues specified in Annex IV; unless otherwise specified, it does not include products containing or derived from those tissues;
- (8) *farmed animal*: any vertebrate or invertebrate animal which is kept, fattened or bred for reproduction or the production of meat, milk, eggs, wool, fur, feathers, skins, or any other product of animal origin;
- (9) *skull*: the bones of the head, including the bones of the lower jaw;
- (10) *animals suspected of being infected*: animals which show clinical signs compatible with TSE and for which no alternative diagnosis has been established, or animals showing post-mortem lesions or reactions in laboratory tests giving rise to reasonable suspicion of the presence of a TSE. BSE shall be suspected in bovine animals aged over 20 months and scrapie in ovine and caprine animals aged over 12 months displaying behavioural or neurological signs where the disease cannot be ruled out either on the basis of response to treatment or following laboratory examination;
- (11) *holding*: any place in which animals covered by this Regulation are held, kept, bred, handled or shown to the public;

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

Article 4

Safeguard measures

1. Where the risk of transmission of a spongiform encephalopathy constitutes a hazard to the life or health of humans or animals in the Community and the competent authority has not taken the appropriate measures, the Commission shall, acting on its own initiative or at the request of a Member State, adopt the appropriate safeguard measures without delay.

Where a Member State has requested such measures the Commission shall decide on that request within ten working days after receipt thereof.

2. Within ten working days after the adoption of the safeguard measures, the Commission shall, in accordance with the procedure laid down in Article 22, confirm, amend or repeal the measures.

CHAPTER II

DETERMINATION OF BSE STATUS

Article 5

Classification

1. Member States or third countries shall submit an application to the Commission, accompanied by the information laid down in Annex II, Chapter A, for their BSE status to be determined.
2. The Commission, acting in accordance with the procedure laid down in Article 23, shall take a decision in respect of each application to place the applicant Member State or third country, or region thereof, in one of the categories set out in Annex II, Chapter B.

The Commission shall take its decision within six months after the submission of the application. If the Commission finds that the application does not include all the information laid down in Annex II, Chapter A, it shall ask for additional information within a delay to be specified. The final decision shall then be taken within six months after submission of the complete information.

3. Member States or third countries which have not submitted an application in accordance with paragraph 1 within six months after the date referred to in the second paragraph of Article 26 shall be placed in a category by the Commission on the basis of all information available to the Commission.
4. Member States shall communicate any changes in the circumstances relevant to their BSE status to the Commission without delay. The eligibility of third countries to export to the Community live animals or products of animal origin,

for which this Regulation provides specific rules, shall be conditional upon their undertaking in writing to communicate any changes in the circumstances relevant to their BSE status to the Commission without delay.

5. The decisions referred to in paragraphs 2 and 3 shall be taken after consultation of the appropriate scientific committee and shall be based on an assessment of the incident, propagation and human exposure risk, taking into consideration the recommended criteria** set out in Annex II, Chapter B.

CHAPTER III

PREVENTION OF TSES

Article 6

Education programme

Member States shall establish education programmes for staff of the competent authority and of diagnostic laboratories, for veterinarians, farmers and workers involved in transportation, marketing and slaughter of farmed animals, animal breeders and keepers and persons handling animals in order to enhance the efficacy of the monitoring system, referred to in Article 7, and to encourage reporting of cases of neurological disease in adult animals and, as appropriate, laboratory findings relating to TSEs.

Article 7

Monitoring system

1. Each Member State shall carry out an annual programme of monitoring of BSE and scrapie in accordance with Annex III, Chapter A.
2. Each Member State shall inform the Commission and the other Member States, within the Standing Veterinary Committee, of the results obtained from the monitoring programme referred to in paragraph 1, and of the emergence of TSEs other than BSE or scrapie.
3. The information for each calendar year shall be presented in a report submitted to the Commission at the latest by 31 March of the following year. It shall cover at least the information referred to in Annex III, Chapter B.

Article 8

Specified risk material

1. The specified risk materials shall be removed and disposed of in accordance with Annex IV. They shall not be placed on the market for human food, animal feed or fertilisers.

** The Commission undertakes to propose during the legislative process, criteria for the assessment of the propagation and human exposure risk.

2. Paragraph 1 shall not apply where animals have been subjected to a test which has been approved by the Commission in accordance with the procedure laid down in Article 22, applied under the conditions laid down in Annex IV, point 7, and the results of that test were negative.
3. In Member States, or regions thereof, which are not placed in Category 1, the following slaughter techniques shall not be used on bovine, ovine or caprine animals whose meat is destined for human or animal consumption:
 - (a) stunning or killing by means of a gas injected into the cranial cavity;
 - (b) laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.
4. Rules for the implementation of this Article shall be adopted in accordance with the procedure laid down in Article 22.

Article 9

Animal feeding

1. The feeding to ruminants of protein derived from mammals is prohibited.
2. In Member States, or regions thereof, which are placed in Category 4, the following are prohibited:
 - (a) the feeding to any farmed animal of protein derived from mammals; and,
 - (b) the feeding to any mammal of protein derived from ruminants.
3. Paragraphs 1 and 2 shall apply without prejudice to the provisions of Annex V.
4. Rules for the implementation of this Article, including rules on the prevention of cross contamination and on sampling and methods of analysis to check compliance, shall be adopted in accordance with the procedure laid down in Article 22.

Article 10

Certain products of animal origin derived from or containing ruminant products

1. In Member States, or regions thereof, which are placed in Category 4, the use of ruminant materials for the production of the products of animal origin referred to in Annex VI shall be subject to the conditions laid down in that Annex.
2. In Member States, or regions thereof, which are not placed in Category 1, the use of ruminant skull and vertebral column for the production of mechanically separated meat is prohibited.
3. Rules for the implementation of this Article, including rules on production standards, shall be adopted in accordance with the procedure laid down in Article 22.

CHAPTER IV

CONTROL AND ERADICATION OF TSES

Article 11

Notification of suspected presence of TSEs

Without prejudice to Council Directive 82/894/EEC⁴, the suspected presence of any TSE in any animal shall be notified immediately to the competent authority of the Member State concerned.

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

Article 12

Measures with respect to suspect animals

1. Any animal suspected of being infected by a TSE shall either be placed under official movement restrictions pending the outcome of an assessment by the competent authority or killed under official supervision.
2. Where the competent authority decides that the possibility of infection with a TSE cannot be ruled out, the suspect animal shall be killed and its brain and such other tissues as the competent authority may determine shall be removed and sent to an officially approved laboratory, the national reference laboratory provided for in Article 17(1) or the Community reference laboratory provided for in Article 17(2), for testing for the presence of a TSE using the methods referred to in Article 18.
3. All parts of the body of the suspect animal, including the hide but excluding the tissues which are being tested in accordance with paragraph 2, shall be retained under official supervision until a negative diagnosis has been made, or until it has been completely destroyed in accordance with Annex IV, point 4 or, as appropriate, point 5.

