

**COMMISSION REGULATION (EC) No 722/2007****of 25 June 2007****amending Annexes II, V, VI, VIII, IX and XI to 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****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

procedure for the classification of countries according to their BSE risk based on three categories was adopted.

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 <sup>(1)</sup>, and in particular Article 23 thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible encephalopathies (TSEs) in animals. It applies 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) Article 5 of Regulation (EC) No 999/2001 provides that the bovine spongiform encephalopathy (BSE) status of Member States or third countries or regions thereof (countries or regions) is to be determined by classification into one of three categories. Annex II to that Regulation lays down rules for the determination of the BSE status of countries or regions. Article 5 of that Regulation also provides for a reassessment of the Community categorisation of countries following the establishment by the World Organisation for Animal Health (OIE) of a procedure for the classification of countries by category.
- (3) Annex V to Regulation (EC) No 999/2001 lays down the rules for the collection and disposal of specified risk materials and Annex IX to that Regulation lays down the rules for the importation into the Community of live animals, embryos, ova and products of animal origin.
- (4) During the General Session of the World Organisation for Animal Health (OIE) in May 2005, a new simplified

- (5) Regulation (EC) No 999/2001 was amended by Regulation (EC) No 1923/2006 in order to transpose that new simplified categorisation system into Community legislation. Following that amendment, Annexes II, V and IX to Regulation (EC) No 999/2001 should be amended to take account of the new categorisation system.

- (6) In the absence of a decision on the classification of countries in accordance with Article 5(2) or (4) of Regulation (EC) No 999/2001, the provisions in Article 9 and Annex VI did not apply. In view of the fact that the new categorisation system is to apply from 1 July 2007 and in order to align this Annex with the rules applicable under the transitional measures based on scientific evidence and with the amendments made to the Articles, Annex VI should be amended.

- (7) Annex VIII to Regulation (EC) No 999/2001 lays down the conditions for the placing on the market and export of live animals, their semen, embryos, ova and products of animal origin. Chapter C of that Annex lays down the conditions for intra-Community trade in certain products of animal origin. Those conditions should be amended to take into account of the new categorisation system.

- (8) Point 5 of Part D of Annex XI to Regulation (EC) No 999/2001 lays down measures concerning intra-Community trade of bovine animals born or reared on the United Kingdom before 1 August 1996 and importation into the Community of meat products derived from cervid animals. For human and animal health protection reasons, these measures should continue to apply after 1 July 2007.

- (9) For clarity and consistency reasons the provisions for intra-Community trade and export to third countries of bovine animals born or reared on the United Kingdom before 1 August 1996 should be laid down in Annex VIII and the provisions for importation of meat products derived from cervid animals should be laid down in Annex IX.

<sup>(1)</sup> OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Regulation (EC) No 1923/2006 (OJ L 404, 30.12.2006, p. 1).

- (10) The transitional measures concerning specified risk material contained in Annex XI to Regulation (EC) No 999/2001 should cease to apply with respect to each country or region immediately following the date of adoption of a decision on classification of that country or region. Annex XI should therefore be repealed.
- (11) Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 25 June 2007.

*For the Commission*  
Markos KYPRIANOU  
*Member of the Commission*

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## ANNEX

Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 are amended as follows:

(1) Annex II to Regulation (EC) No 999/2001 is replaced by the following:

## 'ANNEX II

**DETERMINATION OF BSE STATUS**

## CHAPTER A

**Criteria**

The BSE status of Member States or third countries or regions thereof (hereinafter referred to as countries or regions), shall be determined on the basis of the criteria set out in points (a) to (e).

