COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.12.1998
COM(1998) 749 final

Proposal for a

COUNCIL DECISION

regulating the use of material presenting risks as regards transmissible spongiform encephalopathies and amending Commission Decisions 94/474/EC and 97/534/EC

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. The proposed decision replaces and postpones Commission Decision 97/534/EC laying down the rules on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies (SRM). It respects the invitation to the Commission, of the Council of March 1998, to base an appropriate proposal in the field of SRMs on the OIE Code on BSE.

   It amends the provisions of 97/534/EC in respect of the following points:

   - Cosmetic, medicinal and industrial products and medical devices are excluded from the scope.

   - The Decision allows Member States and exporting third countries to remove SRMs in the light of their geographical risk. The following procedure applies: Member States may submit the data necessary to allow assessment of their geographical BSE risk by 30 June 1999 at the latest. Countries which have not submitted a dossier by this date will be placed in a category by the Commission on the basis of all available information. The data of countries that have submitted a dossier, will be assessed by the Scientific Steering Committee. On the basis of their recommendation, the Commission will take a decision after consultation of the Member States (regulatory committee procedure). Third countries will also be invited to submit the necessary data in the same time scale.

   - The list of SRM is based on the relevant international standard, the OIE Code on BSE, and its currently proposed revision. This implies an enlargement in accordance with the opinion of the Scientific Steering Committee (SSC) of 9 December 1997 in areas which are placed in Category 4, i.e. those with the highest BSE risk. On the basis of the lower infectivity levels of certain tissues, as listed in the opinion of the SSC of 27 March 1998, a choice was made not to require the removal in areas with a lower BSE risk of the tissues with the lowest infectivity level and which were not recommended to be removed by the international standard for those areas. This list will apply as from 1 October 1999, allowing for time for the assessment of the dossiers by the scientific committees and taking into account their recommendations, as well as the development of the international standard after May 1999 and new scientific advice.

   - An exemption for Member States applying a compulsory single carcass test for bovines above a certain age is introduced in the Decision. As a precondition, such tests must be approved by the Commission. A derogation for products derived from tested carcasses to be imported from third countries is also foreseen.

2. This proposed decision follows the advice given by the SSC on 9 December 1997 and on 27 March 1998 and improves consumer safety while avoiding unjustified trade, economic and technical consequences. In addition, it allows future scientific advice to be taken into account and for respects WTO notification requirements.

3. On 18 November the College of Commissioners agreed to submit the proposal to the Standing Veterinary Committee (SVC) for an opinion. On 26 November the proposal was first discussed with the Member States in a working group of the SVC. On 2 December the proposal was presented for a vote to the SVC. The SVC gave a negative opinion. Most Member States objected to the proposed procedure for establishing the TSE status of countries, which requires an opinion of the appropriate scientific committee and will be based on an assessment of the incident, propagation and human exposure risk. In proposing the classification of countries the Commission will base itself on the relevant scientific opinion taking the OIE Code on BSE into consideration. Most Member States feel that no clear criteria are provided for in this text. In addition, most Member States object to the complexity of the ensuing control system resulting from different lists of SRMs applicable in countries classified according to four categories of TSE status. Finally, several technical remarks were made.

The results of the vote were:

Against: B, DK, DE, GR, FR, IRL, IT, L, P, FIN

Abstain: NL, AUS, SW, UK

No vote: SP (because of the absence of Spanish interpretation).

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(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market[1], as last amended by Directive 92/118/EEC[2], and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market[3], as last amended by Directive 92/118/EEC, and in particular Article 10(4) thereof,

Having regard to Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries[4], as last amended by Directive 96/43/EC[5], and in particular Article 19 thereof,

Having regard to the proposal from the Commission[6],

(1) Whereas pursuant to Directive 89/662/EEC and Directive 90/425/EEC, the Member State of origin or dispatch is required to implement on its territory the appropriate measures to prevent all situations likely to constitute a serious hazard to animals or to human health;

(2) 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;

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1 OJ L 395, 30.12.1989, p. 13.
2 OJ L 62, 15.3.1993, p. 49.
3 OJ L 224, 18.8.1990, p. 29.
4 OJ L 373, 31.12.1990, p. 1.
5 OJ L 162, 1.7.1996, p. 1.
6 OJ C

