

## COMMISSION REGULATION (EC) No 270/2002

of 14 February 2002

**amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards specified risk material and epidemio-surveillance for transmissible spongiform encephalopathies and amending Regulation (EC) No 1326/2001 as regards animal feeding and the placing on the market of ovine and caprine animals and products thereof**

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 <sup>(1)</sup>, as last amended by Commission Regulation (EC) No 1326/2001 <sup>(2)</sup>, and in particular Article 23 thereof,

Whereas:

- (1) Detailed rules for monitoring of transmissible spongiform encephalopathies (TSEs) in ovine and caprine animals are laid down in Annex III to Regulation (EC) No 999/2001.
- (2) These rules should again be revised to take account of the opinion of 18-19 October 2001 of the Scientific Steering Committee, which recommended that a survey of the incidence of TSEs should urgently be carried out with the available rapid tests using a statistically sound sample design and size.
- (3) The Scientific Steering Committee has indicated in its opinion of 29-30 November 2001 on requirements for statistically authoritative BSE/TSE surveys that TSE prevalence in adult sheep could range from 20 to 500 TSE positives per 1 million sheep according to Member State. In Member States with a large sheep population a sample size sufficient to detect a prevalence of one positive in 20 000 healthy slaughter animals at a 95 % confidence level is the largest that can be realistically achieved at this time. The sample size for countries with a small sheep population should be adjusted to take account of the practicalities of numbers of eligible animals available for testing.
- (4) The age criteria for defining the populations for sampling should for practical reasons be broadened by making reference to dentition. Member States, which have other systems in place allowing the determination of the age of the animal, should be allowed to continue to use an age of 18 months.
- (5) The Scientific Steering Committee opinion of 29-30 November 2001 also recommends that the prion protein genotype of a randomly selected subsample of

monitored sheep should be determined. The sample size for countries with a small sheep population should be adjusted to take account of the practicalities of numbers of eligible animals available for sampling.

- (6) Finland and Austria confirmed their first cases of bovine spongiform encephalopathy (BSE) on 7 and 13 December 2001 respectively. Therefore it is no longer appropriate that these Member States should be afforded derogations in respect of the monitoring of healthy slaughter cattle, removal of vertebral column and conduct of the conclusive statistical survey.
- (7) During the transitional period, detailed rules for the removal and the destruction of specified risk materials are laid down in Annex XI, part A, to Regulation (EC) No 999/2001.
- (8) In order to avoid any unnecessary disruption of the internal market, and taking into account the opinions of the Scientific Steering Committee referred to under Commission Decision 2001/233/EC <sup>(3)</sup>, carcasses or parts of carcasses of bovine animals that still contain vertebral column should be accepted for trade between Member States and when imported from third countries. To ensure the control by Member states of its removal, specific control measures should be laid down.
- (9) Member States should also have the possibility to allow the removal of the vertebral column in butcher shops specifically authorised, monitored, and registered for this purpose.
- (10) In its opinion of 29 June 2001 on adipose tissue associated with the digestive tract of cattle, sheep and goats, the Scientific Steering Committee pointed out that potential infectivity could be found in the mesenteric nerves and the mesenteric lymph nodes situated near the arteria mesenterica in bovine animals. As control of the removal of this specific area alone is unlikely to be feasible, the whole mesentery from bovine animals should therefore be regarded as SRM.
- (11) It is necessary to clarify the rules following the removal of specified risk material and in particular those relating to the staining of such material.

<sup>(1)</sup> OJ L 147, 31.5.2001, p. 1.

<sup>(2)</sup> OJ L 177, 30.6.2001, p. 60.

<sup>(3)</sup> OJ L 84, 23.3.2001, p. 59.