Article 13

Measures following confirmation of the presence of TSEs

1. Where the presence of a TSE has been officially confirmed, the following measures shall be applied without delay:
 - (a) all parts of the body of the animal shall be completely destroyed, in accordance with Annex IV, point 4 or, as appropriate, point 5;
 - (b) an inquiry shall be carried out to identify all animals at risk in accordance with Annex VII, point 1.

⁴ OJ L 378, 31.12.1982, p. 58.

2. Where the presence of a TSE has been officially confirmed, all animals, semen, ova and embryos referred to in Annex VII, point 2, that have been identified to be at risk by the inquiry referred to in paragraph 1(b) shall be placed under movement restriction or killed and completely destroyed in accordance with Annex IV, point 4 or, as appropriate, point 5.
3. Pending the completion of the measures referred to in paragraph 1(b) and paragraph 2, the holding on which the animal was present when the presence of a TSE was suspected shall be placed under official surveillance and all movement of animals susceptible to TSEs, their semen, ova and embryos, from or to the holding shall be subject to authorization by the competent authority, with a view to ensuring immediate tracing and identification of the animals, their semen, ova and embryos in question.
4. Owners shall be compensated without delay for the loss of the animals that have been killed in accordance with Article 12(2) and paragraph 2 of this Article, or the semen, embryos and ova that have been destroyed in accordance with paragraphs 1 and 2 of this Article. The compensation shall not be less than 100% of the market value.
5. The provisions of paragraph 2 shall be amended in accordance with the procedure laid down in Article 23.
6. Rules for the implementation of this Article shall be adopted in accordance with the procedure laid down in Article 22.

Article 14

Contingency plan

1. A contingency plan specifying the national measures to be implemented in the event of an occurrence of BSE shall be drawn up by each Member State in accordance with the general criteria laid down in Community rules on the control of animal diseases.

This plan must provide for access to the personnel, facilities, equipment and all other appropriate materials necessary for the rapid and efficient eradication of BSE.

2. The contingency plans referred to in paragraph 1 shall be submitted to the Commission no later than six months after the date referred to in the second paragraph of Article 26.
3. The Commission shall approve the contingency plans in accordance with the procedure laid down in Article 22.
The plans may subsequently be amended or supplemented, in accordance with the same procedure.
4. The provisions of paragraphs 1, 2 and 3 may be extended to TSEs other than BSE in accordance with the procedure laid down in Article 23.
5. Rules for the implementation of this Article shall be adopted in accordance with the procedure laid down in Article 22.

CHAPTER V

PLACING ON THE MARKET

Article 15

Live animals, semen, embryos and ova

1. The placing on the market of bovine, ovine or caprine animals and their semen, embryos and ova shall be subject to the conditions laid down in Annex VIII, Chapter A. The animals and their semen, embryos and ova shall be accompanied by the appropriate animal health certificates as required by Community legislation, subject to the conditions laid down in Annex VIII Chapter D.
2. The animals referred to in Annex VIII, Chapter B imported from countries or regions thereof in Categories 2, 3 and 4 shall be identified by a permanent identification system enabling them to be traced back to the dam and herd of origin.
3. Placing on the market of first generation progeny, semen, ova and embryos of TSE suspect or confirmed animals shall be subject to the conditions laid down in Annex VIII, Chapter C.
4. The provisions of paragraphs 1, 2 and 3 may be extended to other animals, semen, ova or embryos in accordance with the procedure laid down in Article 23.
5. Rules for the implementation of this Article shall be adopted in accordance with the procedure laid down Article 22.

Article 16

Bovine, ovine or caprine meat and certain products of animal origin thereof

1. The following products of animal origin containing material derived from bovine, ovine or caprine animals shall be subject to the rules laid down in paragraphs 2 to 6 of this Article and Annex IX.
 - (a) fresh meat as defined by Council Directive 64/433/EEC⁵;
 - (b) minced meat and meat preparations as defined by Council Directive 94/65/EC⁶;
 - (c) meat products and other products of animal origin as defined by Council Directive 77/99/EEC⁷;
 - (d) milk products as defined by Council Directive 92/46/EEC⁸ which are destined for human consumption and contain gelatin or rendered animal fat;

⁵ OJ 121, 29.7.1964, p. 2012/64.

⁶ OJ L 368, 31.12.1994, p. 10.

⁷ OJ L 26, 31.1.1977, p. 85.

⁸ OJ L 268, 14.9.1992, p. 1.

- (e) milk products as defined by Council Directive 92/118/EEC⁹ which are destined for animal consumption and contain gelatin or rendered animal fat;
 - (f) fishery products as defined by Council Directive 91/493/EEC¹⁰ which are destined for human consumption and contain gelatin or rendered animal fat;
 - (g) egg products as defined by Council Directive 89/437/EEC¹¹ which are destined for human consumption and contain gelatin or rendered animal fat;
 - (h) snails or frogs' legs as referred to by Directive 92/118/EEC which are destined for human consumption and contain gelatin or rendered animal fat;
 - (i) rendered fats as referred to by Directive 92/118/EEC;
 - (j) gelatin as referred to by Directive 92/118/EEC;
 - (k) petfood as referred to by Directive 92/118/EEC;
 - (l) processed animal protein as referred to by Directive 92/118/EEC;
 - (m) bones and bone products as referred to by Directive 92/118/EEC;
 - (n) raw material for the manufacture of animal feedingstuffs as referred to by Directive 92/118/EEC.
2. Products referred to in paragraph 1 containing material derived from bovine animals coming from countries or regions thereof in Category 4 shall not be placed on the market.
 3. The prohibition referred to in paragraph 2 shall not apply to the products referred to in Annex IX, Chapter A.I containing material derived from the following bovine animals:
 - (a) animals born after the date from which the ban on the feeding of ruminants with protein derived from mammals has been effectively enforced which are eligible under a Date-based Scheme, or, as appropriate, an equivalent scheme, as laid down in Annex IX, Chapter A.II; or
 - (b) animals which were born, raised and had remained in herds with a certified history of freedom from BSE and are eligible under a Certified Animal Scheme, or, as appropriate, an equivalent scheme, as laid down in Annex IX, Chapter A.III.
 4. For the purpose of import into the Community, products referred to in paragraph 1 shall be accompanied by the appropriate certificate, as required by Community legislation, supplemented in accordance with the provisions laid down in Annex IX, Chapter B.II.

⁹ OJ L 62, 15.3.1993, p. 49.

¹⁰ OJ L 268, 24.9.1991, p. 15.

¹¹ OJ L 212, 22.7.1989, p. 87.

Where such products are imported from third countries or regions thereof in Category 4, or regions within such third countries, they shall also comply with the conditions laid down in Annex IX, Chapter B.I.

5. If necessary, the provisions of paragraphs 1 to 4 may be extended to products of animal origin other than those referred to in paragraph 1 in accordance with the procedure laid down in Article 23.
6. Rules for the implementation of this Article shall be adopted in accordance with the procedure laid down in Article 22.