In the country or region:

- (a) a risk analysis in accordance with the provisions of Chapter B, identifying all the potential factors for BSE occurrence and their historic perspective in the country or region, is carried out;
- (b) a system of continuous surveillance and monitoring of BSE relating in particular to the risks described in Chapter B and complying with the minimal surveillance requirements laid down in Chapter D is in place;
- (c) an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of bovine animals, to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Chapter D of this Annex is in place;
- (d) an obligation to notify and investigate all bovine animals showing clinical signs consistent with BSE is in force;
- (e) the examination of brain or other tissues collected within the framework of the surveillance and monitoring system referred to in point (b) is carried out in an approved laboratory.

## CHAPTER B

**Risk analysis****1. Structure of the risk analysis**

The risk analyses shall comprise a release assessment and an exposure assessment.

**2. Release assessment (external challenge)**

- 2.1. The release assessment shall consist of assessing the likelihood that the BSE agent has either been introduced into the country or region via commodities potentially contaminated with a BSE agent, or is already present in the country or region.

The following risk factors shall be taken into account:

- (a) the presence or absence of the BSE agent in the country or region and, if the agent is present, its prevalence based on the outcome of surveillance activities;
- (b) the production of meat-and-bone meal or greaves from the BSE indigenous ruminant population;
- (c) imported meat-and-bone meal or greaves;
- (d) imported bovine and ovine and caprine animals;
- (e) imported animal feed and feed ingredients;

- (f) imported products of ruminant origin for human consumption, which may have contained tissues listed in point 1 of Annex V and may have been fed to bovine animals;
  - (g) imported products of ruminant origin for *in vivo* use in bovine animals.
- 2.2. Special eradication schemes, surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the bovine animals population) relevant to the risk factors listed in point 2.1 should be taken into account in carrying out the release assessment.

### 3. **Exposure assessment**

The exposure assessment shall consist of assessing the likelihood of exposure of bovine animals to the BSE agent, through a consideration of the following:

- (a) recycling and amplification of the BSE agent through consumption by bovine animals of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;
- (b) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- (c) the feeding or not of ruminants with meat-and-bone meal and greaves derived from ruminants, including measures to prevent cross-contamination of animal feed;
- (d) the level of surveillance for BSE conducted on the bovine animals population to that time and the results of that surveillance.

## CHAPTER C

### **Definition of categories**

#### I. COUNTRY OR REGION WITH A NEGLIGIBLE BSE RISK

A country or region:

- (1) where a risk analysis in accordance with Chapter B has been conducted in order to identify the historical and existing risk factors;
- (2) which has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
- (3) which has demonstrated that Type B surveillance, in accordance with Chapter D, is in place, and the relevant points target, in accordance with Table 2 thereof, has been met; and
- (4) which is:
  - (a) either in the following situation:
    - (i) in the country or region there has been no case of BSE, or, any case of BSE has been demonstrated to have been imported and has been completely destroyed;
    - (ii) the criteria in points (c), (d) and (e) of Chapter A of this Annex have been complied with for at least seven years; and
    - (iii) it has been demonstrated through an appropriate level of control and audit that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

(b) or in the following situation:

- (i) there has been one or more BSE indigenous cases in the country or region but every BSE indigenous case was born more than 11 years ago;
- (ii) the criteria in points (c), (d) and (e) of Chapter A have been complied with for at least seven years;
- (iii) it has been demonstrated through an appropriate level of control and audit that for at least eight years neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;
- (iv) the following animals, if alive in the country or region, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed:
  - all BSE cases,
  - all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
  - if the results of the investigation referred to in the second indent are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases.

## II. COUNTRY OR REGION WITH A CONTROLLED BSE RISK

A country or region

- (1) where a risk analysis based on the information laid down in Chapter B has been conducted in order to identify the historical and existing risk factors;
- (2) which has demonstrated that appropriate measures are been taken to manage all identified risks, but those measures have not been taken for the relevant period of time;
- (3) which has demonstrated that Type A surveillance, in accordance with Chapter D, is in place and the relevant points target, in accordance with Table 2, has been met. Type B surveillance may replace Type A surveillance once the relevant points target is met; and
- (4) which is:
  - (a) either in the following situation:
    - (i) in the country or region there has been no case of BSE, or, any case of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points (c), (d) and (e) of Chapter A are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;
    - (ii) the criteria in points (c), (d) and (e) of Chapter A have been complied with for a period shorter than seven years; and/or
    - (iii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for eight years;
  - (b) or in the following situation:
    - (i) in the country or region there has been a BSE indigenous case, the criteria in points (c), (d) and (e) of Chapter A are complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from ruminants has been fed to ruminants;