- (12) The removal of specified risk material from products destined for food and feed is the single most important public health protection measure. Until classification decisions have been made for third countries, and as a precaution, it is appropriate to keep the minimal protection measures foreseen by Regulation (EC) No 999/2001 for imports from all third countries which are not considered BSE free. Some third countries for which it was demonstrated by the Scientific Steering Committee risk assessment that the risk of BSE being present in native cattle is highly unlikely, benefit from a derogation from the transitional measures. It is necessary to clarify the conditions under which imports from these derogating countries are allowed, and in particular those relating to the sourcing of the products for import.
- (13) In its opinion of 29 June 2001 on the geographic BSE risk of certain third countries, the Scientific Steering Committee concluded that, in addition to previously evaluated countries, the occurrence of BSE in native cattle is highly unlikely in Panama and El Salvador. Panama and El Salvador should therefore be added to the list of third countries benefiting from a derogation for all imports of products of animal origin, live bovine animals, embryos and ova.
- (14) Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (15) Experience has shown that it is necessary to clarify the measures applying to animal feeding laid down in Regulation (EC) No 1326/2001, while maintaining the prohibition established by Council Decision 2000/766/EC<sup>(1)</sup> during the transitional period. It should also be clarified that the rules in that Regulation concerning the placing on the market of live ovine and caprine animals, their semen, embryos and ova, apply during the transitional period.
- (16) Regulation (EC) No 1326/2001 should therefore be amended accordingly.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS REGULATION:

#### Article 1

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

1. Annex III is replaced by the text in Annex I to this Regulation.

<sup>(1)</sup> OJ L 306, 7.12.2000, p. 32.

2. Annex XI is amended as follows:

- (a) Part A is replaced by the text in Annex II to this Regulation.
- (b) In part B, point 2 is replaced by the following:
- ‘2. Sweden may decide to derogate from the provisions of point 1, second indent, in remote areas with low animal density.’
- (c) In part D, point 4 is replaced by the following:
- ‘4. Points 2 and 3 shall not apply to imports of bovine animals born and continuously reared in the following countries and to imports of embryos and ova derived from such animals:

Argentina

Australia

Botswana

Brazil

Chile

Costa Rica

El Salvador

Namibia

New Zealand

Nicaragua

Panama

Paraguay

Uruguay

Singapore

Swaziland.’

#### Article 2

Regulation (EC) No 1326/2001 is amended as follows:

1. In Article 1, point 2 is replaced by the following:
- ‘2. Article 7 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, part C, shall apply to that Member State until Article 7 becomes applicable there.’
2. In Annex I, the second indent is replaced by the following:
- ‘— Article 15(1) concerning the placing on the market of live bovine animals, their semen, embryos and ova.’

*Article 3*

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

It shall apply from 1 April 2002.

However, the provisions referred to in Article 1(2)(c) and Annex XI(A)(10) to Regulation (EC) No 999/2001, as amended by Annex II to this Regulation, shall apply from 1 March 2002.

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

Done at Brussels, 14 February 2002.

*For the Commission*  
David BYRNE  
*Member of the Commission*

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## ANNEX I

## 'ANNEX III

## MONITORING SYSTEM

## CHAPTER A

## I. Monitoring in bovine animals

## 1. General

Monitoring in bovine animals shall be carried out in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.1(b).

## 2. Monitoring in animals slaughtered for human consumption

## 2.1. All bovine animals over 24 months of age:

- subject to "special emergency slaughtering" as defined in Article 2(n) of Council Directive 64/433/EEC <sup>(1)</sup>, or
  - slaughtered in accordance with Annex I, Chapter VI, point 28(c), to Directive 64/433/EEC,
- shall be tested for BSE.

## 2.2. All bovine animals over 30 months of age subject to normal slaughter for human consumption shall be tested for BSE.

## 2.3. By way of derogation from point 2.2, and with regard to bovine animals born, reared and slaughtered on its territory, Sweden may decide to examine only a random sample. The sample shall comprise at least 10 000 animals per year.

## 3. Monitoring in animals not slaughtered for human consumption

Bovine animals over 24 months of age which have died or been killed but which were not:

- killed for destruction pursuant to Commission Regulation (EC) No 716/96 <sup>(2)</sup>,
- killed in the framework of an epidemic, such as foot-and-mouth disease,
- slaughtered for human consumption,

shall be tested for BSE at random. The number of samples shall not be less than the sample size indicated in the table. The sampling must be representative for each region and continuous.