CHAPTER VII

REFERENCE LABORATORIES, SAMPLING, TESTING AND CONTROLS

Article 17

Reference laboratories

1. The national reference laboratory in each Member State and their functions and duties shall be those laid down in Annex X, Chapter A.
2. The Community reference laboratory and its function and duties shall be those laid down in Annex X, Chapter B.

Article 18

Sampling and laboratory methods

1. Sampling and laboratory testing for the presence of a TSE shall be carried out using the methods and protocols laid down in Annex X, Chapter C. In the absence of such methods and protocols, those recommended in the Manual of Standards for Diagnostic Tests and Vaccines of the International Office for Epizootics (IOE/OIE), May 1998 edition shall apply.
2. Rules for the implementation of paragraph 1 shall be adopted in accordance with the procedure laid down Article 22.

Article 19

Community controls

1. The Commission shall, in cooperation with the competent authorities of the Member States, carry out on-the-spot inspections and audits of all levels of production and placing on the market of animals and products of animal origin covered by this Regulation and of the organisation and functioning of the competent authorities in the Member States and in third countries, in order to ensure that the provisions of this Regulation, rules adopted pursuant thereto and any safeguard measures are applied uniformly.
2. Rules for the implementation of paragraph 1 shall be adopted in accordance with the procedure laid down in Article 22.

CHAPTER VIII

FINAL PROVISIONS

Article 20

Amendments to Annexes and transitional measures

The Commission shall, after obtaining the opinion of the appropriate Scientific Committee on any matter likely to have an effect on health:

- (a) amend or supplement the Annexes in accordance with the procedure laid down in Article 23;
- (b) adopt any appropriate transitional measures in accordance with the procedure laid down in Article 22.

Article 21

Committees

The Commission shall be assisted by the Standing Veterinary Committee. However, the Commission shall be assisted by the Standing Committee for Feedingstuffs or the Standing Committee for Foodstuffs for matters falling exclusively within their respective competences.

Article 22

Management procedure

Where reference is made to the procedure laid down in this Article, the representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt measures which shall apply immediately. However, if these measures are not in accordance with the opinion of the committee, they shall be communicated by the Commission to the Council forthwith. In that event, the Commission may defer application of the measures which it has decided for a period of not more than one month from the date of such communication.

The Council, acting by a qualified majority, may take a different decision within the time limit referred to in the previous paragraph.

Article 23

Regulatory procedure

Where reference is made to the procedure laid down in this Article, the representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission.

Article 24

Consultation of scientific committees

The appropriate scientific committees shall be consulted on any matter falling within the scope of this Regulation which is likely to have an effect on public health.

Article 25

Communication of national provisions

The Member States shall communicate to the Commission the text of all provisions of national law which they adopt in the field covered by this Regulation.

Article 26

Entry into force

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

It shall apply from 1 July 2000.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

DEFINITIONS

- (a) *indigenous case of BSE*: a case of BSE which has not been clearly demonstrated to originate directly from the importation of live cattle, bovine embryos or ova;
- (b) *batch of animals*: a group of animals slaughtered after one complete process of emptying, cleaning and disinfection of the slaughter room and before the next such process;
- (c) *rendered ruminant fat*: rendered fats derived in part or entirely from ruminant animals;
- (d) *mechanically separated meat*: residual meat obtained by mechanical means from flesh-bearing bones after initial boning;
- (e) *discrete adipose tissue*: internal and external body fat removed during the slaughter and cutting process, in particular fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms;
- (f) *cohort*: a group of animals which were reared together during the first year of their life;
- (g) *ovine or caprine animals for breeding and fattening*: ovine and caprine animals intended to be transported to the place of destination, either directly or via an approved market or assembly centre, other than ovine or caprine animals for slaughter, meaning animals of the ovine or caprine species intended to be taken either directly or via an approved market or assembly centre to a slaughterhouse in order to be slaughtered there;
- (h) *fresh meat*: fresh meat as defined by Council Directive 64/433/EEC;
- (i) *minced meat and meat preparations*: minced meat and meat preparations as defined by Directive 94/65/EC;
- (j) *meat products*: meat products as defined by Directive 77/99/EEC;
- (k) *official passport*: passport as defined by Council Regulation (EC) No 820/97¹²;
- (l) *official computerised identification and tracing system*: a database system as provided for by Regulation (EC) No 820/97;

¹² OJ L 117, 7.5.1997, p. 1.

DETERMINATION OF BSE STATUS**Chapter A****Information to be submitted in support of an application for recognition of risk classification under Article 5**

All data must be provided on an annual basis and preferably from 1980 onwards, but at least from 1988.

Applicant States must make every effort to provide comprehensive and consistent information. Data which are not provided or are incomplete or are considered as unsatisfactory may be completed by reference to other sources of information available to the Commission, or may have to be replaced by a worst-case assumption for the purposes of a risk assessment.

Information must be provided on:

- 1. Structure and dynamics of the bovine, ovine and caprine animal populations**
 - (a) absolute numbers of animals per species and breed, alive and at time of slaughter;
 - (b) age distributions of animals per species and breed, sex and type;
 - (c) age distribution of animals per species and breed, sex and type at time of slaughter;
 - (d) geographical distribution of the animals by species and breeds;
 - (e) geographical distribution of the animals by husbandry systems, herd sizes and production purposes;
 - (f) system of identification and capacities for tracing of animals and a system of control and possible sanctions in accordance with Community legislation on animal identification and registration.

- 2. Animal trade**
 - (a) imports and exports;
 - (b) trade within the geographical area;
 - (c) imports of embryos and semen;
 - (d) use made of imported animals, embryos or semen;
 - (e) mechanisms used by slaughterhouses to identify animals and their origins, as well as data from these procedures.

3. Animal feed

- (a) domestic production of Meat and Bone Meal (MBM), and its use per species and husbandry system (in particularly the proportion of the domestically produced MBM fed to bovine, ovine and caprine animals);
- (b) imports of MBM, specifying country of origin, and its use per species and husbandry system (in particularly the proportion of that MBM fed to bovine, ovine and caprine animals);
- (c) exported MBM, specifying country of destination.

4. Meat and bone meal (MBM) bans

- (a) complete description;
- (b) dates of introduction;
- (c) actual implementation, policing and compliance figures;
- (d) possibilities of cross-contamination with other feed.

5. Specified bovine offal (SBO) and specified risk materials (SRM) bans

- (a) complete description;
- (b) dates of introduction;
- (c) actual implementation, policing and compliance figures.

6. Surveillance of TSE, with particular reference to BSE and scrapie

- (a) incidence of laboratory confirmed cases of BSE and scrapie;
- (b) age distribution, geographical distribution, and countries of origin of cases;
- (c) incidence of neurological disorders in which TSE could not be excluded on clinical grounds in any animal species;
- (d) methodologies and programmes of surveillance and recording of clinical cases of BSE and scrapie, including awareness training for farmers, veterinarians, supervisory bodies and authorities;
- (e) incentives for reporting cases, compensation and reward schemes;
- (f) methodologies of laboratory confirmation and recording of suspect cases of BSE and scrapie;
- (g) strains of BSE and scrapie agents possibly involved;
- (h) existing systems or current plans for targeted active surveillance.