- (ii) the criteria in points (c) to (e) of Chapter A of this Annex have been complied with for a period shorter than seven years; and/or
- (iii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal or greaves derived from ruminants to ruminants have been in place for at least eight years;
- (iv) the following animals, if alive in the country or region, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed: and
  - all BSE cases, and
  - all bovine animals which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
  - if the results of the investigation referred to in the second indent are inconclusive, all bovine animals born in the same herd as, and within 12 months of the birth of, the BSE cases.

### III. COUNTRY OR REGION WITH UNDETERMINED BSE RISK

A country or region for which the determination of BSE status has not been concluded, or which does not meet the conditions to be fulfilled by the country or region to be classified in one of the other categories.

## CHAPTER D

### Minimal surveillance requirements

#### 1. Surveillance types

For the purpose of this Annex, the following definitions shall apply:

##### (a) Type A surveillance

The application of Type A surveillance will allow the detection of BSE at a design prevalence <sup>(1)</sup> of at least one case per 100 000 in the adult bovine animals population in the country or region of concern, at a confidence level of 95 %;

##### (b) Type B surveillance

The application of Type B surveillance will allow the detection of BSE at a design prevalence of at least one case per 50 000 in the adult bovine animals population in the country or region of concern, at a confidence level of 95 %.

Type B surveillance may be carried out by countries or region of negligible BSE risk status to confirm the conclusions of the risk analysis, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by countries or regions of controlled BSE risk status, following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

For the purpose of this Annex, the following four sub-populations of bovine animals have been identified for surveillance purposes:

- (a) bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

<sup>(1)</sup> Design prevalence is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

- (b) bovine animals over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; bovine animals over 30 months of age sent for emergency slaughter or with abnormal observations at ante-mortem inspection (casualty or emergency slaughter);
- (c) bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock);
- (d) bovine animals over 36 months of age at routine slaughter.

## 2. Surveillance strategy

- 2.1. The surveillance strategy shall be designed to ensure that samples are representative of the herd of the country or region, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made shall be fully documented, and the documentation retained for seven years.
- 2.2. In order to implement the surveillance strategy for BSE, a country shall use documented records or reliable estimates of the age distribution of the adult bovine animals population and the number of bovine animals tested for BSE stratified by age and by sub-population within the country or region.

## 3. Points values and point targets

Surveillance samples must meet the point targets set out in Table 2, on the basis of "point values" fixed in Table 1. All clinical suspects shall be investigated, regardless of the number of points accumulated. A country shall sample at least three out of the four sub-populations. The total points for samples collected shall be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points. The total points accumulation shall be periodically compared to the target number of points for a country or region.

Table 1

### Surveillance point values for samples collected from animals in the given sub-population and age category

Surveillance sub-population			
Routine slaughter <sup>(1)</sup>	Fallen stock <sup>(2)</sup>	Casualty slaughter <sup>(3)</sup>	Clinical suspect <sup>(4)</sup>
Age ≥ 1 year and < 2 years			
0,01	0,2	0,4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0,1	0,2	0,4	260
Age ≥ 4 years and < 7 years (middle adult)			
0,2	0,9	1,6	750
Age ≥ 7 years and < 9 years (older adult)			
0,1	0,4	0,7	220
Age ≥ 9 years (aged)			
0,0	0,1	0,2	45

<sup>(1)</sup> Bovine animals over 36 months of age at routine slaughter.

<sup>(2)</sup> Bovine animals over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock).