Total population over 24 months	Minimum annual sample size (*)	Total population over 24 months	Minimum annual sample size (*)
100 000	950	4 500 000	6 000
200 000	1 550	5 000 000	6 500
300 000	1 890	5 500 000	7 000
400 000	2 110	6 000 000	7 500
500 000	2 250	6 500 000	8 000
600 000	2 360	7 000 000	8 500
700 000	2 440	7 500 000	9 000
800 000	2 500	8 000 000	9 500
900 000	2 550	8 500 000	10 000
1 000 000	2 590	9 000 000	10 500
1 500 000	3 000	9 500 000	11 000
2 000 000	3 500	10 000 000	11 500
2 500 000	4 000	10 500 000	12 000
3 000 000	4 500	11 000 000	12 500
3 500 000	5 000	11 500 000	13 000
4 000 000	5 500	12 000 000	13 500

(\*) The sample size has been calculated to detect a prevalence of 0,1 % with a 95 % confidence in the subpopulation referred to in point 3, based on the assumption that the proportion of this subpopulation in the total population of bovine animals over 24 months of age is 1 %. Where the size of the total population of bovine animals over 24 months of age is 1 500 000 animals or more, the sample size has been increased by 500 samples per 500 000 animals as a proportionality adjustment, to take account of the larger likelihood of variation in risk for BSE within the population.

<sup>(1)</sup> OJ 121, 29.7.1964, p. 2012/64.

<sup>(2)</sup> OJ L 99, 20.4.1996, p. 14.

4. *Monitoring in animals purchased for destruction pursuant to Regulation (EC) No 716/96*
- 4.1. All animals subject to casualty slaughter or found sick at ante-mortem inspection shall be tested for BSE.
- 4.2. All animals born between 1 August 1996 and 1 August 1997 shall be tested for BSE.
- 4.3. A random sample comprising at least 50 000 animals annually of animals not covered by points 4.1 or 4.2 shall be tested for BSE.

5. *Monitoring in other animals*

In addition to the testing referred to in points 2 to 4, Member States may on a voluntary basis decide to test other bovine animals on their territory, in particular where those animals originate from countries with indigenous BSE, have consumed potentially contaminated feedingstuffs or were born or derived from BSE infected dams.

6. *Measures following testing*

- 6.1. Where an animal slaughtered for human consumption is tested for BSE, the health marking provided for in Chapter XI of Annex I to Directive 64/433/EEC shall not be carried out on the carcass of that animal until a negative result to the rapid test has been obtained.
- 6.2. Member States may derogate from the provisions of point 6.1 where an official system is in place in the slaughterhouse ensuring that no parts of examined animals bearing the health mark leave the slaughterhouse until a negative result to the rapid test has been obtained.
- 6.3. All parts of the body of an animal tested for BSE including the hide shall be retained under official control until a negative result to the rapid test has been obtained, unless they are destroyed in accordance with Annex V, point 3 or 4.
- 6.4. All parts of the body of an animal found positive to the rapid test including the hide shall be destroyed in accordance with Annex V, point 3 or 4, apart from material to be retained in conjunction with the records provided for in Chapter B, section III.
- 6.5. Where an animal slaughtered for human consumption is found positive to the rapid test, at least the carcass immediately preceding the test-positive carcass and two carcasses immediately following the test-positive carcass on the same slaughter line shall be destroyed in accordance with point 6.4, in addition to the test-positive carcass.
- 6.6. Member States may derogate from the provisions of point 6.5 where a system is in place in the slaughterhouse preventing contamination between carcasses.

## II. Monitoring in ovine and caprine animals

1. *General*

Monitoring in ovine and caprine animals shall be carried out in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b).

2. *Monitoring in animals slaughtered for human consumption*

Animals over 18 months of age or which have more than two permanent incisors erupted through the gum and which are slaughtered for human consumption shall be tested in accordance with the sample size indicated in the table. The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, species, age, breed, production type or any other characteristic. The age of the animals shall be estimated based on dentition, obvious signs of maturity or other reliable information. Multiple sampling in the same flock shall be avoided, where possible.