7. Rendering and feed processing

- (a) all rendering and feed processing systems used;
- (b) nature of the records of rendering and processing plants;
- (c) quantitative and qualitative parameters of MBM and rendered animal fat production by each of the processing systems;
- (d) the geographical areas from which the rendered materials originate;
- (e) the type of raw material used;
- (f) parameters on separate processing lines for materials from healthy and suspected animals;
- (g) transport and storage systems for MBM or feed containing MBM.

8. BSE or scrapie related culling

- (a) culling criteria;
- (b) date of introduction of the culling scheme and of any subsequent modification;
- (c) animals culled (details as specified in point 1);
- (d) sizes of herds in which animals were culled.

Chapter B

Definition of categories

- I. For the purpose of determining the BSE status of Member State or regions thereof, the following categories are recommended:

CATEGORY 1

- (1) a risk assessment based on the information laid down in Chapter A has demonstrated that appropriate measures have been taken to manage any risk identified;
- (2) the measures laid down in Articles 6, 7, 11 and 12 have been complied with for at least seven years ;
- (3) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle, embryos or ova and the measures laid down in Article 12 and 13 have been applied with respect to all animals in which the disease has been confirmed.

However, where the measures laid down in Articles 6 and 7 are not complied with, the Member State or region thereof may be placed in Category 1 provided that:

- the measures laid down in Articles 11 and 12 have been complied with for at least seven years; and
- it has been proven that for at least eight years no ruminant meat-and-bone meal has been fed to ruminants.

However, where indigenous cases of BSE have occurred, the Member State or region thereof may be placed in Category 1 provided that:

- the last indigenous case of BSE occurred more than seven years ago; and,
- the measures laid down in Articles 6, 7, 11 and 12 have been complied with for at least seven years; and,
- the measures laid down in Article 9 are complied with and have been effectively enforced for at least eight years.

CATEGORY 2

- (1) a risk assessment based on the information laid down in Chapter A has demonstrated that appropriate measures have been taken to reduce any risk identified;
- (2) the measures laid down in Articles 6, 7, 11 and 12 are complied with, but have not been complied with for seven years;
- (3) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle, embryos or ova and the measures laid down in Article 12 and 13 have been applied with respect to all animals in which the disease has been confirmed.

However, where the measures laid down in Articles 6 and 7 are not complied with, the Member State or region thereof may be placed in Category 2 provided that:

- measures laid down in Articles 11 and 12 are complied with but have not been complied with for seven years; and,
- it has been proven that for at least eight years no meat-and-bone meal has been fed to ruminants.

However, where indigenous cases of BSE have occurred, the Member State or region thereof may be placed in Category 2 provided that:

- the last indigenous case of BSE occurred more than seven years ago; and either
- the measures laid down in Articles 6, 7, 11 and 12 are complied with but have not been complied with for seven years; or

- the measures laid down in Article 9 are complied with but have not been effectively enforced for eight years.

However, where indigenous cases of BSE have occurred during the past seven years, the Member State or region thereof may be placed in Category 2 provided that:

- the measures laid down in Articles 6, 7, 11 and 12 have been complied with for seven years; and,
- the BSE incidence rate, calculated on the basis of indigenous cases during the past 12 months, has been less than 1 case per million within the cattle population over 24 months of age in the Member State or region thereof.

CATEGORY 3

- (1) a risk assessment based on the information laid down in Chapter A has demonstrated that appropriate measures have been taken to reduce any risk identified;
- (2) the measures laid down in Articles 6, 7, 11 and 12 are complied with;
- (3) the BSE incidence rate, calculated on the basis of indigenous cases during the past 12 months, has been greater than or equal to 1 case per million and less than or equal to 200 cases per million within the cattle population over 24 months of age in the Member State or region thereof.

However, where the BSE incidence rate, calculated on the basis of indigenous cases during the past 12 months, has been less than 1 case per million within the cattle population over 24 months of age in the Member State or region thereof, the Member State or region thereof shall also be placed in Category 3 if one or more of the requirements of points (1) and (2) of Category 2 are not met.

However, where there has been no case of BSE, the Member State or region thereof shall also be placed in Category 3 if:

- a risk assessment based on the information laid down in Chapter A has been conducted which demonstrates the presence of one or more risk factors; and
- the measures laid down in Articles 11 and 12 are not complied with.

CATEGORY 4

- (1) a risk assessment based on the information laid down in Annex II Chapter A has demonstrated that appropriate measures have been taken to reduce any risk identified;
- (2) the measures laid down in Articles 6, 7, 11 and 12 are complied with;
- (3) the BSE incidence rate, calculated on the basis of indigenous cases during the past 12 months, has been greater than 200 cases per million within the cattle population over 24 months of age in the Member State or region thereof.

However, where the BSE incidence rate, calculated on the basis of indigenous cases during the past 12 months, has been greater than or equal to 1 case per million and less than or equal to 200 cases per million within the cattle population over 24 months of age in the Member State or region thereof, the Member State or region thereof shall be placed in Category 4 if one or more of the requirements of point (1) or the measures laid down in Articles 6, 7, 11 and 12 are not met.

Where a Member State or region thereof should be placed in Category 4 pursuant to the criterion of point (3), but one or more of the requirements of point (1) and the measures laid down in Articles 6, 7, 11 and 12 are not met, the Member State or region thereof shall be placed in Category 4 and Article 4 applies.

- II. For the purpose of determining the BSE status of third countries or regions thereof, the same four categories on the basis of equivalent health guarantees shall be defined providing equivalent health guarantees to those referred to in Part I.
- III. Where an animal moves from one category of a country or region to another, it shall acquire or retain the highest numerical BSE category of any country or region in which it has been kept for more than 24 hours, unless adequate guarantees can be provided that the animals were not fed with feed from that country or region with the highest numerical BSE category.

MONITORING SYSTEM**CHAPTER A****Minimal requirements for a programme for monitoring of BSE and scrapie****Selection of subpopulation**

Without prejudice to Article 12, selection must be by means of a risk assessment of subpopulations of native-born animals displaying clinical signs compatible with TSEs and, in a decreasing order of relevance, of higher-risk animals. Within each subpopulation and age group, selection must be random.

Animals examined in accordance with Article 12 may be included in the sample.

1. Criteria for the selection of native-born animals displaying clinical signs compatible with TSEs:

- animals displaying behavioural or neurological signs lasting for at least 15 days and resistant to treatment. However, animals displaying such signs which die within 15 days and in which case an alternative diagnosis has not been identified, should be considered as suspect animals. They shall be examined in accordance with Article 12 and may be included in the monitoring programme;
- moribund animals without signs of infectious or traumatic illness;
- animals displaying other progressive disease conditions.

2. The following risks must be taken into account for the selection of higher risk animals:

- animals originating from countries with indigenous TSE;
- animals which have consumed potentially contaminated feedingstuffs;
- animals born or derived from TSE infected dams or sires.

