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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies [1], as last amended by Commission Regulation (EC) No 1003/2003 [2], and in particular Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the monitoring of transmissible spongiform encephalopathy (TSE) in ovine and caprine animals, including monitoring of a sample of animals not slaughtered for human consumption. It is necessary to clarify the definition of this group of animals, in order to avoid the inappropriate targeting of samples.

(2) Regulation (EC) No 999/2001 provides for eradication measures following the confirmation of TSE in ovine and caprine animals. Targeted testing should be carried out on animals destroyed under these measures, in order to gather epidemiological information.

(3) There is a theoretical possibility that BSE may exist in the ovine and caprine population. It is not possible using routine methods to distinguish between BSE and scrapie infection in these animals. The level of infectivity in the ileum in both diseases is significant from an early stage of infection. As a precautionary measure, the ileum of ovine and caprine animals of all ages should be added to the list of specified risk materials.

(4) In its opinion of 7 and 8 November 2002 on TSE infectivity distribution in ruminant tissues, the Scientific Steering Committee (SSC) recommended that tonsils of bovine animals of any age should be regarded as posing a risk of bovine spongiform encephalopathy (BSE).

(5) The SSC has stated that contamination with central nervous tissue and tonsil material are to be avoided when harvesting head meat and tongues of bovine animals for human consumption, to avoid any risk of BSE.

(6) As the condition of heads depends mainly on their careful handling and a safe sealing of the frontal shot hole and the foramen magnum, control systems must be in place in the slaughterhouses and in the specifically authorised cutting plants.

(7) The rules to dispatch carcases, half carcases and quarter carcases containing no specified risk material other than vertebral column to other Member States without the latter's prior agreement should be expanded to half carcases cut into no more than three wholesale cuts reflecting the actual trade between Member States.

(8) Regulation (EC) No 1774/2002 of the European Parliament and of the Council [3], amended by Commission Regulation (EC) No 808/2003 [4], lays down animal and public health rules for the collection, transport, storage, handling, processing and use or disposal of all animal by-products not intended for human consumption, including their placing on the market and, in certain specific cases, their export and transit. Special rules on removal and disposal of such products provided for in Annex XI to Regulation (EC) No 999/2001 should therefore be deleted.

(9) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(10) 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 III 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 20th day following that of its publication in the *Official Journal of the European Communities*.

It shall apply from 1 October 2003.

[1] OJ L 147, 31.5.2001, p. 1.
[2] OJ L 152, 20.6.2003, p. 8.
[3] OJ L 273, 10.10.2002, p. 1.
[4] OJ L 117, 13.5.2003, p. 1.

The new provision of Annex XI, Part A, point 1(a)(ii) to Regulation (EC) No 999/2001, as set out in point 2 of the Annex to this Regulation, shall apply to animals slaughtered from 1 October 2003 onwards.

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

Done at Brussels, 27 June 2003.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Annexes III and XI are amended as follows:

1. Annex III is replaced by the following:

'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 ([1]), or

— slaughtered in accordance with Annex I, Chapter VI, point 28(c), to Directive 64/433/EEC, except animals without clinical signs of disease slaughtered in the context of a disease eradication campaign,

shall be tested for BSE.

2.2. All bovine animals over 30 months of age:

— subject to normal slaughter for human consumption, or

— slaughtered in the context of a disease eradication campaign in accordance with Annex I, Chapter VI, point 28(c), to Directive 64/433/EEC, but showing no clinical signs of disease,

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**

3.1. All 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 ([2]),

— killed in the framework of an epidemic, such as foot-and-mouth disease,

— slaughtered for human consumption,

shall be tested for BSE.

3.2. Member States may decide to derogate from the provisions of point 3.1 in remote areas with a low animal density, where no collection of dead animals is organised. Member States making use of this derogation shall inform the Commission thereof, and submit a list of the derogated areas. The derogation shall not cover more than 10 % of the bovine population in the Member State.

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 over 42 months of age born after 1 August 1996 shall be tested for BSE.

4.3. A random sample comprising at least 10 000 animals annually of animals not covered by points 4.1 or 4.2 shall be tested for BSE.

([1]) OJ 121, 29.7.1964, p. 2012/64
([2]) OJ L 99, 20.4.1996, p. 14.

