COMMISSION REGULATION (EC) No 1326/2001
of 29 June 2001
laying down transitional measures to permit the changeover to the Regulation of the European Parliament and of the Council (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, and amending Annexes VII and XI to that Regulation

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (1), as last amended by Commission Regulation (EC) No 1248/2001 (2), and in particular Article 23 thereof,

Whereas:

(1) Articles 7, 9 and 15 to 18 of Regulation (EC) No 999/2001 lay down rules concerning animal feeding, and impose further restrictions for products of ruminant origin and marketing of live animals and products of animal origin. Their requirements vary depending on the classification of the BSE status of the Member States or third countries concerned. The classification for the determination of BSE status is to be decided according to the criteria laid down in Article 5 of Regulation (EC) No 999/2001. To date no decisions have been taken to place any Member State or third country in a category based on the new provisions under Article 5. The provisions of the Regulation would take effect in their entirety from 1 July 2001, unless transitional measures have been adopted on the basis of Article 23. In absence of decisions on classification Articles 7, 9 and 15 to 18 cannot be applied: transitional measures are therefore necessary.

(2) Transitional measures for certain rules based on classification, namely those concerning specified risk material, are already foreseen by Article 22, which provides that they shall apply at least until 1 January 2002 and shall cease to apply immediately following the date of adoption of a decision on classification in accordance with Article 5, on which date Article 8, concerning specified risk material, shall apply. In the interest of clarity the same rules for the changeover from the transitional rules to the rules of the Regulation should apply to the other Articles based on classification.

(3) The transmissible spongiform encephalopathy-related Community rules on prohibitions concerning animal feeding, in force immediately prior to the implementation of Regulation (EC) No 999/2001, are laid down in Council Decision 2000/766/EC (3), concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein and Commission Decision 2001/9/EC (4), as amended by Decision 2001/165/EC (5), concerning control measures required for the implementation of Decision 2000/766/EC. Decision 2000/766/EC, suspends the feeding, with few exceptions, of processed animal proteins to all farmed animals until 30 June 2001. The Council concluded on 24 April 2001 that the period of application of the Decision should be extended. This latter Decision shall therefore be amended accordingly as a transitional measure. Any further amendments will depend on a decision on the classification of Member States as well as the efficacy of control measures put in place by individual Member States.

(4) The transmissible spongiform encephalopathy-related Community rules on placing on the market and export of live bovine animals and of certain products of bovine animal origin, in force immediately prior to the implementation of Regulation (EC) No 999/2001, are laid down in, or have been adopted pursuant to, Commission Decision 92/290/EEC of 14 May 1992 concerning certain protection measures relating to bovine embryos in respect of bovine spongiform encephalopathy (BSE) in the United Kingdom (6), Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC (7), Commission Decision 98/351/EC of 29 May 1998 setting the date on which dispatch from Northern Ireland of bovine products under the Export Certified Herds Scheme may commence by virtue of Article 6(5) of Council Decision 98/256/EC (8), Commission Decision 1999/514/EC of 23 July 1999 setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence by virtue of Article 6(5) of Council Decision 98/256/EC (9), Commission Decision 2000/345/EC of 22 May 2000 setting the date on which dispatch from Portugal to Germany of certain products for the purpose of incineration may commence by virtue

of Article 3(6) of Decision 98/653/EC (1), Commission Decision 2000/371/EC of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to France may commence by virtue of Article 3(7) of Decision 98/653/EC (2), Commission Decision 2000/372/EC of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to Spain may commence by virtue of Article 3(7) of Decision 98/653/EC (3) and Commission Decision 200/376/EC of 18 April 2001 concerning measures made necessary by the occurrence of bovine spongiform encephalopathy in Portugal and implementing a date-based export scheme (4). These Decisions shall therefore remain in force during the transitional period.

(5) The transmissible spongiform encephalopathy related Community rules on specified risk material, in force immediately prior to the implementation of Regulation (EC) No 999/2001, are laid down in, or have been adopted pursuant to, Commission Decision 2000/418/EC of 29 June 2000 regulating the use of material presenting risks as regards transmissible spongiform encephalopathies and amending Decision 94/474/EC (5), as last amended by Decision 2001/384/EC (6). This Decision has been amended with respect to bovine vertebral column, mechanically recovered meat and the import from third countries, after the adoption by the Council, on 12 February 2001, of its Common Position (EC) No 8/2001 with a view to adopting Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (7). Annex XI to that Regulation sets out the rules on specified risk material which apply during the transitional period. Section A of that Annex should therefore be updated to include the specified risk material provisions adopted since the adoption by Council of its Common Position.