Animal species and type of TSE

1. Bovine animals must be examined for the presence of BSE.
2. Ovine and caprine animals must be examined for the presence of scrapie and BSE.

Age of the targeted animals

The sample must target the oldest animals in the subpopulation. However, all targeted bovine animals must be over 20 months of age and all targeted ovine and caprine animals must be over 12 months of age. Targeted bovine animals displaying progressive disease conditions without showing neurological signs must be over four years of age.

Sample size

The minimum number of animals to be examined on an annual basis must comply at least with the sample sizes referred to in the Table for animals in subpopulations of native-born animals displaying clinical signs compatible with TSEs. Suspected animals which have been examined in accordance with Article 12 may be included within the minimum sample size.

Samples from the subpopulations of higher-risk animals must be collected at the time when the animals are slaughtered or killed.

Table

Minimum number of annual neurohistological investigations of animals showing clinical signs compatible with TSE

| Native-born cattle population 20 months of age or older or native- born ovine and caprine population 12 months of age or older | Minimum number of brains to be examined |
|---|--|
| | |
| 100 000 | 10 |
| 300 000 | 30 |
| 500 000 | 50 |
| 700 000 | 69 |
| 1 000 000 | 99 |
| 2 500 000 | 195 |
| 5 000 000 | 300 |
| 7 000 000 | 336 |
| 10 000 000 | 367 |
| 20 000 000 | 409 |
| 30 000 000 | 425 |
| 40 000 000 | 433 |

Chapter B

Annual report

The annual report must contain data on:

1. the total number of animals and age structure examined within the different groups of the respective populations of bovine, ovine and caprine animals categorized according to epidemiological criteria;
2. the overall mortality and mortality due to neurological diseases per animal species;
3. official records on the number and types of animals or carcasses placed under movement restrictions in accordance with Article 12;
4. the number and outcome of the investigations carried out in accordance with Article 12; these records must be kept for at least seven years;
5. TSEs in animals other than bovine, ovine and caprine animals;
6. training, in particular of official veterinarians with responsibilities for the epidemiosurveillance of TSEs, in accordance with Article 6.

SPECIFIED RISK MATERIAL

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

CATEGORY 1

No tissues are designated as specified risk materials.

CATEGORY 2

In countries or regions thereof placed in Category 2 the following are only designated as specified risk materials where BSE has occurred*:

- (a) the brain and spinal cord of:
- bovine animals aged over 30 months,
 - ovine and caprine animals which are aged over 12 months or have a permanent incisor erupted through the gum;
- (b) the distal ileum and spleen of ovine and caprine animals of all ages.

CATEGORY 3

- (a) the entire head excluding the tongue, including the brain and dura mater, pituitary gland, eyes, trigeminal ganglia and tonsils; the spinal cord and dura mater of bovine animals aged over six months and of ovine and caprine animals aged over 12 months;
- (b) the distal ileum of bovine, ovine and caprine animals, and spleen of ovine and caprine animals of all ages.

CATEGORY 4*

- (a) the entire head excluding the tongue, including the brain and dura mater, pituitary gland, eyes, trigeminal ganglia and tonsils; the thymus; the intestines from the duodenum to the rectum; the vertebral column, including dorsal root ganglia, spinal cord and dura mater of bovine animals aged over six months and of ovine and caprine animals aged over 12 months;
- (b) and other bones of bovine animals aged over 30 months;
- (c) the distal ileum and spleen of bovine, ovine and caprine animals of all ages.

* Pending OIE confirmation during the legislative process.

2. Member States shall ensure that the specified risk materials are removed at slaughterhouses.

However, in Member States or regions thereof which are not placed in Category 4, the removal and subsequent destruction according to point 4 of specified risk materials from raw material for the production of rendered ruminant fat derivatives is not required provided that the derivatives are produced in accordance with Annex VI.

3. By way of derogation from point 2, Member States may allow the removal of:
 - (a) specified risk material at cutting plants, high risk processing plants or premises referred to in Article 7 of Council Directive 90/667/EEC¹³, under the direct supervision of an official of the competent authority. Those establishments shall be approved for that purpose by the competent authority;
 - (b) the vertebral column or bones at the point of sale to the consumer on their territory.

Member States shall set up a system to ensure and check that, where the removal of specified risk materials takes place at establishments other than slaughterhouses, those materials are completely separated from other waste, are collected separately and are disposed of in accordance with point 4.

4. Member States shall ensure that specified risk material is stained with a dye immediately on removal, and that all specified risk material is completely destroyed:
 - (a) by direct incineration; or,
 - (b) provided that the colour of the dye is detectable after processing, by processing followed by:
 - (i) incineration;
 - (ii) burning as fuel; or,
 - (iii) another method, which precludes all risk of transmission of a TSE, and is authorized and supervised by the competent authority.

5. Without prejudice to Articles 12 and 13, where bovine, ovine or caprine animals have died or have been killed in the context of disease control measures, Member States may allow disposal of the entire body of those animals without removal of the specified risk materials.

6. Member States may derogate from the provisions of points (2) and (4) to allow the burning 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 Directive 90/667/EEC.

¹³ OJ L 363, 27.12.1990, p. 51.

7. The application of a test as an alternative to the removal of specified risk materials may be authorised under the following conditions:
 - (a) tests are carried out in slaughterhouses on all animals eligible for the removal of specified risk materials;
 - (b) no bovine, ovine or caprine product intended for human food or animal feed leaves the slaughterhouse before the results of the tests on all slaughtered animals produced in the same batch have been received and accepted by the competent authority;
 - (c) when a post-slaughter test gives a positive result, all bovine, ovine and caprine material produced in the same batch is destroyed in accordance with point 4.

8. By way of derogation from Article 8 the Commission may;
 - (a) acting in accordance with the procedure laid down in Article 22, take a decision in respect of the date of effective enforcement of the provisions of Article 9(1), or as appropriate, the prohibition on the feeding of mammalian protein to ruminants in each country or region thereof placed in Category 2 or 3, and allow the provisions of Article 8 to be confined to animals which were born before that date in those countries or regions;
 - (b) after consultation of the appropriate scientific committee and based on an assessment of the incident, propagation and human exposure risk, acting in accordance with the procedure laid down in Article 22, take a decision to allow the use of vertebral column and dorsal root ganglia for food, feed and fertilisers from animals in or coming from each country or region thereof in Category 4.

9. Member States shall carry out frequent official controls, particularly in slaughterhouses, cutting plants, animal waste processing plants, high risk processing plants or premises referred to in Article 7 of Directive 90/667/EEC, points of sale to the consumer and storage facilities, and shall ensure that measures are taken to avoid contamination.

ANIMAL FEEDING

The prohibition laid down in Article 9(1) and (2) shall not apply to the following products:

- (a) milk and milk products;
- (b) hydrolysed proteins derived from fleshings from hides;
- (c) dried plasma and other blood products.

The prohibition laid down in Article 9(2)(b) shall not apply to the production of dog food.