(3) Whereas rules should be laid down concerning the production and placing on the market of live animals and products of animal origin with respect to removal of, or absence of, specified risk material on the basis of the risk classification of the country or region concerned; whereas, however, those rules should not apply to cosmetic or medicinal products or 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 Decision are kept separate from those covered by it unless they meet at least the same health standards as the latter;

(4) Whereas existing Community Directives provide for the protection of public health in respect of the use of specified risk material in cosmetic or medicinal products and medical devices placed on the market in the Community; whereas, therefore, those products may be excluded from the scope of this Decision;

(5) 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;

(6) Whereas at its general assembly in Paris on 29 May 1998, the Office International des Epizooties (OIE) adopted a revised version of its Animal Health Code on BSE (OIE Code on BSE); whereas Article 3.2.13.14 of that Code recommends that bovine brain, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia and bones, and protein products derived from them from cattle over six months of age originating from countries with a high incidence of BSE should not be traded between countries; whereas the same Article recommends that bovine brain, eyes, spinal cord and distal ileum and protein products derived from them from cattle over six months of age originating from countries with a low incidence of BSE and born before the feedban was effectively enforced, should not be traded between countries; whereas it further recommends that brains and spinal cord (list under study) and protein products derived therefrom, from cattle, originating from a country or zone that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease, which were born before the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants was effectively enforced, and which were at the time of slaughter aged over 30 months (under study) should not be traded between countries;

(7) Whereas the Code Commission of the OIE, following recommendations of the scientific Ad Hoc Group on BSE epidemiology, issued proposed amendments to the OIE Code on BSE in September 1998; whereas the effect of those amendments would be to require that those tissues, instead of not being traded, should not be used for the preparation of human food, animal feed, cosmetics, pharmaceuticals or medical devices;

(8) Whereas the Scientific Veterinary Committee in its opinion of 21 October 1996, recommended on the basis of its risk assessment that specified risk materials, defined as brain, spinal cord and eyes from cattle, sheep and goats over one year of age and spleens from sheep and goats over six months of age, should be removed from all human food and animal feed chains in countries or regions where a potential risk was identified, and that, in the case of fallen bovine animals, sheep and goats, either the specified risk materials should be removed so that they do not enter any human food or animal feed chain, or the whole carcase should be destroyed;

(9) Whereas the Scientific Steering Committee (SSC) adopted an opinion on 9 December 1997; whereas in that opinion the SSC suggested a new and enlarged list of specified risk materials and proposed that those materials should be excluded temporarily from human and animal consumption depending on the geographical source;

(10) Whereas on the basis of the advice of the Scientific Veterinary Committee of 21 October 1996, in accordance with the risk assessment carried out by that Committee, the Commission adopted Decision 97/534/EC of 30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies[7]; as last amended by Council Decision 98/248/EC[8]; whereas in the light of the new scientific advice and the development of international standards the list of specified risk materials laid down in Decision 97/534/EC is no longer appropriate;

(11) 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; whereas it is necessary for practical and precautionary reasons to exclude the use of distal ileum and spleens from sheep and goats and, as appropriate, bovine animals, irrespective of age, and mechanically recovered meat from the skull and vertebral column of bovine animals, sheep and goats;

(12) Whereas equivalent guarantees should be required for imports from third countries; whereas the situation as regards TSEs may vary between countries and the import requirements should therefore be adapted to the particular situation of the country of origin;

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[7] OJ L 216, 8.8.1997, p. 95.
[8] OJ L 102, 2.4.1998, p. 26.

(13) Whereas Commission Decision 94/474/EC of 27 July 1994 concerning certain protection measures relating to bovine spongiform encephalopathy and repealing Decisions 89/469/EEC and 90/200/EEC[9], as last amended by Decision 98/272/EEC[10], and Decision 97/534/EC should be amended accordingly;

(14) Whereas this Decision should be reviewed in the light of new scientific information with regard to risk of exposure to TSEs resulting from infectivity in animal species, age categories, tissues or materials not yet covered by this Decision;

(15) Whereas the measures provided for in this Decision are not in accordance with the opinion of the Standing Veterinary Committee; whereas they must therefore be adopted by the Council,

HAS ADOPTED THIS DECISION:

Article 1
Scope

1. This Decision regulates the use of material presenting risks as regards 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 Decision shall not apply to:

   (a) cosmetic or medicinal products or medical devices, together with their starting materials or intermediate products;

   (b) products 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.

