Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1 This Regulation lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It shall apply to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

2 This Regulation shall not apply to:

- a cosmetic or medicinal products or medical devices, or to their starting materials or intermediate products;
- b products which are not intended for use in human food, animal feed or fertilisers, or to their starting materials or intermediate products;
- c products of animal origin intended for exhibition, teaching, scientific research, special studies or analysis, provided those products are not eventually consumed or used by humans or by animals other than those kept for the research projects concerned;
- d live animals used in or intended for research.

Article 2

Separation of live animals and of products of animal origin

In order to avoid cross-contamination or substitution between the live animals or of the products of animal origin referred to in Article 1(1) and the products of animal origin referred to in Article 1(2)(a), (b) and (c), or the live animals referred to in Article 1(2)(d), they shall be kept separate at all times unless such live animals or products of animal origin are produced under at least the same conditions of health protection in respect of TSEs.

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

Article 3

Definitions

1 For the purposes of this Regulation the following definitions shall apply:

- a TSEs: all transmissible spongiform encephalopathies with the exception of those occurring in humans;

b placing on the market: any operation the purpose of which is to sell live animals or products of animal origin covered by this Regulation to a third party in the Community, or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;

c products of animal origin: any product derived from or containing a product derived from any animal covered by the provisions of Directive 89/662/EEC[(1)] or Directive 90/425/EEC[(2)];

d starting materials: raw materials or any other product of animal origin out of which, or with the help of which, the products referred to in Article 1(2)(a) and (b) are produced;

e competent authority: the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that central authority has delegated that competence, in particular for the control of feedingstuffs; it shall also include, where appropriate, the corresponding authority of a third country;

f category: one of the classification categories referred to in Chapter C of Annex II;

g specified risk material: the tissues specified in Annex V; unless otherwise indicated, it does not include products containing or derived from those tissues;

h animal suspected of being infected by a TSE: live, slaughtered or dead animals, which show or have shown neurological or behavioural disorders or a progressive deterioration of the general condition linked to impairment of the central nervous system and for which the information gathered on the basis of a clinical examination, response to treatment, a post-mortem examination or an ante or post-mortem laboratory analysis do not allow an alternative diagnosis to be established. Bovine spongiform encephalopathies (BSE) shall be suspected in bovine animals which have produced a positive result from a rapid test specifically for BSE;

i holding: any place in which animals covered by this Regulation are held, kept, bred, handled or shown to the public;

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

k fertilisers: any substance containing products of animal origin utilised on land to enhance growth of vegetation; it may include digestion residues from bio-gas production or composting;

[[F1]l rapid tests: the screening methods listed in Annex X, for which the results are known within 24 hours;**]**

m alternative test: the tests referred to in Article 8(2) which are used as an alternative to the withdrawal of specified risk material**[**[F1];**]**

[[F2]n mechanically separated meat or 'MSM': the product obtained by removing meat from flesh-bearing bones after boning, using mechanical means resulting in the loss or modification of the muscle fibre structure;

o passive surveillance: the reporting of all animals suspected of being infected by a TSE and, where TSE cannot be excluded by clinical investigation, the laboratory testing of such animals;

p active surveillance: the testing of animals not reported as suspected of being infected by a TSE, such as emergency slaughtered animals, animals with observations at ante mortem inspection, fallen stock, healthy slaughtered animals and animals culled in connection with a TSE case, in particular in order to determine the evolution and prevalence of TSE in a country or region thereof.**]**

2 The specific definitions set out in Annex I shall also apply.

3 Where the terms in this Regulation are not defined in paragraph 1 or Annex I, the relevant definitions given in Regulation (EC) No 1760/2000[3] and those given in or pursuant to Directives 64/432/EEC[4], 89/662/EEC, 90/425/EEC and 91/68/EEC[5] shall apply insofar as reference is made to them in this text.

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F2 Inserted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 4

Safeguard measures

1 With regard to the implementation of safeguard measures, the principles and provisions set out in Article 9 of Directive 89/662/EEC, Article 10 of Directive 90/425/EEC, Article 18 of Directive 91/496/EEC[6] and Article 22 of Directive 97/78/EC[7] shall apply.

2 The safeguard measures shall be adopted in accordance with the procedure referred to in Article 24(2) and shall be notified at the same time to the European Parliament, stating the reasons.

CHAPTER II

DETERMINATION OF BSE STATUS

Article 5

Classification

[F1 1 The BSE status of Member States or third countries or regions thereof (hereinafter referred to as 'countries or regions') shall be determined by classification into one of the following three categories:

— negligible BSE risk as defined in Annex II,

— controlled BSE risk as defined in Annex II,

— undetermined BSE risk as defined in Annex II.