STANDARDS FOR CERTAIN PRODUCTS OF ANIMAL ORIGIN DERIVED FROM OR CONTAINING RUMINANT MATERIAL**1. Conditions for production of certain products of animal origin as referred to in Article 10(1)**

The use of ruminant material for the production of the following products of animal origin is prohibited:

- (a) mechanically separated meat;
- (b) dicalcium phosphate destined for feeding to all farmed animals;
- (c) gelatine, unless it is produced from ruminant hides;
- (d) rendered ruminant fat derivatives;
- (e) rendered ruminant fat, unless it is produced from:
 - (i) discrete adipose tissue, which itself was found fit for human consumption;
 - (ii) raw material which has been processed in accordance with the standards laid down pursuant to Directive 90/667/EEC.

The prohibition on the use of ruminant material shall not apply to material derived from animals which have been tested in accordance with Annex IV, point 7, and have given a negative result.

2. Appropriate production processes

For rendered ruminant fat derivatives derived from ruminant materials for use in the production of human food, animal feed or fertilisers: validated and strictly certified methods such as:

1. Transesterification or hydrolysis at not less than 200°C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production); or,
2. Saponification with NaOH 12 M (glycerol and soap production):
 - in a batch process: at not less than 95°C for not less than three hours; or
 - in a continuous process: at not less than 140°C, two bars for not less than eight minutes, or equivalent.

Moreover, other tallow derivatives (e.g. fatty alcohols, fatty amines, fatty amides) produced from the abovementioned products and submitted to further processes may also be used.

ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

1. The inquiry referred to in Article 13(1)(b) shall identify:
 - (a) in the case of bovine animals:
 - all embryos, ova and first generation progeny of a female animal in which the disease was confirmed and which embryos or progeny were collected or born after or within two years before clinical onset or diagnosis of the disease in its dam;
 - all animals of the cohort of the animal in which the disease was confirmed;
 - the possible origin of the disease and other holdings on which there are animals which may have become infected by the TSE agent or exposed to the same feed or contamination source;
 - the movement of potentially contaminated feedingstuffs, animals, ova, semen or embryos, 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 other ruminants on the holding of the animal in which the disease was confirmed;
 - the parents, all semen, embryos, ova and first generation progeny of the animal in which the disease was confirmed;
 - all animals of the cohort of the animal in which the disease was confirmed;
 - the possible origin of the disease and the identification of other holdings on which there are animals which may have become infected by the TSE agent or exposed to the same feed or contamination source;
 - the movement of potentially contaminated feedingstuffs, animals, ova, semen or embryos, or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question.
2. The requirement of Article 13(2) shall:
 - (a) in case of confirmation of BSE in a bovine animal, apply to bovine animals, embryos and ova identified by the inquiry referred to in point (1)(a), first and second indent;
 - (b) in case of confirmation of BSE in an ovine or caprine animal, apply to all ruminant animals, embryos and ova and ovine and caprine semen identified by the inquiry referred to in point (1)(b), first to fifth indent.

**PLACING ON THE MARKET OF LIVE ANIMALS, SEMEN,
EMBRYOS AND OVA**

Chapter A

Conditions for placing on the market

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

(1) The conditions as referred to in Article 15(1) shall apply to movements relating to:

- dispatch to other Member States;
- dispatch to third countries;
- import into the Community from third countries.

(2) The following conditions shall apply to movements as referred to in point (1) of bovine embryos and ova:

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

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

(3) The following conditions shall apply to movements as referred to in point (1) of ovine and caprine animals:

Ovine or caprine animals for breeding or fattening shall:

(a) come from a holding satisfying the following requirements:

- the animals are identified;
- no case of scrapie has been confirmed for at least two years;
- checking by sampling is carried out at slaughter on old female animals, intended for culling coming from that holding;
- female animals are only introduced into that holding if they come from a holding which complies with the same requirements;

(b) have been continuously kept on a holding or holdings complying with the requirements laid down in point (a) since birth or for the last two years.

- (4) Ovine or caprine animals imported into the Community shall meet requirements which provide equivalent health guarantees to those required by this Regulation or pursuant to this Regulation.

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

- (1) The conditions as referred to in Article 15(1) shall apply to movements relating to:
- dispatch to other Member States;
 - dispatch to third countries;
 - import into the Community from third countries.
- (2) The BSE category of bovine, ovine and caprine animals shall be communicated to the Member State of destination.
- (3) The following conditions shall apply to movements as referred to in point (1) of bovine animals coming from or having resided in countries or regions thereof placed in:

CATEGORY 2 AND 3

The animals must have:

- (a) been born, raised and have remained in herds in which no case of BSE had been confirmed for at least seven years; or
- (b) been born after the date at which ban on the feeding of ruminants with meat-and-bone meal derived from mammals has been effectively enforced.

In addition bovine animals imported into the Community shall come from a country or region thereof in which:

- (a) the BSE affected cattle are killed and completely destroyed;
- (b) the feeding of ruminants with meat-and-bone meal derived from mammals has been banned and the ban has been effectively enforced.

CATEGORY 4

The animals must have:

- (a) never been fed mammalian meat-and-bone meal and been born after the date at which the ban on the feeding of farmed animals with meat-and-bone meal derived from mammals has been effectively enforced;

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

In addition, bovine animals imported into the Community shall come from a country or a region thereof in which the BSE affected cattle are killed and completely destroyed.

Chapter B

Identification of live animals on import

The requirement laid down in Article 15(2) shall apply to:

- bovine animals.

Chapter C

Conditions relating to progeny of TSE suspect or confirmed animals referred to in Article 15(3)

It is prohibited to place on the market:

- the first generation progeny, embryos and ova of TSE suspect or confirmed female bovine animals;
- the first generation progeny, semen, embryos and ova of BSE confirmed ovine and caprine animals.

Chapter D

Animal health certificates

- (1) The certificates referred to in Article 15(1) shall be required for animals and semen, embryos and ova of those animals when:

- dispatched to other Member States;
- imported into the Community from third countries.

- (2) The certificates shall be supplemented in accordance with the following conditions:

- (a) **Intra-Community trade in bovine animals**

The animal health certificates referred to in Annex F to Council Directive 64/432/EEC¹⁴ shall be supplemented by the following words to be entered in the section "Health data concerning bovine animals":

¹⁴ OJ 121, 29.7.1964, p. 1977/64.

"The animals listed below comply with the conditions laid down in Regulation [.../.....] of the European Parliament and of the Council, and their BSE category is Category ...^(*). This category was established by Commission Decision [.../.....]^(**);

(*) Complete as appropriate with 1, 2, 3 or 4.

(**) Complete."

(b) Intra-Community trade in ovine and caprine animals

The animal health certificates corresponding to Model III in Annex E to Council Directive 91/68/EEC¹⁵ shall be supplemented by the following words to be entered in section V "Health information":

"BSE category of the animals listed below: Category ...^(*). This category was established by Commission Decision [.../.....]^(**);

(*) Complete as appropriate with 1, 2, 3 or 4.

(**) Complete."

