[F1ANNEX XI

TRANSITIONAL MEASURES REFERRED TO IN ARTICLES 22 AND 23

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1139/2003 of 27 June 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring programmes and specified risk material.

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

[F2 1.

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

(i) [F3the skull excluding the mandible and including the brain and eyes, and the spinal cord of bovine animals aged over 12 months, the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia of bovine animals aged over 24 months, and the tonsils, the intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages;]

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

The age specified in (i) for the removal of the bovine vertebral column may be adjusted by amending this Regulation 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 as established by Chapter A.I of 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: the entire head excluding the tongue, including the brain, eyes and trigeminal ganglia; the thymus, the spleen and the spinal cord of bovine animals aged over six months.

Textual Amendments

F3 Substituted by Commission Regulation (EC) No 1974/2005 of 2 December 2005 amending Annexes X and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards national reference laboratories and specified risk material (Text with EEA relevance).

Textual Amendments

F2 Substituted by Commission Regulation (EC) No 1993/2004 of 19 November 2004 amending Regulation (EC) 999/2001 of the European Parliament and of the Council as regards Portugal (Text with EEA relevance).

2. 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 the 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 and Sweden may benefit from this derogation on the basis of previously submitted and evaluated evidence. Other Member States may apply for this derogation by submitting conclusive supporting evidence to the 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:

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

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

This derogation shall not be granted to allow the use of vertebral column and dorsal root ganglia from bovine animals aged over 30 months from the United Kingdom.

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

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

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

5. Specified risk material shall be removed at:

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

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

(c) where appropriate, in intermediate plants referred to in Regulation (EC) No 1774/2002 of the European Parliament and of the Council[(1)], Article 10 or users and collection centres authorised and registered pursuant to Regulation (EC) No 1774/2002, Article 23(2)(c)(iv), (vi) and (vii).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) specified risk material used for purposes authorised pursuant to Article 1(2) and to Regulation (EC) No 1774/2002 are used solely for authorised purposes;

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

[[F3]13. Member States may decide to allow dispatch of heads or of un-split carcases containing specified risk material to another Member State, only after that other Member State has agreed to receive the material and has approved the specific dispatching conditions applicable to such transport.

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

Exports outside the Community of heads and of fresh meat of bovine, ovine or caprine animals containing specified risk materials shall be prohibited.**]**

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

(a) when removal of the vertebral column is not required, carcases or wholesale cuts of carcases of bovine animals containing vertebral column, shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000;

(b) a specific indication of the number of bovine carcases or wholesale cuts of carcases, from which removal of the vertebral column is required and from which removal of the vertebral column is not required, shall be added to the commercial document referred to in Article 3(1)(A)(f)(ii) of Directive 64/433/EEC or to the document referred to in Article 1(2) of Commission Decision 93/13/EEC[(2)], as applicable;

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

15.

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

— the specified risk material referred to in point 1(a),
— 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[(3)],
— meat products: the meat products defined by Directive 77/99/EEC[(4)],
— other products of animal origin: other products of animal origin as defined by Directive 77/99/EEC,
— rendered fats as referred to in Regulation (EC) No 1774/2002,
— gelatine as referred to by Directive 92/118/EEC and Regulation (EC) No 1774/2002,
— pet food as referred to in Regulation (EC) No 1774/2002,
— blood products as referred to in Regulation (EC) No 1774/2002
— the processed animal protein referred to in Regulation (EC) No 1774/2002,
— bones and bone products as referred to in Regulation (EC) No 774/2002,
— category 3 material as referred to in Regulation (EC) No 1774/2002.

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

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

This product does not contain and is not derived from:

either[5]

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

Carcases, half carcases and quarter carcases may contain vertebral column on import;

or ([1])

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

[[F4]Argentina
Australia
Iceland
Nouvelle Calédonie
New-Zealand
Panama
Paraguay
Singapore
Uruguay
Vanuatu.**]]**

Textual Amendments

F4 Substituted by Commission Regulation (EC) No 339/2006 of 24 February 2006 amending Annex XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the rules for importation of live bovine animals and products of bovine, ovine and caprine origin (Text with EEA relevance).