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 has been selected for testing 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 carcase 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 carcase immediately preceding the test-positive carcase and two carcases immediately following the test-positive carcase on the same slaughterline shall be destroyed in accordance with point 6.4, in addition to the test-positive carcase.

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 carcase.

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 State	Minimum annual sample size Slaughtered animals (1)
Belgium	3 750
Denmark	3 000
Germany	60 000
Greece	60 000
Spain	60 000
France	60 000
Ireland	60 000
Italy	60 000
Luxembourg	250
Netherlands	39 000

Member State	Minimum annual sample size Slaughtered animals (1)
Austria	8 200
Portugal	22 500
Finland	1 900
Sweden	5 250
United Kingdom	60 000

(1) 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.

A Member State may test a number of animals less than that indicated in the table if the most recent official slaughter statistics indicate that this number is equivalent to 25 % of cull ewes slaughtered annually in the Member State.

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 a disease eradication campaign,

— 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 may decide to exclude remote areas with a low animal density, where no collection of dead animals is organised, from the sampling. Member States making use of this derogation shall inform the Commission thereof, and submit a list of the derogated areas. The derogation shall not cover more than 10 % of the ovine and caprine population in the Member State.

Member State	Minimum annual sample size Dead animals (1)
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

(1) 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 with a smaller sheep population, the sample size is calculated as 50 % of the estimated number of dead animals (estimated mortality 1%).

4. **Monitoring in infected flocks**

From 1 October 2003, animals over 12 months or which have a permanent incisor erupted through the gum, which are killed in accordance with the provisions of Annex VII, point 2(b)(i) or (ii) or point 2(c), shall be tested based on the selection of a simple random sample, in accordance with the sample size indicated in the table

Number of culled animals over 12 months in the herd or flock	Minimum sample size [1]
70 or less	All eligible animals
80	68
90	73
100	78
120	86
140	92
160	97
180	101
200	105
250	112
300	117
350	121
400	124
450	127
500 or more	150

[1] The sample size is calculated to be 95 % certain of including at least one positive if the disease is present at a minimum prevalence of 2 % in the test population.

5. **Monitoring in other animals**

In addition to the monitoring programmes set out in points 2, 3 and 4, 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.

6. **Measures following testing of ovine and caprine animals**

6.1. Where an animal slaughtered for human consumption has been selected for testing for TSE, the health marking provided for in Chapter XI of Annex I to Directive 64/433/EEC shall not be carried out on the carcase 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 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.

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.

7. **Genotyping**

7.1. 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.

7.2. In addition to the animals genotyped under the provisions of point 7.1, 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.

III. MONITORING IN OTHER ANIMAL SPECIES

Member States may on a voluntary basis carry out monitoring for TSE in animal species other than bovine, ovine and caprine animals.

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 5, 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 subpopulation referred to in Chapter A, part II, points 7.1 and 7.2.

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 work-books and, where appropriate, paraffin blocks and photographs of western blots.'

2. Annex XI, Part A is replaced by the following:

'ANNEX XI

TRANSITIONAL MEASURES REFERRED TO IN ARTICLES 22 AND 23

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

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

(i) the skull excluding the mandible and including the brain and eyes, the vertebral column excluding the vertebrae of the tail, the transverse processes of the lumbar and thoracic vertebrae and the wings of the sacrum, but including dorsal root ganglia, and the spinal cord of bovine animals aged over 12 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 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.

(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 and trigeminal ganglia; 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:

(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 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, 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,

[1] OJ L 273, 10.10.2002, p. 1.

— 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.

13. Member States may decide to allow dispatch of heads or carcases 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, carcases, half carcases or half carcases cut into no more than three wholesale cuts, and quarters 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

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 [1], as applicable;

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

[1] OJ L 9, 15.1.1993, p. 3.

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 [1],

— meat products: the meat products defined by Directive 77/99/EEC [2],

— other products of animal origin: other products of animal origin as defined by Directive 77/99/EEC,

— rendered fats as referred to 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 (*)

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 [3]

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

— Iceland

— Namibia

— New Zealand

— Nicaragua

— Panama

— Paraguay

— Singapore

— Swaziland

— Uruguay

— Vanuatu."'

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[1] 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).

[2] 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).

(*) Delete one of these as appropriate.

[3] OJ 121, 29.7.1964, p. 2012/64