Point (e) of section V "Health information" of the certificate corresponding to Model III in Annex E to Council Directive 91/68/EEC states that:

"(e) they meet the requirements with regard to scrapie laid down in Article 15 of Regulation [.../.....] of the European Parliament and of the Council".

(c) Intra-Community trade in bovine embryos and ova

The appropriate animal health certificates as laid down in Community rules on trade in bovine embryos and ova shall be supplemented by the following words to be entered in the section on health data:

"The embryos and ova were derived from females which, at the time of collection, were not suspected of being affected by BSE, and which themselves complied with the conditions laid down in Regulation [.../.....] of the European Parliament and of the Council. The BSE category of the Member State, or region within a Member State, in which the embryos or ova were collected, is Category ...^(*). This category was established by Commission Decision [.../.....]^(**);

(*) Complete as appropriate with 1, 2, 3 or 4.

(**) Complete."

¹⁵ OJ L 46, 19.2.1991, p. 19.

(d) Intra-Community trade in ovine or caprine semen, embryos or ova

The appropriate animal health certificates as laid down in Community rules on trade in ovine or caprine semen, embryos and ova, shall be supplemented by the following words to be entered in the section on health data:

"The semen, embryos and ova were derived from donor animals which, at the time of collection, were not suspected of being affected by either BSE or scrapie, and which themselves complied with the conditions laid down in Regulation [.../.....] of the European Parliament and of the Council. The BSE category of the Member State, or region within a Member State, in which the semen, embryos or ova were collected, is Category ...^(*). This category was established by Commission Decision [.../.....]^(**);

^(*) Complete as appropriate with 1, 2, 3 or 4.

^(**) Complete."

(e) Import into the Community of bovine, ovine and caprine animals

The appropriate certificates, as required by Community legislation, shall be supplemented by the following words:

"The animals listed below provide equivalent guarantees to those of Regulation [.../.....] of the European Parliament and of the Council and their BSE category is Category ...^(*). This category was established by Commission Decision [.../.....]^(**);

^(*) Complete as appropriate with 1, 2, 3 or 4.

^(**) Complete."

(f) Import into the Community of bovine embryos and ova

The appropriate certificates, as required by Community legislation, shall be supplemented by the following words:

"The embryos and ova were derived from females which, at the time of collection, were not suspected of being affected by BSE, and which themselves provide guarantees equivalent to those of Regulation [.../.....] of the European Parliament and of the Council.

The BSE category of the country, or region within a country, in which the embryos or ova were collected, is Category ...^(*). This category was established by Commission Decision [.../.....]^(**);

^(*) Complete as appropriate with 1, 2, 3 or 4.

^(**) Complete."

(g) Import into the Community of ovine or caprine semen, embryos or ova

The appropriate certificates, as required by Community legislation, shall be supplemented by the following words:

"The semen, embryos and ova were derived from donor animals which, at the time of collection, were not suspected of being affected by either BSE or scrapie, and which themselves provide guarantees equivalent to those of Regulation [..../.....] of the European Parliament and of the Council.

The BSE category of the country, or region within a country, in which the semen, embryos or ova were collected, is Category ...^(*). This category was established by Commission Decision [..../.....]^(**);

(*) Complete as appropriate with 1, 2, 3 or 4.

(**) Complete."

**PLACING ON THE MARKET OF BOVINE, OVINE OR CAPRINE MEAT AND
CERTAIN PRODUCTS OF ANIMAL ORIGIN**

Chapter A

Conditions for placing on the market

- I. The following products of animal origin are exempt from the prohibition referred to in Article 16(2), provided that they are derived from animals that comply with the conditions of Article 16(3):
- fresh meat;
 - minced meat;
 - meat preparations;
 - meat products;
 - food which is destined for domestic carnivores.

DATE-BASED SCHEME (DBS)

- II. Deboned fresh meat of which all adherent tissues, including obvious nervous and lymphatic tissue has been removed, and the products of animal origin referred to in Part I therefrom, derived from eligible animals from countries or regions thereof in Category 4 may be marketed in accordance with Article 16(3)(a) when obtained from animals born after the date at which the animal feeding standards laid down in Article 9 were effectively enforced, and which are certified to meet the conditions laid down in point (1) and produced in establishments which meet the condition laid down in point (10). The competent authority shall ensure that the conditions with respect to controls, laid down in points (2) to (8) and (10), are complied with.
1. (a) The animal is clearly identified, enabling it to be traced back to the dam and herd of origin; its unique eartag number, date and holding of birth and all movements after birth are recorded either in the animal's official passport or on an official computerised identification and tracing system; the identity of its dam is known;
- (b) the animal is more than six months but less than 30 months of age, determined by reference to an official computer record of its date of birth, or to the animal's official passport;
- (c) the competent authority has obtained and verified positive evidence that the dam of the animal has lived for at least six months after the birth of the eligible animal;
- (d) the dam of the animal has not developed BSE and is not suspected of having contracted BSE.

Controls

2. If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Regulation, the animal must be automatically rejected and its passport withheld. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates, and cancel issued certificates. 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 exclusively used for slaughter of animals under a Date-based Scheme or under a Certified Animal Scheme.
4. The competent authority must ensure that procedures used in the cutting plants ensure that the following lymph nodes have been removed:

Popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal prefemoral, lumbar, costocervical, sternal, prescapular, axillary and caudal 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 case of petfood accompanying documents and records must enable 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) 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 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 to be employed must be given, in writing, by the management of the establishment to the competent authority.

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

CERTIFIED ANIMAL SCHEME (CAS)

- III. Deboned fresh meat of which all adherent tissues, including obvious nervous and lymphatic tissue has been removed, and the products of animal origin referred to in Part I therefrom, derived from eligible animals from countries or regions thereof in Category 4, may be marketed in accordance with Article 16(3)(b) when obtained from animals which are certified to meet 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 to meet 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 with respect to the computerised tracing system and the controls, laid down in points (3) to (10) and (12), are complied with.

Herd conditions

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, taking into account compliance with each of the following conditions to the satisfaction of that authority:

- (i) all animals of the affected herd previously established 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.

Animal conditions

- 2. (a) all records of its birth, identity and movements are recorded on an official computerised tracing system;
- (b) it 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 ever moved are eligible.

Computerised tracing system

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

Controls

- 4. If any animal presented for slaughter or any circumstance surrounding its slaughter does not meet all of the requirements of this Regulation, the animal must be automatically rejected and its passport withheld. If that information becomes available after slaughter, the competent authority must immediately cease issuing certificates, and cancel issued certificates. 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, exclusively used for slaughter of animals under a Date-based Scheme or under a Certified Animal Scheme.