(6) Until classification decisions have been made for third countries, and as a precaution, it is appropriate to provide that the minimal protection measures foreseen by Regulation (EC) No 999/2001 for imports from all third countries which are not considered BSE-free should apply to all imports of live bovine animals, embryos and ova. Furthermore, the removal of specified risk material from products destined for food and feed is the single most important public health protection measure. It is therefore appropriate to extend, as a transitional measure, the list of products covered by restrictions on import pursuant to Decision 2000/418/EC, to include all products containing bovine, ovine or caprine material covered by Community health certificates. However, those third countries that benefit from a derogation for Decision 2000/418/EC should also benefit from a derogation from this transitional measure. In order to respect international obligations under the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures, in particular the notification procedures, the provisions relating to import should not apply until 1 October 2001.

(7) Annex VII to Regulation (EC) No 999/2001 sets out the detailed rules for the measures to be implemented following confirmation of the presence of a TSE. These rules should be updated to reflect the detailed technical eradication provisions applied by the Member States, taking into account the opinion of the Scientific Steering Committee (SSC) on BSE related culling in cattle of 15 September 2000. The SSC concluded in this opinion that already (entire) herd culling is having some effect both in terms of eliminating otherwise not identified cases and in terms of preventing future cases to appear. However, (...) largely the same effect can be reached by culling all animals born and/or raised in the same herds as the confirmed case within approximately 12 months before and after the date of birth of the index case (birth-cohort culling). The SSC recommended the culling of at least the birth cohort whenever a domestic BSE case appears, irrespective of the prevailing epidemiological situation. It is therefore appropriate to amend the detailed eradication provisions accordingly by making the culling of the entire herd optional depending upon the prevailing local situation.

(8) In the interest of clarity 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 (8), Commission Decision 94/381/EC of 27 June 1994 concerning certain protection measures with regard to bovine spongiform encephalopathy and the feeding of mammalian derived protein (9), and Decision 2000/418/EC regulating the use of material presenting risks as regards transmissible spongiform encephalopathies and amending Decision 94/474/EC, should be repealed.

(2) OJ L 134, 7.6.2000, p. 34.
HAS ADOPTED THIS REGULATION:

Article 1

By way of transitional measure derogating from Regulation (EC) No 999/2001:

1. the provisions of Regulation (EC) No 999/2001 listed in Annex I to this Regulation shall not apply to a Member State or third country until the entry into force of the decision determining the BSE status of that Member State or third country, adopted pursuant to Article 5 of Regulation (EC) No 999/2001. Annex XI, section D, shall apply to the Member State or third country concerned until that date. No such decision shall enter into force before 1 January 2002;

2. Article 7(2), (3) and (4) shall not apply to a Member State until the coming into force of the decision determining the BSE status of that Member State, and until the Community provisions on animal feeding relevant to transmissible spongiform encephalopathies are effectively enforced there. Annex XI, section C, shall apply to that Member State until Article 7(2), (3) and (4) become applicable there.

Article 2

1. In Article 4 of Decision 2000/766/EC, the second and third paragraphs, are hereby deleted.

2. Decisions 94/381/EC, 94/474/EC and 2000/418/EC are repealed.

Article 3

Regulation (EC) No 999/2001 is amended as follows:

1. The text in Annex VII is replaced by the text in Annex II to this Regulation.

2. The text in Annex XI, section A, is replaced by the text in Annex III to this Regulation.

3. The text in Annex XI is completed with the text in Annex IV to this Regulation.

Article 4

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.

However, the provisions of Annex XI, section A, point 5, fourth to seventh, ninth and tenth indents, and section D, point 2 and 3, to Regulation (EC) No 999/2001, as amended by the present Regulation, shall apply from 1 October 2001.

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


For the Commission
David BYRNE
Member of the Commission

ANNEX I

— Article 9 concerning certain products of ruminant animal origin,
— Article 15(1) concerning the placing on the market of live animals, their semen, embryos and ova,
— Article 16(2), (3), (4) and (6) concerning the placing on the market of products of animal origin,
— Article 17 concerning the health certificates or commercial documents relating to trade,
— Article 18 concerning the health certificates relating to imports,
— Annex VIII, Chapter A(II), concerning the placing on the market of live bovine animals within the Communities,
— Annex VIII, Chapter C, concerning the placing on the market of products of bovine animal origin within the Communities,
— Annex IX, Chapters A, B, C, D, F and G, concerning the import from third countries of live bovine animals, products of bovine animal origin, bovine embryos and ova, and other products of ruminant animal origin.