Member States	Minimum annual sample size Slaughtered animals (*)
Belgium	3 750
Denmark	3 000
Germany	60 000
Greece	60 000
Spain	60 000
France	60 000
Ireland	60 000

Member States	Minimum annual sample size Slaughtered animals (*)
Italy	60 000
Luxembourg	250
Netherlands	39 000
Austria	8 200
Portugal	22 500
Finland	1 900
Sweden	5 250
United Kingdom	60 000

(\*) The sample size has been calculated to detect a prevalence of 0,005 % with a 95 % confidence in slaughtered animals in Member States which slaughter a large number of adult sheep. In those Member States which slaughter a smaller number of adult sheep, the sample size is calculated as 25 % of the estimated or recorded number of cull ewes slaughtered in 2000.

### 3. *Monitoring in animals not slaughtered for human consumption*

Animals over 18 months of age or which have more than two permanent incisors erupted through the gum which have died or been killed, but which were not:

- killed in the framework of an epidemic, such as foot-and-mouth disease,
- slaughtered for human consumption,

shall be tested in accordance with the sample size indicated in the table. The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, species, age, breed, production type or any other characteristic. The age of the animal shall be estimated based on dentition, obvious signs of maturity or other reliable information. Multiple sampling in the same flock shall be avoided, where possible.

Member States	Minimum annual sample size Dead animals (*)
Belgium	450
Denmark	400
Germany	6 000
Greece	6 000
Spain	6 000
France	6 000
Ireland	6 000
Italy	6 000
Luxembourg	30
Netherlands	5 000
Austria	1 100
Portugal	6 000
Finland	250
Sweden	800
United Kingdom	6 000

(\*) The sample size has been calculated to detect a prevalence of 0,05 % with a 95 % confidence in dead animals in Member States with a large sheep population. In those Member States which slaughter a smaller sheep population, the sample size is calculated as 50 % of the estimated number of dead animals (estimated mortality 1 %).

#### 4. *Monitoring in other animals*

In addition to the monitoring programmes set out in points 2 and 3, Member States may on a voluntary basis carry out monitoring in other animals, in particular:

- animals used for dairy production,
- animals originating from countries with indigenous TSEs,
- animals which have consumed potentially contaminated feedingstuffs,
- animals born or derived from TSE infected dams,
- animals from flocks infected with TSE.

#### 5. *Measures following testing of ovine and caprine animals*

All parts of the body of a tested animal including the hide shall be retained under official control until a negative result to the rapid test has been obtained, unless they are destroyed in accordance with Annex V, point 3 or 4.

All parts of the body of an animal found positive to the rapid test including the hide shall be destroyed in accordance with Annex V, point 3 or 4, apart from material to be retained in conjunction with the records provided for in Chapter B, section III.

#### 6. *Genotyping*

- 6.1. The prion protein genotype shall be determined for each positive TSE case in sheep. TSE cases found in resistant genotypes (sheep of genotypes which encode alanin on both alleles at codon 136, arginin on both alleles at codon 154 and arginin on both alleles at codon 171) shall immediately be reported to the Commission. Where possible, such cases shall be submitted for strain-typing. Where strain-typing of such cases is not possible, the herd of origin and all other herds where the animal has been shall be subjected to enhanced monitoring with a view to find other TSE cases for strain-typing.
- 6.2. In addition to the animals genotyped under the provisions of point 6.1, the prion protein genotype of a random subsample of the ovine animals tested under the provisions of Chapter A, section II, point 2, shall be determined. This subsample shall represent at least one per cent of the total sample for each Member State, and shall not be less than 100 animals per Member State. By derogation, Member States may choose to genotype an equivalent number of live animals of a similar age.

## CHAPTER B

### I. **Information to be presented by Member States in their report**

1. The number of suspected cases per animal species placed under movement restrictions in accordance with Article 12(1).
2. The number of suspected cases per animal species subject to laboratory examination in accordance with Article 12(2) and the outcome of the examination.
3. The number of flocks where suspected cases in ovine and caprine animals have been reported and investigated pursuant to Article 12(1) and (2).
4. The estimated size of each subpopulation referred to in Chapter A, section I, points 3 and 4.
5. The number of bovine animals tested within each subpopulation referred to in Chapter A, section I, point 2 to 5, the method for sample selection and the outcome of the tests.
6. The estimated size of those subpopulations referred to in Chapter A, section II, points 2 and 3, which have been selected for sampling.
7. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, section II, points 2 to 4, the method for sample selection and the outcome of the tests.
8. Number, age distribution and geographical distribution of positive cases of BSE and scrapie. The country of origin, if not the same as the reporting country, of positive cases of BSE and scrapie. Number and geographical distribution of scrapie positive flocks. The year and, where possible, month of birth should be given for each BSE case.