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

Popliteal, ischiatic, superficial inguinal, deep inguinal, medial and lateral iliac, renal prefemoral, lumbar, costocervical, sternal, prescapular, axillary and caudal 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 case of petfood accompanying documents and records must enable tracing.
8. All approved eligible carcasses must have individual numbers correlated with the ear tag number.
9. The Member State must have detailed protocols in place covering:
 - (a) tracing and controls prior to slaughter;
 - (b) controls during slaughter;
 - (c) 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 to be 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 B

IMPORT INTO THE COMMUNITY OF PRODUCTS OF ANIMAL ORIGIN

- I. Import into the Community from countries or regions thereof, placed in Category 4 of the products of animal origin referred to in Article 16 (3) shall be prohibited if they contain or are derived from the following products or material derived from ruminant animals:

- mechanically separated meat;
- dicalcium phosphate destined for feeding farmed species;
- gelatine unless produced from hides;
- rendered ruminant fat derivatives;
- rendered ruminant fat unless produced from discrete adipose tissue, which itself was found fit for human consumption, or from raw material which has been processed in accordance with the standards laid down pursuant to Directive 90/667/EEC.

II. The appropriate certificates, as required by Community legislation, shall be supplemented by the following words:

"The products of animal origin provide guarantees equivalent to those of Regulation [.../.....] of the European Parliament and of the Council and originate from a country, or region within a country in BSE Category ...^(*). This category was established by Commission Decision [.../.....]^(**);

(*) Complete as appropriate with 1, 2, 3 or 4.

(**) Complete."

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

"The product does not contain, and is not derived from, specified risk material as defined in Regulation [.../.....] of the European Parliament and of the Council. The animals have not been slaughtered by stunning or killing by means of a gas injected into the cranial cavity, or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity"

or

"The product contains, or is derived from, material of bovine, or as appropriate, ovine or caprine animals which were tested and found negative for the presence of BSE using a test which was approved in accordance with Commission Decision [.../.....]".

REFERENCE LABORATORIES, SAMPLING AND LABORATORY METHODS

CHAPTER A

NATIONAL REFERENCE LABORATORIES

1. The designated national reference laboratory shall:
 - (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 TSEs, and to confirm results obtained by regional diagnostic laboratories. Where it is not capable of identifying the strain-type of the agent, it shall set up a procedure to ensure that the identification of the strain is referred to the Community reference laboratory;
 - (b) verify diagnostic methods used in regional diagnostic laboratories;
 - (c) be responsible for coordination of diagnostic standards and methods within the Member State. To this end, it:
 - may provide diagnostic reagents to laboratories approved by the Member State;
 - shall control the quality of all diagnostic reagents used in the Member State;
 - shall periodically arrange comparative tests;
 - shall hold isolates, or corresponding tissues, of, or containing, the agents of the disease in question from cases confirmed in the Member State;
 - shall ensure confirmation of results obtained in diagnostic laboratories approved by the Member State.
 - (d) cooperate with the Community reference laboratory.
2. However, by way of derogation from point 1, Member States which do not have a national reference laboratory shall use the services of the Community reference laboratory or of national reference laboratories in other Member States.
3. The national reference laboratories are:
 - Austria:
 - Belgium:
 - Denmark:
 - Germany:

Finland:

France:

Greece:

Ireland:

Italy:

Luxembourg:

Netherlands:

Portugal:

Spain:

Sweden:

United Kingdom:

CHAPTER B

COMMUNITY REFERENCE LABORATORY

1. The Community reference laboratory for TSEs is:
2. The functions and duties of the Community reference laboratory are:
 - (a) to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing transmissible spongiform encephalopathies, specifically by:
 - storing and supplying corresponding tissues containing the agent, for the development or production of the relevant diagnostic tests, typing strains of the agent;
 - supplying standard sera and other reference reagents to the national reference laboratories in order to standardize 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;
 - organizing periodic comparative tests of diagnostic procedures at Community level;
 - collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;
 - characterizing isolates of the TSE agent by the most up-to-date methods to allow greater understanding of the epidemiology of the disease;

- keeping abreast of the developments in the surveillance, epidemiology and prevention of TSEs throughout the world;
 - retaining 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 receiving samples from TSE infected animals for confirmatory diagnosis, characterization and epidemiological studies;
- (c) to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonization of diagnostic techniques throughout the Community.

CHAPTER C

SAMPLING AND LABORATORY METHODS

1. The tests performed in the framework of the monitoring programme, referred to in Article 7, shall comprise on an annual basis, a range of tests, including at least histopathology examination of brain tissue, immunocytochemical, immunodiagnostic tests for the detection of scrapie associated fibrils (SAFs) and, when the TSE occurs in ovine or caprine animals, tests to identify the strain-type of the agent.
2. For confirmation of the suspected presence of a TSE, pursuant to Article 12(2), the tests performed shall at least comprise histopathology examination of brain tissue. The competent authority may also require the use of other laboratory tests such as immunocytochemical and immunodiagnostic tests for the detection of scrapie associated fibrils (SAFs), where their use is considered appropriate. In case of a first appearance of the disease all three tests should be performed.

**Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE**

amending Council Directive 91/68/EEC as regards scrapie

98/ 0324(COD)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a* thereof

Having regard to the proposal from the Commission¹⁶,

Having regard to the opinion of the Economic and Social Committee¹⁷,

Acting in accordance with the procedure laid down in Article 189 b of the Treaty¹⁸,

- (1) Whereas the animal health conditions for scrapie, covering placing on the market of animals are laid down in Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals¹⁹, as last amended by Commission Decision 94/953/EC²⁰;
- (2) Whereas the Commission has obtained new scientific opinions, in particular from the Scientific Steering Committee, on several aspects of TSEs, whereas the rules laid down in Directive 91/68/EEC must be reviewed in the light of those opinions;
- (3) Whereas provisions should be laid down for all the issues related to TSEs; whereas these rules should apply to the production and placing on the market of live animals and products of animal origin; whereas the European Parliament and the Council have adopted Regulation [.../...] laying down rules for the prevention and control of certain transmissible spongiform encephalopathies²¹;
- (4) Whereas this Directive directly concerns public health and is relevant to the functioning of the internal market; whereas, therefore, it is appropriate to choose Article 100a of the Treaty as the legal basis;
- (5) Whereas Directive 91/68/EEC should therefore be amended accordingly,

* At the moment at which the Amsterdam Treaty comes into force, please read Article 152.

¹⁶ OJ C

¹⁷ OJ C

¹⁸ OJ C

¹⁹ OJ L 46, 19.2.1991, p. 19.

²⁰ OJ L 371, 31.12.1994, p. 14.

²¹ OJ L

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/68/EEC is hereby amended as follows:

- (1) In Article 2(7), the words "as listed under sections I and II of Annex B" are replaced by the words "as listed under section I of Annex B".
- (2) Article 6(b) is deleted.
- (3) In Article 7(1), the words "referred to in Annex B, sections II and III" are replaced by the words "referred to in Annex B, section III".
- (4) In Article 8(1), the words "listed in Annex B, sections II and III" are replaced by the words "listed in Annex B, section III".
- (5) Section II of Annex B is deleted.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive 30 June 2000 at the latest. They shall forthwith inform the Commission thereof.

They shall apply those provisions as from 1 July 2000.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive. The Commission shall inform the other Member States thereof.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

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