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

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

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

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

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

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

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

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

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

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

[[F1]4 Member States and third countries which have not submitted an application in accordance with the third subparagraph of paragraph 1 shall, with respect to the dispatch from their territory of live animals and products of animal origin, comply with the import requirements applicable to countries with an undetermined BSE risk, until they have submitted such an application and a final decision has been taken on their BSE status.**]**

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

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

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

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

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

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

CHAPTER III

PREVENTION OF TSE

Article 6

Monitoring system

[F1 1 Each Member State shall carry out an annual monitoring programme for TSEs based on active and passive surveillance in accordance with Annex III. If available for the animal species, that programme shall include a screening procedure using rapid tests.

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

[F2 1a The annual monitoring programme referred to in paragraph 1 shall cover as a minimum the following subpopulations:

a all bovine animals above 24 months of age sent for emergency slaughter or with observations at ante mortem inspections;

b all bovine animals above 30 months of age slaughtered normally for human consumption;

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

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

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

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

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

a a clearly declining or consistently low BSE prevalence, based on up-to-date testing results;

b that it has implemented and enforced for at least six years a full BSE testing scheme (Community legislation on traceability and identification of live animals and BSE surveillance);

c that it has implemented and enforced for at least six years Community legislation on total feed ban for farmed animals.**]**

2 Each Member State shall inform the Commission and the other Member States, within the Standing Veterinary Committee, of the emergence of a TSE other than BSE.

3 All official investigations and laboratory examinations shall be recorded in accordance with Annex III, Chapter B.

4 Member States shall submit an annual report to the Commission covering at least the information referred to in Annex III, Chapter B, Part I. The report for each calendar year shall be submitted at the latest by 31 March of the following year. The Commission shall present a summary of the national reports covering at least the information referred to in Annex III, Chapter B, Part II, to the Standing Veterinary Committee within three months of the receipt of the said reports.

[[F2]5 Rules for the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 24(2).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F2 Inserted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

[F2 Article 6a

Breeding Programmes

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

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

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

Textual Amendments

F2 Inserted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 7

Prohibitions concerning animal feeding

[F1 1 The feeding to ruminants of protein derived from animals shall be prohibited.

2 The prohibition provided for in paragraph 1 shall be extended to animals other than ruminants and restricted, as regards the feeding of those animals with products of animal origin, in accordance with Annex IV.

3 Paragraphs 1 and 2 shall apply without prejudice to the provisions laid down in Annex IV setting out the derogations from the prohibition contained in those paragraphs.

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

4 Member States, or regions thereof, with an undetermined BSE risk shall not be permitted to export or store feed intended for farmed animals which contains protein derived

from mammals or feed intended for mammals, except feed for dogs, cats and fur animals, which contains processed protein derived from mammals.

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

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

[F2 4a Based on a favourable risk assessment taking into account at least the amount and possible source of contamination and the final destination of the consignment, a decision may be taken in accordance with the procedure referred to in Article 24(3) to introduce a tolerance level for insignificant amounts of animal proteins in feedingstuffs caused through adventitious and technically unavoidable contamination.**]**

[F1 5 Rules for the implementation of this Article, in particular rules on the prevention of cross-contamination and on the methods of sampling and analysis required to check compliance with this Article, shall be adopted in accordance with the procedure referred to in Article 24(2). Those rules shall be based on a report of the Commission covering sourcing, processing, control and traceability of feedingstuffs of animal origin.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F2 Inserted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 8

Specified risk material

[F1 1 The specified risk material shall be removed and disposed of in accordance with Annex V to this Regulation and with Regulation (EC) No 1774/2002. It shall not be imported into the Community. The list of specified risk material referred to in Annex V shall include at least the brain, spinal cord, eyes and tonsils of bovine animals aged over 12 months and the vertebral column of bovine animals above an age to be determined in accordance with the procedure referred to in Article 24(3). Taking into account the different risk categories laid down in the first subparagraph of Article 5(1) and the requirements of Article 6(1a) and (1b) (b), the list of specified risk material in Annex V shall be amended accordingly.

2 Paragraph 1 of this Article shall not apply to tissues from animals which have undergone an alternative test approved for that distinct purpose in accordance with the procedure referred to in Article 24(3) provided that this test is listed in Annex X, is applied under the conditions provided for in Annex V and the test results are negative.

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

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

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

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

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

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 9

Products of animal origin derived from or containing ruminant material

[[F1]1 The products of animal origin listed in Annex VI shall be produced using production processes approved in accordance with the procedure referred to in Article 24(3).