ANNEX II

ANNEX VII

ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

1. The inquiry referred to in Article 13(1)(b) must identify:
   (a) in the case of bovine animals:
      — all other ruminants on the holding of the animal in which the disease was confirmed,
      — where the disease was confirmed in a female animal, all its embryos, ova and its progeny collected or born within two years prior to, or after, clinical onset of the disease,
      — all animals of the cohort of the animal in which the disease was confirmed,
      — the possible origin of the disease,
      — other animals, embryos or ova, on the holding of the animal in which the disease was confirmed or on other holdings, which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
      — the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;
   (b) in the case of ovine and caprine animals:
      — all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,
      — in so far as they are identifiable, the parents, all embryos, ova and the last progeny of the animal in which the disease was confirmed,
      — all animals of the cohort, to be defined in accordance with the procedure laid down in Article 24(2), of the animal in which the disease was confirmed,
      — all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those mentioned in the second and third indents,
      — the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
      — the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the BSE agent to or from the holding in question.

2. The measures laid down in Article 13(1)(c) shall comprise at least:
   (a) in case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals and the destruction of embryos and ova identified by the inquiry referred to in point 1(a), first, second and third indent. The Member State may decide not to kill and destroy all bovine animals on the holding of the animal in which the disease was confirmed as referred to in the first indent of point 1(a), depending upon the epidemiological situation and traceability of the animals on that holding;
   (b) in case of confirmation of BSE in an ovine or caprine animal, killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in point 1(b), second to sixth indents.’
ANNEX III

A. Concerning the removal of specified risk material

1. Member States shall ensure that the specified risk material designated below is removed and destroyed in accordance with points 7 to 11.

(a) The following tissues are designated as specified risk material:

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

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

A decision may be taken in accordance with the procedure referred to in Article 24(2) in particular with a view to adjust the age for the removal of bovine vertebral column, in the light of the statistical probability of the occurrence of BSE in the relevant age groups of the Community's bovine population, based on the results of BSE monitoring, with particular reference to testing of bovine animals, as established by Annex III.

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

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

2. Specified risk material or processed material derived from it may be despatched only with a view to subsequent incineration, in accordance with point 11 or, where appropriate, point 7(b).

3. Member States shall ensure that bones of bovine, ovine and caprine animals are not used for the production of mechanically recovered meat.

4. Member States shall ensure that laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity is not effected within their territory with regard to bovine, ovine or caprine animals whose meat is intended for human or animal consumption.

5. The specified risk material referred to in point 1(a) shall not be imported into the Community after 31 March 2001.

The products of animal origin listed below shall be subject to restrictions on import into the Community:

— fresh meat: the meat defined by Directive 64/433/EEC,
— minced meat and meat preparations: the minced meat and meat preparations defined by Directive 94/65/EC (1);
— meat products: the meat products defined by Directive 77/99/EEC (2),
— other products of animal origin: other products of animal origin as defined by Directive 77/99/EEC,
— rendered fats as referred to by Directive 92/118/EEC,
— gelatin as referred to by Directive 92/118/EEC,
— petfood as referred to by Directive 92/118/EEC,
— the processed animal protein referred to in Directive 92/118/EEC,
— bones and bone products as referred to by Directive 92/118/EEC,
— raw material for the manufacture of animal feedingstuffs as referred to by Directive 92/118/EEC,
— bovine intestines as referred to in Article 2(b)(v) of Directive 77/99/EEC.

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

“The product of animal origin does not contain, and is not derived from specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals, produced after 31 March 2001. After 31 March 2001 the animals have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

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

(b) Any reference to “products of animal origin” designates products of animal origin listed in this point and does not concern other products of animal origin containing or derived from those products of animal origin.

6. Point 5 shall not apply to imports from:
   Australia
   Argentina
   Botswana
   Brazil
   Chile
   Costa Rica
   Namibia
   New Zealand
   Nicaragua
   Paraguay
   Uruguay
   Singapore
   Swaziland.