3. In order to avoid cross-contamination or substitution of the products of animal origin referred to in paragraph 1 by those referred to in paragraph 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.

Article 2
Definitions

For the purposes of this Decision, the following definitions shall apply:

(1) *transmissible spongiform encephalopathies*: all TSEs with the exception of those occurring in humans;

[9] OJ L 194, 29.7.1994, p. 96.
[10] OJ L 122, 24.4.1998, p. 59.

(2) *placing on the market*: any operation the purpose of which is to supply live animals, or products of animal origin covered by this Decision 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 from a third country to a Member State;

(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 Decision or any authority to which that central authority has delegated such competence;

(6) *categories*: the categories set out in Annex I;

(7) *specified risk material*: those tissues specified in Annex III; unless otherwise specified, it does not include products containing or derived from those tissues;

(8) *skull*: the bones of the head, including the bones of the lower jaw.

Article 3

Classification for determination of BSE status

1. Member States and third countries, or regions thereof, shall be placed in one of four categories in accordance with Annex I.

2. Member States or third countries shall submit an application to the Commission, accompanied by the information laid down in Annex II for their BSE status to be determined.

3. The Commission, acting in accordance with the procedure laid down in Article 17 of Directive 89/662/EEC, shall take a decision in respect of each application to place the applicant Member State or third country, or region thereof, in one of four categories.

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, 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.

4. Member States or third countries which have not submitted an application in accordance with paragraph 2 within six months after the date referred to in the first paragraph of Article 11 shall be placed in a category by the Commission on the basis of all information available to the Commission.

5. 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 Decision 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.

6. The decisions referred to in paragraphs 3 and 4 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 recommendations of the OIE Code on BSE.

Article 4

Specified risk material

1. Member States shall ensure that after 30 September 1999 the specified risk materials are, under the direct supervision of an official of the competent authority, removed from animals which were slaughtered or which died on their territory and disposed of in accordance with Annex III. They shall not be placed on the market for human food, animal feed or fertilisers after 30 September 1999.

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 17 of Directive 89/662/EEC, applied under the conditions laid down in Annex III, point 8, 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. The use of the skull and vertebral column of bovine, ovine and caprine animals for the production of mechanically recovered meat in Member States, or regions thereof which are not placed in Category 1 shall be prohibited after 30 September 1999. This shall not apply to animals which will are subjected to a test in accordance with Annex III, point 8.

5. By way of derogation from paragraph 1 the Commission, acting in accordance with the procedure laid down in Article 17 of Directive 89/662/EEC, may take a decision in respect of the date of effective enforcement of the prohibition on the feeding of mammalian protein to ruminants in each Member State or region thereof placed in Category 2 or 3, and allow the application of paragraph 1 to be confined to animals which were born before that date in those countries or those regions.

Article 5

Placing on the market

1. Where bovine, ovine or caprine animals coming from countries, or regions thereof, placed in one category are to be slaughtered after 30 September 1999 in the territory of Member States in a lower category, paragraphs 2, 3 and 4 shall apply.

2. The Member State of destination shall ensure that the specified risk materials are removed from the animals referred to in paragraph 1 and destroyed in accordance with Article 4. Those animals shall be slaughtered in slaughterhouses approved for that purpose by the competent authority and at the end of the normal slaughtering process.

3. The Member State of dispatch shall ensure that:

   (a) for bovine animals, the animal health certificates referred to in Annex F to Council Directive 64/432/EEC[11] are supplemented by the following words to be entered in the section "Health data concerning bovine animals":

   "The BSE category of the animals listed below is Category ... (*);

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

   (b) for ovine or caprine animals the animal health certificates corresponding to Model III in Annex E to Council Directive 91/68/EEC[12] shall be supplemented by the following words to be entered in section V "Health information":

   "BSE category of the animals listed below: Category ... (*);

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

   (c) for all animals, the competent authority of the Member State of destination is informed of the BSE category of the animals in each consignment by means of a specifically coded ANIMO message or by fax.