<sup>(3)</sup> Bovine animals over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; bovine animals over 30 months of age sent for emergency slaughter or with abnormal observations at ante-mortem inspection (casualty or emergency slaughter).

<sup>(4)</sup> Bovine animals over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects).

Table 2

**Points targets for different adult bovine animals population sizes in a country or region**

Points targets for countries or regions		
Adult bovine animals population size (24 months and older)	Type A surveillance	Type B surveillance
≥ 1 000 000	300 000	150 000
800 000-1 000 000	240 000	120 000
600 000-800 000	180 000	90 000
400 000-600 000	120 000	60 000
200 000-400 000	60 000	30 000
100 000-200 000	30 000	15 000
50 000-100 000	15 000	7 500
25 000-50 000	7 500	3 750

**4. Specific targeting**

Within each of the sub-populations above in a country or region, a country may target bovine animals identifiable as imported from countries or regions where BSE has been detected and bovine animals which have consumed potentially contaminated feedstuffs from countries or regions where BSE has been detected.

**5. BSE surveillance model**

A country may choose to use the full BSurvE model or an alternative method based on the BSurvE model to estimate its BSE presence/prevalence.

**6. Maintenance surveillance**

Once the points target has been achieved, and in order to continue to designate the status of a country or region as controlled BSE risk or negligible risk, surveillance can be reduced to Type B surveillance (provided all other indicators remain positive). However, to continue to comply with the requirements laid down in this Chapter, ongoing annual surveillance must continue to include at least three of the four prescribed sub-populations. In addition all bovine animals clinically suspected of being infected with BSE shall be investigated regardless of the number of points accumulated. The annual surveillance in a country or region following the achievement of the required points target, shall be no less than the amount required for one-seventh of its total Type B surveillance target.'

(2) Annex V is replaced by the following:

## ‘ANNEX V

**SPECIFIED RISK MATERIAL****1. Definition of specified risk material**

The following tissues shall be designated as specified risk material if they come from animals whose origin is in a Member State or third country or of one of their region with a controlled or undetermined BSE risk:

(a) as regards bovine animals:

- (i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months;
- (ii) 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 animals aged over 24 months; and



(iii) the tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages.

(b) as regards ovine and caprine animals

(i) the skull including the brain and eyes, the tonsils and the spinal cord of animals aged over 12 months or which have a permanent incisor erupted through the gum, and

(ii) the spleen and ileum of animals of all ages.

## 2. Derogation for Member States

By way of derogation from point 1, tissues listed in that point whose origin is in Member States with a negligible BSE risk shall continue to be considered as specified risk material.

## 3. Marking and disposal

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

## 4. Removal of specified risk material

4.1. 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 Article 10 of Regulation (EC) No 1774/2002 or users and collection centres authorised and registered pursuant to Article 23(2)(c)(iv), (vi) and (vii) of Regulation (EC) No 1774/2002.

4.2. By way of derogation from point 4.1, the use of an alternative test to the removal of specified risk material may be authorised under the following conditions:

(a) tests must be carried out in slaughterhouses on all animals eligible for the removal of specified risk material;

(b) no bovine, ovine or caprine product intended for human food or animal feed may leave the slaughterhouse before the competent authority has received and accepted the results of the tests on all slaughtered animals potentially contaminated if BSE has been confirmed in one of them;

(c) when an alternative test gives a positive result, all bovine, ovine and caprine material which has been potentially contaminated in the slaughterhouse is destroyed in accordance with point 3, unless all parts of the body including the hide of the affected animal can be identified and kept separate.

4.3. By way of derogation from point 4.1, Member States may decide to allow:

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

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

(c) the harvesting of head meat from bovine animals in cutting plants specifically authorised for this purpose in accordance with the provisions laid down in point 9.