2 Bones of bovine, ovine and caprine animals from countries or regions with a controlled or undetermined BSE risk shall not be used for the production of mechanically separated meat (MSM). Before 1 July 2008, the Member States shall submit a report to the Commission on the use and the production method of MSM in their territory. This report shall include a statement as to whether the Member State intends to continue with the production of MSM.

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

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

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

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 10

Education programmes

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

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

CHAPTER IV

CONTROL AND ERADICATION OF TSEs

Article 11

Notification

Without prejudice to Directive 82/894/EEC[8], the Member States shall ensure that any animal suspected of being infected by a TSE is notified immediately to the competent authorities.

Member States shall regularly inform each other and the Commission of the cases of TSE notified.

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

Article 12

Measures with respect to suspect animals

[F1 1 Any animal suspected of being infected by a TSE shall be either placed under an official movement restriction until the results of a clinical and epidemiological examination carried out by the competent authority are known, or killed for laboratory examination under official control.

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

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

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

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

2 Where the competent authority decides that the possibility of infection with a TSE cannot be ruled out, the animal shall be killed, if it is still alive; its brain and all other tissues as the competent authority may determine shall be removed and sent to an officially approved laboratory, the national reference laboratory provided for in Article 19(1) or the Community reference laboratory provided for in Article 19(2), for examination in accordance with the testing methods laid down in Article 20.

[F1 3 All parts of the body of the suspect animal shall be either retained under official control until a negative diagnosis has been made, or disposed of in accordance with Regulation (EC) No 1774/2002.**]**

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

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 13

Measures following confirmation of the presence of a TSE

1 When the presence of a TSE has been officially confirmed, the following measures shall be applied as soon as possible:

[F1 a all parts of the body of the animal shall be disposed of in accordance with Regulation (EC) No 1774/2002 except for material retained for records in accordance with Annex III, Chapter B, of this Regulation.**]**

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

[F1c all animals and products thereof at risk, as listed in Annex VII, point 2, of this Regulation, identified by the inquiry referred to in point (b) of this paragraph shall be killed and disposed of in accordance with Regulation (EC) No 1774/2002.**]**

[F2At the request of a Member State and based on a favourable risk assessment taking particularly into account the control measures in that Member State, a decision may be taken in accordance with the procedure referred to in Article 24(2) to allow the use of bovine animals referred to in this paragraph until the end of their productive lives.**]**

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

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

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

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

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

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

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

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F2 Inserted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 14

Contingency plan

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

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

CHAPTER V

PLACING ON THE MARKET AND EXPORT

Article 15

Live animals, their semen, embryos and ova

1 Placing on the market or, if need be, export of bovine, ovine or caprine animals and their semen, embryos and ova shall be subject to the conditions laid down in Annex VIII, or, in the case of imports, to the conditions laid down in Annex IX. The live animals and their embryos and ova shall be accompanied by the appropriate animal health certificates as required by Community legislation, in accordance with Article 17 or, in the case of imports, Article 18.

2 The placing on the market of first generation progeny, semen, embryos and ova of TSE suspect or confirmed animals shall be subject to the conditions laid down in Annex VIII, Chapter B.

[[F1]3 In accordance with the procedure referred to in Article 24(3), the provisions of paragraphs 1 and 2 may be extended to other animal species.

4 Rules for implementing this Article may be adopted in accordance with the procedure referred to in Article 24(2).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 16

Placing on the market of products of animal origin

1 The following products of animal origin derived from healthy ruminants shall not be subject to restrictions on placing on the market or, if need be, export pursuant to this Article, to Annex VIII, Chapters C and D, and to Annex IX, Chapters A, C, F and G:

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

[F1b milk and dairy products, hides and skins, and gelatine and collagen derived from hides and skins.**]**

[F12 Products of animal origin imported from a third country with a controlled or undetermined BSE risk shall come from healthy bovine, ovine and caprine animals which have not been subjected to a laceration of the central nervous tissue or gas injection into the cranial cavity as referred to in Article 8(3).

3 Food products of animal origin containing material obtained from bovine animals originating in a country or region with an undetermined BSE risk shall not be placed on the market unless they come from animals which:

a were born eight years after the date from which the prohibition on the feeding to ruminants of animal protein derived from mammals was effectively enforced; and

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

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

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

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

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

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

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

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

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 17

Under the procedure referred to in Article 24(2), the health certificates referred to in Annex F to Directive 64/432/EEC, Models II and III in Annex E to Directive 91/68/EEC and the appropriate health certificates laid down by Community legislation relating to trade in the semen, embryos and ova of bovine, ovine or caprine animals shall be supplemented, where necessary, by a reference to the category specifying the classification of the Member State or region of origin given in accordance with Article 5.