4. The third country of dispatch shall ensure that:

   (a) for bovine, ovine and caprine animals the appropriate certificates, as required by Community legislation, are supplemented by the following words:

   "The BSE category of the animals listed below is Category ... (*).

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

   (b) the competent authority of the Member State of destination is informed of the BSE category of the animals in each consignment by means of a specifically coded ANIMO message or by fax.

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[11] OJ L 121, 29.7.1964, p. 1977/64.
[12] OJ L 46, 19.2.1991, p. 19.

5. Products listed in Annex IV which contain material derived from bovine, ovine or caprine animals and are imported into the Community after 30 September 1999 shall be accompanied by the appropriate certificate, as required by Community legislation, supplemented by the following words:

"The products 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".

Where those products are imported from third countries, or regions thereof, in Categories 3 and 4 or from third countries, or regions thereof, in Category 2 in which BSE has occurred, the appropriate certificates, as required by Community legislation, shall be supplemented by one of the following declarations signed by the competent authority of the country of production:

"The product does not contain, and is not derived from, specified risk material as defined in Decision [.../...], produced after 30 September 1999, or mechanically recovered meat obtained from the skull or vertebral column of bovine, ovine or caprine animals, produced after 30 September 1999. 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 produced after 30 September 1999 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 [.../...]".

Any reference to "products" in this Article is a reference to the products listed in Annex IV, not to other products containing or derived from those products.

6. By way of derogation from paragraph 5, the Commission acting in accordance with the procedure laid down in Article 17 of Directive 89/662/EEC, may take a decision in respect of the date of effective enforcement of a prohibition on the feeding of mammalian protein to ruminants in any third country, or region thereof, in Category 2 or 3, and allow the application of paragraph 5 to be confined to specified risk materials derived from animals which were born before that date in those countries or those regions.

Article 6
Official controls

1. Member States shall carry out frequent official controls to verify the correct application of this Decision and ensure that measures are taken to avoid contamination, particularly in slaughterhouses, cutting plants, animal waste processing plants, high risk processing plants or premises authorised by the Member States in accordance with Article 7 of Council Directive 90/667/EEC[13], points of sale to the consumer and storage facilities.

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

   (a) specified risk materials used for products referred to in Article 1(2) are exclusively used for the authorised purpose;

   (b) where live bovine, ovine or caprine animals are received by Member States placed in a lower BSE category than that of the animals, those animals remain under official supervision until slaughter or dispatch from their territory.

Article 7
Further precautionary measures

Member States may take precautionary measures going beyond the measures provided for in this Decision in relation to animals slaughtered on their own territory.

Article 8
Other acts

This Decision shall be without prejudice to the provisions of Council Decision 98/256/EC[14], Decision 94/474/EEC and Commission Decision 98/653/EC[15].

Article 9
Amendments

1. Article 3(3) of Decision 94/474/EEC is hereby amended as follows:

   (a) Point (a) is deleted;

   (b) In point (c), the words "scientific tests are used to monitor the implementation of (a) and (b)" are replaced by "scientific tests are used to monitor the implementation of (b)".

[13] OJ L 363, 27.12.1990, p. 51.
[14] OJ L 113, 15.4.1998, p. 33.
[15] OJ L 311, 20.11.1998, p. 23.

2. Article 10 of Decision 97/534/EC is replaced by the following:

"Article 10

This Decision shall apply from such time as the Commission, acting in accordance with the procedure laid down in Article 17 of Directive 89/662/EEC, shall determine".

Article 10
Review

This Decision and the Decisions referred to in Article 3 shall be reviewed regularly in the light of new epidemiological information and scientific information with regard to criteria determining the level of risk in regions, and the risk of exposure to TSEs resulting from infectivity in other animal species, age categories, tissues or materials. Where necessary this Decision shall be amended after consultation of the appropriate Scientific Committee and in accordance with the procedure laid down in Article 17 of Directive 89/662/EEC.

Article 11
Application

This Decision shall apply from 1 January 1999.

It does not apply to products which were produced before 1 October 1999 referred to in this Decision, containing or derived from specified risk materials.