4.4. The rules on removal of specified risk material laid down in this Chapter shall not apply to Category 1 material as defined in Regulation (EC) No 1774/2002 used under the supervision of competent authorities for feeding of endangered and protected species of necrophagous birds.

**5. Measures concerning mechanically separated meat**

Notwithstanding the individual decisions referred to in Article 5(2), and by way of derogation from Article 9(3), it shall be prohibited in all Member States to use bones or bone-in cuts of bovine, ovine and caprine animals for the production of mechanically separated meat.

**6. Measures concerning laceration of tissues**

Notwithstanding the individual decisions referred to in Article 5(2), and by way of derogation from Article 8(3), in all Member States, until all Member States are classified as countries with negligible BSE risk, laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity after stunning shall be prohibited in bovine, ovine or caprine animals whose meat is intended for human or animal consumption.

**7. Harvesting of tongues from bovine animals**

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.

**8. Harvesting of bovine head meat**

8.1. 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:

- (a) harvesting shall take place in a dedicated area, physically separated from the other parts of the slaughterline;
- (b) 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;
- (c) 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;
- (d) head meat shall not be harvested from heads which have not been properly sealed in accordance with the second indent;
- (e) 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;
- (f) 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.

8.2. By way of derogation from the requirements of point 8.1, 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.

8.3. If the harvesting is performed without removing the bovine head from the conveyor or hooks, points 8.1 and 8.2 shall not apply.

**9. Harvesting of bovine head meat in authorised cutting plants**

By way of derogation from point 8, Member States may decide to allow the harvesting of head meat from bovine in cutting plants specifically authorised for this purpose and provided that the following conditions are complied with:

- (a) the heads intended for transport to the cutting plant shall be suspended on a rack during the storing period and the transport from the slaughterhouse to the cutting plant;

- (b) 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;
- (c) the heads which have not been properly sealed in accordance with point (b), 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;
- (d) a sampling plan for the slaughterhouse 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;
- (e) the harvesting of head meat shall be carried out in accordance with a control system, recognized by the competent authority, to ensure the prevention of possible contamination of head meat. The system shall include at least:
  - (i) all heads shall be visually checked for signs of contamination or damage and proper sealing before the harvesting of the head meat begins;
  - (ii) 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;
  - (iii) 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;
- (f) a sampling plan for the cutting plant 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.

## 10. Rules on trade and export

- 10.1. Member States may allow dispatch of heads or of un-split carcasses containing specified risk material to another Member State only after that Member State has agreed to receive the material and has approved the conditions of dispatch and transport.
- 10.2. By way of derogation from point 10.1, carcasses, half carcasses or half carcasses 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 dispatched from one Member State to another without the latter's prior agreement.
- 10.3. Exports outside the Community of heads and of fresh meat of bovine, ovine or caprine animals containing specified risk materials shall be prohibited.

## 11. Controls

- 11.1. Member States shall carry out frequent official controls to verify the correct application of this Annex 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 4.1 (c).
- 11.2. Member States shall in particular set up a system to ensure and check that specified risk material is handled and disposed of in accordance with Regulation (EC) No 999/2001 and Regulation (EC) No 1774/2002.
- 11.3. A control system shall be put in place for the removal of the vertebral column as specified in point 1(a). The system shall include at least the following measures:
  - (a) when removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000;

(b) specific information on the number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as the number where removal of the vertebral column is not required, shall be added on the commercial document relating to consignments of meat. When applicable, the specific information shall be added to the document referred to in Article 2(1) of Commission Regulation (EC) No 136/2004 (\*) in the case of imports;

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

(\*) OJ L 21, 28.1.2004, p. 11.'

(3) Annex VI is replaced by the following:

‘ANNEX VI

**PRODUCTS OF ANIMAL ORIGIN DERIVED FROM OR CONTAINING RUMINANT MATERIAL, AS REFERRED TO IN ARTICLE 9(1)**

(4) Annex VIII is amended as follows:

(a) Chapter A is amended as follows:

(i) The title of Part I is replaced by the following:

I. Conditions which apply to ovine and caprine animals and semen and embryos thereof.

(ii) Part II is replaced by the following:

II. Conditions which apply to bovine animals

The United Kingdom shall ensure that bovine animals born or reared on its territory before 1 August 1996 are not dispatched from its territory to other Member States or third countries.’