Appropriate commercial documents relating to trade in products of animal origin shall be supplemented, where necessary, by a reference to the category of the Member State or region of origin given by the Commission in accordance with Article 5.

Article 18

The appropriate health certificates relating to imports provided for by Community legislation shall, under the procedure referred to in Article 24(2), be supplemented in respect of third countries classified in a category pursuant to Article 5 by the specific requirements laid down in Annex IX, as soon as that classification decision has been taken.

CHAPTER VI

REFERENCE LABORATORIES, SAMPLING, TESTING AND CONTROLS

Article 19

Reference laboratories

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

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

Article 20

Sampling and laboratory methods

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

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

Article 21

Community controls

1 Experts from the Commission may make on-the-spot checks in cooperation with the competent authorities of the Member States, insofar as is necessary for the uniform application

of this Regulation. The Member State in whose territory checks are made shall provide the experts with all the assistance necessary for carrying out their duties. The Commission shall inform the competent authority of the results of the checks made.

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

2 Community checks concerning third countries shall be made in accordance with Articles 20 and 21 of Directive 97/78/EC.

CHAPTER VII

TRANSITIONAL AND FINAL PROVISIONS

Article 22

Transitional measures concerning specified risk material

1 The provisions of Annex XI, Part A shall apply for a period of at least six months from 1 July 2001 and shall cease to apply immediately following the date of adoption of a decision in accordance with Article 5(2) or (4), on which date Article 8 shall enter into force.

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

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

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

Article 23

Amendment of the annexes and transitional measures

After consultation of the appropriate scientific committee on any question which could have an impact on public health, the annexes shall be amended or supplemented and any appropriate transitional measures shall be adopted in accordance with the procedure referred to in Article 24(2).

[[F3]In accordance with that procedure, transitional measures shall be adopted for a period ending on 1 July 2007 at the latest, to permit the change-over from the current arrangements to the arrangements established by this Regulation.**]**

Textual Amendments

F3 Substituted by Regulation (EC) No 932/2005 of the European Parliament and of the Council of 8 June 2005 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and

eradication of certain transmissible spongiform encephalopathies as regards the extension of the period for transitional measures (Text with EEA relevance).

[F2 Article 23a

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

(a) approval of the rapid tests referred to in Article 6(1) and Article 8(2),

(b) adaptation of the age referred to in Article 6(1b),

(c) criteria to demonstrate improvement of the epidemiological situation referred to in Article 6(1b),

(d) decision to allow feeding of young animals of ruminant species with proteins derived from fish as referred to in Article 7(3),

(e) criteria for granting exemptions from the restrictions referred to in Article 7(4),

(f) decision to introduce a tolerance level as referred to in Article 7(4a),

(g) decision on age as referred to in Article 8(1),

(h) rules providing for exemptions from the requirement to remove and destroy specified risk material as referred to in Article 8(5),

(i) approval of production processes referred to in Article 9(1),

(j) decision to extend certain provisions to other animal species as referred to in Article 15(3).**]**

Textual Amendments

F2 Inserted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

[F1 Article 24

Committees

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health. However, the Standing Committee on Zootechnics shall also be consulted by the Commission with regard to Article 6a.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits referred to in Article 5(6) of that Decision shall be three months and, in the case of safeguard measures referred to in Article 4(2) of this Regulation, 15 days.

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

Textual Amendments

F1 Substituted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

[F2 Article 24a

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

Textual Amendments

F2 Inserted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Article 25

Consultation of the scientific committees

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

Article 26

Entry into force

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

It shall apply from 1 July 2001.

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

(**1**) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 395, 30.12.1989, p. 13). Directive as last amended by Council Directive 92/118/EEC (OJ L 62, 15.3.1993, p. 49).

(**2**) Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29). Directive as last amended by Council Directive 92/118/EEC.

(**3**) Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

(**4**) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121 29.7.1964, p. 1977/64). Directive as last amended by Directive 2000/20/EC of the European Parliament and of the Council (OJ L 163, 4.7.2000, p. 35).

(**5**) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Commission Decision 94/953/EC (OJ L 371, 31.12.1994, p. 14).

(**6**) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ L 268, 24.9.1991, p. 56). Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).

(**7**) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

(**8**) Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58). Directive as last amended by Commission Decision 2000/556/EC (OJ L 235, 19.9.2000, p. 27).

Status:
Point in time view as at 19/01/2007.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council.