9. Positive TSE cases confirmed in animals other than bovine, ovine and caprine animals.
10. The genotype and where possible breed of each animal sampled within each sub-population referred to in Chapter A, part II, points 6.1 and 6.2.

#### II. Information to be presented by the Commission in its summary

The summary shall be presented in a tabled format covering at least the information referred to in part I for each Member State.

#### III. Records

1. The competent authority shall keep, for seven years, records of:
    - the number and types of animals placed under movement restrictions as referred to in Article 12(1),
    - the number and outcome of clinical and epidemiological investigations as referred to in Article 12(1),
    - the number and outcome of laboratory examinations as referred to in Article 12(2),
    - the number, identity and origin of animals sampled in the framework of the monitoring programmes as referred to in Chapter A and, where possible, age, breed and anamnestic information,
    - the prion protein genotype of positive TSE cases in sheep.
  2. The investigating laboratory shall keep, for seven years, all records of testing, in particular laboratory workbooks and, where appropriate, paraffin blocks and photographs of Western blots.
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## ANNEX II

## ANNEX XI

## TRANSITIONAL MEASURES REFERRED TO IN ARTICLES 22 AND 23

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

1. The specified risk material designated below shall be removed and destroyed in accordance with points 5 to 8 and, as appropriate, point 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 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 of ovine and caprine animals of all ages.

The age set forth above for the removal of 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, and Chapter B, point 1, of this Annex.

(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 6 months.

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 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, 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:

- (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.

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

- (c) 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.

Where specified risk material is not removed from dead animals, the parts of the body containing specified risk material or the entire body must be treated as specified risk material. However, entire bodies of dead animals can be exempted from the staining requirement set forth in point 7.

6. By way of derogation from point 5, Member States may decide to allow:
- (a) harvesting of cheek meat and tongue from bovine, ovine and caprine heads in cutting plants specifically authorised for this purpose;
  - (b) removal of spinal cord of ovine and caprine animals in cutting plants specifically authorised for this purpose;
  - (c) removal of vertebral column from carcasses or parts of carcasses in butcher shops specifically authorised, monitored and registered for this purpose.
7. All specified risk material shall be stained with a dye or, as appropriate, marked immediately on removal, and completely destroyed:
- (a) by incineration without pre-processing, or
  - (b) 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.
- The pre-processed material shall be re-stained or, as appropriate, re-marked if the dye is no longer visible or the marker no longer detectable.
8. Member States may derogate from the provisions of points 5 and 7 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.
9. Member States may despatch specified risk material or the material processed therefrom to other Member States only with a view to subsequent incineration, under the conditions laid down in Article 4(2) of Decision 97/735/EC, or where appropriate in accordance with point 11(b).

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, once the conditions governing such export have been adopted.

10. (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<sup>(1)</sup>,
  - meat products: the meat products defined by Directive 77/99/EEC<sup>(2)</sup>,
  - 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,
  - gelatine as referred to by Directive 92/118/EEC,
  - pet food as referred to by Directive 92/118/EEC,
  - the processed animal protein referred to by 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.

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.

<sup>(1)</sup> 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).

<sup>(2)</sup> 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).

- (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 (\*)

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.

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

or (\*)

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

Argentina

Australia

Botswana

Brazil

Chile

Costa Rica

El Salvador

Namibia

New Zealand

Nicaragua

Panama

Paraguay

Uruguay

Singapore

Swaziland

(\*) Delete one of these as appropriate."

11. 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, 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, butcher shops registered in accordance with point 6, 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 5 to 9. 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.

12. 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) carcasses or parts of carcasses, as defined by Directive 64/433/EEC, of bovine animals shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000, when removal of the vertebral column is not required;
  - (b) a specific indication of the number of bovine carcasses or parts 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 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 <sup>(1)</sup>, as applicable;
  - (c) butcher shops shall keep, for at least one year, the commercial documents referred to in point (b).'
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<sup>(1)</sup> OJ L 9, 15.1.1993, p. 33.