7. Member States shall carry out frequent official inspections to verify the correct application of this Section and shall ensure that measures are taken to avoid any contamination, particularly in slaughterhouses, cutting plants, animal waste processing plants, high-risk processing plants or premises approved by the Member States in accordance with Article 7 of Directive 90/667/EEC, points of sale to the consumer, landfill sites and other facilities for storage or incineration. Member States shall in particular set up a system to ensure and check that:
   (a) specified risk material used in the production of products referred to in Article 1(2) are used solely for authorised purposes;
   (b) specified risk material, especially where the removal takes place at establishments or premises other than slaughterhouses, is completely separated from other waste not intended for incineration, is collected separately and is disposed of in accordance with point 1 and points 8 to 11. Member States may decide to allow dispatch of heads or carcasses containing specified risk material to another Member State after that other Member State has agreed to receive the material and has approved the specific conditions applicable to such transport.

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

8. Member States shall ensure that specified risk material is removed at:
   (a) slaughterhouses;
   (b) cutting plants, high-risk processing plants or premises referred to in Articles 3 and 7 of Directive 90/667/EEC, under the supervision of a designated agent appointed by the competent authority. Those establishments shall be approved for that purpose by the competent authority.

However, Member States may provide for the vertebral column to be removed at points of sale to the consumer.

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

9. Member States shall ensure that all specified risk material is stained with a dye and, as appropriate, marked immediately on removal, and completely destroyed:
   (a) by incineration without pre-processing; or,
provided that the dye or marking remains detectable, after pre-processing:

(i) in accordance with the systems described in Chapters I to IV, VI and VII of the Annex to Decision 92/562/EEC:
   — by incineration,
   — by co-incineration;

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

10. Member States may derogate from the provisions of points 8 and 9 to allow the incineration or burial of specified risk material or entire bodies, without prior staining, or, as appropriate, without removal of the specified risk material, in the circumstances set out in Article 3(2) of Directive 90/667/EEC and by a method which precludes all risk of transmission of a TSE and is approved and verified by the competent authority, in particular where animals have died or have been killed in the context of disease control measures.

11. Member States may despatch specified risk material or the material processed therefrom to other Member States for incineration under the conditions laid down in Article 4(2) of Decision 97/735/EC, where applicable.

This point may be amended at the request of a Member State to allow the despatch of specified risk material or the material processed therefrom to third countries for incineration, conditions governing such export having been adopted.

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

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

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

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

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

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

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

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

Experts from the Commission may carry out on-the-spot checks to further verify the submitted evidence in accordance with Article 21:
**ANNEX IV**

**C. Concerning prohibitions on animal feeding**


A decision may be taken in accordance with the procedure referred to in Article 24(2) to adapt Decision 2000/766/EC to the situation of each Member State in the light of the results of Commission inspections and the incidence of BSE, based on the results of BSE monitoring, with particular reference to testing of bovine animals, as established by Annex III.

**D. Concerning placing on the market and export**

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

   - Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC.
   - Commission Decision 98/351/EC of 29 May 1998 setting the date on which dispatch from Northern Ireland of bovine products under the Export Certified Herds Scheme may commence by virtue of Article 6(5) of Council Decision 98/256/EC.
   - Commission Decision 1999/514/EC of 23 July 1999 setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence by virtue of Article 6(5) of Council Decision 98/256/EC.
   - Commission Decision 2000/345/EC of 22 May 2000 setting the date on which dispatch from Portugal to Germany of certain products for the purpose of incineration may commence by virtue of Article 3(6) of Decision 98/653/EC.
   - Commission Decision 2000/371/EC of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to France may commence by virtue of Article 3(7) of Decision 98/653/EC.
   - Commission Decision 2000/372/EC of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to Spain may commence by virtue of Article 3(7) of Decision 98/653/EC.

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

   - (a) the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced;
   - (b) the bovine animals intended for export to the Community are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspected females.

3. Imports of bovine embryos and ova are to be subject to the presentation of an international animal health certificate attesting that the feeding of ruminants with proteins derived from mammals has been banned and the ban has been effectively enforced.

4. Points 2 and 3 shall not apply to imports from:

   - Australia
   - Argentina
   - Botswana
   - Brazil
   - Chile
   - Costa Rica
   - Namibia
   - New Zealand
   - Nicaragua
   - Paraguay
   - Uruguay
   - Singapore
   - Swaziland.'