[F5]B. Concerning statistical surveys

1. . . . . .

2. . . . . .

Textual Amendments

F5 Deleted by Commission Regulation (EC) No 1494/2002 of 21 August 2002 amending Annexes III, VII and XI to Regulation (EC) No 999/2001 of the European Parliament and the Council as regards monitoring of bovine spongiform encephalopathy, eradication of transmissible spongiform encephalopathy, removal of specified risk materials and rules for importation of live animals and products of animal origin (Text with EEA relevance).

F6C. Concerning prohibitions on animal feeding

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Textual Amendments

F6 Deleted by Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding (Text with EEA relevance).

[F7D. 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.]

Textual Amendments

F8 Deleted by Commission Regulation (EC) No 260/2003 of 12 February 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos (Text with EEA relevance).

F9 Deleted by Commission Regulation (EC) No 1993/2004 of 19 November 2004 amending Regulation (EC) 999/2001 of the European Parliament and of the Council as regards Portugal (Text with EEA relevance).

[F72. 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.

[F4 3. Point 2 shall not apply to imports of bovine animals born and continuously reared in the following countries:

— Argentina
— Australia
— Iceland
— Nouvelle Calédonie
— New-Zealand
— Panama
— Paraguay
— Singapore
— Uruguay
— Vanuatu.]]

F5 4. . . . . .

[F10 4.

(a) When the farmed game meat defined by Council Directive 91/495/EEC(6), meat preparations defined by Council Directive 94/65/EC(7), and meat products defined by Council Directive 77/99/EEC(8), derived from farmed cervid animals, are imported into the Community from Canada or the United States of America, the health certificates shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

> This product contains or is derived exclusively from meat, excluding offal and spinal cord, of cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognised by the competent authority with negative results and is not derived from animals coming from a herd where chronic wasting disease has been confirmed or is officially suspected.

(b) When game meat as defined by Council Directive 92/45/EEC(9), meat preparations defined by Council Directive 94/65/EC, and meat products defined by Council Directive 77/99/EEC, derived from wild cervid animals, is imported into the Community from Canada or the United States of America, the health certificate shall be accompanied by a declaration signed by the competent authority of the country of production, worded as follows:

> This product contains or is derived exclusively from meat, excluding offal and spinal cord, of cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognised by the competent authority with negative results and is not derived from animals coming from a region where chronic wasting disease has been confirmed in the last three years or is officially suspected.]

Textual Amendments

F10 Inserted by Commission Regulation (EC) No 1471/2004 of 18 August 2004 amending Annex XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the import of cervid products from Canada and the United States (Text with EEA relevance).

Textual Amendments

F7 Inserted by 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.

(1) **[**[F1]OJ L 273, 10.10.2002, p. 1.**]**

(2) **[**[F1]OJ L 9, 15.1.1993, p. 3.**]**

(3) **[**[F1]Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations (OJ L 368, 31.12.1994, p. 10).**]**

(4) **[**[F1]Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products (OJ L 26, 31.1.1977, p. 85). Directive as last amended by Council Directive 97/76/EC (OJ L 10, 16.1.1998, p. 25).**]**

(5) **[**[F1]Delete one of these as appropriate.'**]**

(6) **[**[F10]OJ L 268 24.9.1991, p. 41.**]**

(7) **[**[F10]OJ L 368, 31.12.1994, p. 10.**]**

(8) **[**[F10]OJ L 26, 31.1.1977, p. 85.**]**

(9) **[**[F10]OJ L 268, 14.9.1992, p. 35.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1139/2003 of 27 June 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring programmes and specified risk material.

F10 Inserted by Commission Regulation (EC) No 1471/2004 of 18 August 2004 amending Annex XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the import of cervid products from Canada and the United States (Text with EEA relevance).

Status:
Point in time view as at 17/03/2006.

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, ANNEX XI.