Article 12
Addressees

This Decision is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I

CLASSIFICATION

I. For the purpose of determining the BSE status of Member States or third countries, or regions within Member States or third countries, the following categories are established:

A. MEMBER STATES

Category 1 (BSE free)

Category 2 (provisionally BSE free)

Category 3 (low BSE risk)

Category 4 (high BSE risk)

B. THIRD COUNTRIES

Category 1 (BSE free)

Category 2 (provisionally BSE free)

Category 3 (low BSE risk)

Category 4 (high BSE risk)

II. 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.

ANNEX II

Information to be submitted in support of an application for recognition of risk classification under Article 3

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.

ANNEX III

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 3:

CATEGORY 1

No tissues are designated as specified risk materials.

CATEGORY 2

In countries, or regions within countries, placed in Category 2, the following are only designated as specified risk materials where BSE has occurred[16]:

(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, unless specific measures have been taken covering meat-and-bone meal and maternal transmission and in the light of the latest available scientific advice; spinal cord and dura mater of bovine animals aged over six months and of ovine and caprine animals aged over 12 months;

[16] pending OIE confirmation.

(b) other bones of bovine animals aged over 30 months;

(c) the distal ileum and spleen of bovine, ovine and caprine animals of all ages.

2. Pursuant to a Decision in respect of the date of effective enforcement of a prohibition on the feeding of mammalian protein to ruminants in each country, or region of within a country, placed in Category 2 or 3, as referred to in Articles 4(5) and 5(6), the application of the provisions related to specified risk materials may be confined to those derived from animals which were born before that date in those countries or those regions.

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

However, in Member States or regions within Member States that are not placed in Category 4, the removal and subsequent destruction according to point 5 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 V.

4. By way of derogation from point 3, 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 Directive 90/667/EEC, 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 5.

5. 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.

6. 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.

7. Member States may derogate from the provisions of points 3 and 5 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.

8. 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 5.

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.

The products referred to in Article 5(5) are:

(a) *fresh meat:* fresh meat as defined by Council Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat[17];

(b) *minced meat* and *meat preparations:* minced meat and meat preparations as defined by Council Directive 94/65/EC[18];

(c) *meat products* and *other products of animal origin:* meat products and other products of animal origin as defined by Council Directive 77/99/EEC[19];

(d) *milk products,* as defined by Council Directive 92/46/EEC[20], which are destined for human consumption and containing gelatin or rendered animal fat;

(e) *milk products,* as defined by Council Directive 92/118/EEC[21], which are destined for animal consumption and containing gelatin or rendered animal fat;

(f) *fishery products,* as defined by Council Directive 91/493/EEC[22], which are destined for human consumption and containing gelatin or rendered animal fat;

(g) *egg products,* as defined by Council Directive 89/437/EEC[23], which are destined for human consumption and containing gelatin or rendered animal fat;

(h) *snails or frogs' legs,* as referred to by Council Directive 92/118/EEC, which are destined for human consumption and containing gelatin or rendered animal fat;

(i) *rendered fats,* as referred to by Council Directive 92/118/EEC;

(j) *gelatin,* as referred to by Council Directive 92/118/EEC;

(k) *petfood,* as referred to by Council Directive 92/118/EEC;

(l) *processed animal protein,* as referred to by Council Directive 92/118/EEC;

(m) *bones and bone products,* as referred to by Council Directive 92/118/EEC;

(n) *raw material for the manufacture of animal feedingstuffs,* as referred to by Council Directive 92/118/EEC.

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17 OJ 121, 29.7.1964, p. 2012/64. Directive as last amended by Directive 95/23/EC (OJ L 243, 11.10.1995, p. 7).
18 OJ L 368, 31.12.1994, p. 10.
19 OJ L 26, 31.1.1977, p. 85.
20 OJ L 268, 14.9.1992, p. 1.
21 OJ L 62, 15.3.1993, p. 49.
22 OJ L 268, 24.9.1991, p. 15.
23 OJ L 212, 22.7.1989, p. 87.

Tallow derivatives may be used for the production of human food, animal feed or fertilisers provided that they are produced by an appropriate, validated and strictly certified method 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, 2 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 and submitted to further processes may also be used.

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