(b) Chapter C is replaced by the following:

‘CHAPTER C

**Conditions for intra-Community trade in certain products of animal origin**

SECTION A

**Products**

The following products of animal origin are exempt from the prohibition referred to in Article 16(3), provided that they are derived from bovine, ovine and caprine animals that satisfy the requirements of Section B:

- fresh meat,
- minced meat,
- meat preparations,
- meat products.

SECTION B

**Requirements**

The products referred to in Section A must satisfy the following requirements:

(a) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;

- (b) the animals from which the products of bovine, ovine and caprine animal origin were 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;
  - (c) the products of bovine, ovine and caprine animal origin are not derived from:
    - (i) specified risk material as defined in Annex V;
    - (ii) nervous and lymphatic tissues exposed during the deboning process; and
    - (iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.
- (5) Annex IX is amended as follows:
- (a) Chapter A is deleted;
  - (b) Chapters B, C and D are replaced by the following:

‘CHAPTER B

**Imports of bovine animals**

SECTION A

***Imports from a country or a region with a negligible BSE risk***

Imports of bovine animals from a country or a region with a negligible BSE risk shall be subject to the presentation of an animal health certificate attesting that:

- (a) the animals were born and continuously reared in a country or region classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk;
- (b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, part I, point (4) (b) (iv) of Annex II; and
- (c) if there have been BSE indigenous cases in the country concerned, the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

SECTION B

***Imports from a country or a region with a controlled BSE risk***

Imports of bovine animals from a country or a region with a controlled BSE risk shall be subject to the presentation of an animal health certificate attesting that:

- (a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;
- (b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, Part II, point (4)(b)(iv) of Annex II;
- (c) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

## SECTION C

**Imports from a country or a region with undetermined BSE risk**

Imports of bovine animals from a country or a region with an undetermined BSE risk shall be subject to the presentation of an animal health certificate attesting that:

- (a) the country or region has not been categorized in accordance with Article 5(2) of Regulation (EC) No 999/2001 or has been categorized as a country or region with undetermined BSE risk;
- (b) the animals are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed bovine animals as described in Chapter C, Part II, point (4)(b)(iv) of Annex II;
- (c) the animals were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced or after the date of birth of the last BSE indigenous case if born after the date of the feed ban.

## CHAPTER C

**Imports of products of animal origin from bovine, ovine or caprine animals**

## SECTION A

**Products**

The following products of bovine, ovine and caprine animal origin, as defined by Regulation (EC) No 853/2004 of the European Parliament and of the Council (\*) listed below shall be subject to the conditions laid down in Sections B, C and D depending on the BSE risk category of the country of origin:

- fresh meat,
- minced meat and meat preparations,
- meat products,
- rendered animal fats,
- greaves, and
- gelatine.

## SECTION B

**Imports from a country or a region with a negligible BSE risk**

Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with a negligible BSE risk shall be subject to the presentation of an animal health certificate attesting that:

- (a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk;
- (b) the animals from which the products of bovine, ovine and caprine animal origin were derived were born, continuously reared and slaughtered in the country with negligible BSE risk and passed ante-mortem and post-mortem inspections;
- (c) if in the country or region there have been BSE indigenous cases:
  - (i) the animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced; or

