COMMISSION REGULATION (EC) No 1494/2002

of 21 August 2002

amending Annexes III, VII and XI to Regulation (EC) No 999/2001 of the European Parliament and the Council as regards monitoring of bovine spongiform encephalopathy, eradication of transmissible spongiform encephalopathy, removal of specified risk materials and rules for importation of live animals and products of animal origin

(Text with EEA relevance)

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 270/2002 [2], and in particular Article 23 thereof,

Whereas:

(1) Rules for monitoring of bovine spongiform encephalopathy (BSE) in bovine animals, for destruction of bovine embryos and ova of BSE cases, for trade in bovine embryos and ova, and for removal of specified BSE risk material are laid down in Regulation (EC) No 999/2001.

(2) When the BSE monitoring programme in bovine animals was amended by Commission Regulation (EC) No 1248/2001 [3], provision was made for a review of the monitoring programme in the light of the results obtained during the first six months.

(3) During the second half of 2001, more than five million bovine animals were tested for BSE, 457 of which were positive. Most positive cases were found in dead-on-farm animals, emergency slaughtered animals and animals the slaughter of which was deferred due to a suspected disease or disorder of their general conditions.

(4) To ensure the uniform application of the monitoring programme, it is necessary to clarify under Annex III, Chapter A.I.2, the definition of animals the slaughter of which was deferred due to a suspected disease or disorder of their general conditions.

(5) All dead-on-farm animals over 24 months of age have been tested for BSE during a one-year statistical survey set out as a transitional measure in Regulation (EC) No 999/2001. To ensure the effective detection of BSE cases, all dead-on-farm animals above 24 months of age should continue to be tested on a permanent basis. To avoid disproportionate costs, a derogation should be provided for animals dying in remote areas where no collection of dead animals has been organised.

(6) It is important to follow the evolution of the BSE epidemic in animals born after the introduction of the reinforced feed ban in the United Kingdom. To this end the testing of animals slaughtered and destroyed under the Over Thirty Months Scheme should be expanded to cover all animals born after the feed ban. However, the detection of positive cases in animals below 42 months of age is highly unlikely and it would, therefore, be disproportionate to require the testing of healthy animals below that age intended for destruction under the exceptional scheme provided for by Commission Regulation (EC) No 716/96 of 19 April 1996 adopting exceptional support measures for the beef market in the United Kingdom [4] as last amended by Regulation (EC) No 1176/2000 [5].

(7) It is necessary to clarify the rules on health marking of carcasses selected for testing for transmissible spongiform encephalopathy.

(8) To avoid disproportionate costs in the monitoring programme for small ruminants, a derogation should be provided for animals dying in remote areas where no collection of dead animals has been organised.

(9) The provisions regarding voluntary monitoring programmes in animal species other than bovine, ovine and caprine animals should be clarified.

(10) In its opinion of 16 May 2002 on the safety of bovine embryos, the Scientific Steering Committee (SSC) concluded that there is no need for measures other than those prescribed by the International Embryo Transfer Society protocols. In its general session of May 2002, the world animal health organisation Office international des Epizooties (OIE) decided on similar scientific grounds to delete all trade conditions related to bovine embryos and ova. The provisions on the destruction of bovine embryos and ova from BSE cases and the BSE-related trade conditions for bovine embryos and ova should therefore be repealed.

(11) It is necessary to clarify the rules on the removal and control of specified risk material.

[1] OJ L 147, 31.5.2001, p. 1.
[2] OJ L 45, 15.2.2002, p. 4.
[3] OJ L 173, 27.6.2001, p. 12.
[4] OJ L 99, 20.4.1996, p. 14.
[5] OJ L 131, 1.6.2000, p. 37.

(12) In its opinion of 27 June 2002 on the Geographical BSE Risk of certain third countries, the SSC concluded that, in addition to previously evaluated countries, the occurrence of BSE in native cattle is highly unlikely in Iceland and in Vanuatu. Therefore Iceland and Vanuatu should be exempt from the trade conditions related to live bovine animals and products of bovine, ovine and caprine origin.

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

(14) 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, VII 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 that of its publication in the *Official Journal of the European Communities*.

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

Done at Brussels, 21 August 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX

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 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 State	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
Italy	60 000
Luxembourg	250

Member State	Minimum annual sample size Slaughtered animals (*)
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 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 (*)
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

Member State	Minimum annual sample size Dead animals (*)
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 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 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*

5.1. 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 carcass of that animal until a negative result to the rapid test has been obtained.

5.2. Member States may derogate from the provisions of point 5.1 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.

5.3. 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.

5.4. 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 sub-sample of the ovine animals tested under the provisions of Chapter A, Section II, point 2 shall be determined. This sub-sample 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 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 subpopulation 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 work-books and, where appropriate, paraffin blocks and photographs of Western blots.'

2. Annex VII is amended as follows:

(a) in point 1(a), the second indent is replaced by the following:

'— where the disease was confirmed in a female animal, its progeny born within two years prior to, or after, clinical onset of the disease;'

(b) in point 1(a), the words 'embryos and ova' are deleted in the fifth indent;

(c) in point 2(a), the words 'and the destruction of embryos and ova' are deleted.

3. Annex XI is amended as follows:

(a) in part A, point 1(a)(i) is replaced by the following:

'(i) the skull including the brain and eyes, the tonsils, 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 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;'

(b) in part A, point 5(a) is replaced by the following:

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

(c) in part A, the list of countries referred to in point 10(b) is replaced by the following:

'Argentina
Australia
Botswana
Brazil
Chile
Costa Rica
El Salvador
Iceland
Namibia
New-Zealand
Nicaragua
Panama
Paraguay
Singapore
Swaziland
Uruguay
Vanuatu.'

(d) In part A, point 12(a) is replaced by the following:

'(a) when removal of the vertebral column is not required, carcasses or parts of carcasses, as defined by Directive 64/433/EEC, of bovine animals containing vertebral column, shall be identified by a blue stripe on the label referred to in Regulation (EC) No 1760/2000, except at the delivery stage to the final consumer;'

(e) Part B is deleted.

(f) In part D, point 3 is replaced by the following:

'3. Point 2 shall not apply to imports of bovine animals born and continuously reared in the following countries:
Argentina
Australia
Botswana
Brazil
Chile
Costa Rica
El Salvador
Iceland
Namibia
New-Zealand
Nicaragua
Panama
Paraguay
Singapore
Swaziland
Uruguay
Vanuatu.'

(g) In part D, point 4 is deleted.