- (ii) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

#### SECTION C

##### **Imports from a country or a region with a controlled BSE risk**

1. Imports of products of bovine, ovine and caprine animal origin referred to in section A from a country or a region with a controlled BSE risk shall be subject to the presentation of an animal health certificate attesting that:
  - (a) the country or region is classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a controlled BSE risk;
  - (b) the animals from which the products of bovine, ovine and caprine animal origin were derived passed ante-mortem and post-mortem inspections;
  - (c) animals from which the products of bovine, ovine and caprine animal origin destined for export were 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;
  - (d) the products of bovine, ovine and caprine animal origin do not contain and are not derived from specified risk material as defined in Annex V to Regulation (EC) No 999/2001, or mechanically separated meat obtained from bones of bovine, ovine or caprine animals.
2. By way of derogation from point 1(d) carcasses, half carcasses or half carcasses 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.
3. When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column, shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000.
4. The number of bovine carcasses or wholesale cuts of carcasses, from which removal of the vertebral column is required as well as the number where removal of the vertebral column is not required shall be added to the document referred to in Article 2(1) of Regulation (EC) No 136/2004 in case of imports.

#### SECTION D

##### **Imports from a country or a region with an undetermined BSE risk**

1. Imports of products of bovine, ovine and caprine animal origin referred to in Section A from a country or a region with an undetermined BSE risk, shall be subject to the presentation of an animal health certificate attesting that:
  - (a) the animals from which the products of bovine, ovine and caprine animal origin were derived have not been fed meat-and-bone meal or greaves derived from ruminants and passed ante-mortem and post-mortem inspections;
  - (b) the animals from which the products of bovine, ovine and caprine animal origin were 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;
  - (c) the products of bovine, ovine and caprine animal origin are not derived from:
    - (i) specified risk material as defined in Annex V;
    - (ii) nervous and lymphatic tissues exposed during the deboning process;
    - (iii) mechanically separated meat obtained from bones of bovine, ovine or caprine animals.

2. By way of derogation from point 1(c), carcasses, half carcasses or half carcasses 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.
3. When removal of the vertebral column is not required, carcasses or wholesale cuts of carcasses of bovine animals containing vertebral column, shall be identified by a clearly visible blue stripe on the label referred to in Regulation (EC) No 1760/2000.
4. Specific information on the number of bovine carcasses or wholesale cuts of carcasses, 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 document referred to in Article 2(1) of Regulation (EC) No 136/2004 in case of imports.

#### CHAPTER D

### **Imports of animal by-products and processed products derived therefrom from bovine, ovine and caprine animal origin**

#### SECTION A

##### ***Animal by-products***

This Chapter shall apply to the following animal by-products and processed products derived therefrom from bovine, ovine and caprine animal origin as referred to in Regulation (EC) No 1774/2002:

- rendered fats,
- pet food,
- blood products,
- the processed animal protein,
- bones and bone products,
- category 3 material, and
- gelatine.

#### SECTION B

Imports of the animal by-products processed products derived therefrom from bovine, ovine and caprine animal origin referred to in Section A. shall be subject to the presentation of an animal health certificate attesting that:

- (a) the animal by-product does not contain and is not derived from specified risk material as defined in Annex V or mechanically separated meat obtained from bones of bovine, ovine or caprine animals;
  - (b) the animals from which this animal by-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 of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity,
- or
- (c) the animal by-product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified in accordance with Article 5(2) of Regulation (EC) No 999/2001 as a country or region posing a negligible BSE risk.

(\*) OJ L 139, 30.4.2004, p. 55, as corrected by OJ L 226, 25.6.2004, p. 22.'



(c) Chapter F is replaced by the following:

‘CHAPTER F

**Imports of products of animal origin from farmed and wild cervid animals**

1. When fresh meat, minced meat, meat preparations and meat products as defined by Regulation (EC) No 853/2004, 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 farmed cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognized 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.”

2. When fresh meat, minced meat, meat preparations and meat products as defined by Regulation (EC) No 853/2004, derived from wild 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 wild cervid animals which have been examined for chronic wasting disease by histopathology, immunohistochemistry or other diagnostic method recognized 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.”’

(d) Chapter G is deleted.

(6) Annex XI is deleted.

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