COMMISSION REGULATION (EC) No 2245/2003

of 19 December 2003

amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine and caprine animals

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], and in particular the first paragraph of 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.

(2) Separate sample sizes should be set for ovine and caprine animals to make it easier to interpret results of testing for TSEs.

(3) Monitoring of large numbers of ovine animals slaughtered for human consumption in Member States with large sheep populations has made it possible to estimate the prevalence of TSEs in those populations. The level of monitoring in large sheep populations should therefore be reduced. Monitoring of ovine animals slaughtered for human consumption in Member States with small sheep populations provides limited information and should therefore no longer be compulsory.

(4) Monitoring of sufficiently large numbers of caprine animals slaughtered for human consumption to detect the likely prevalence of TSEs in this group is difficult or impractical in most Member States. Monitoring in that group should therefore no longer be compulsory.

(5) Monitoring of dead-on-farm stock in both ovine and caprine animals should be increased, to provide information on prevalence of TSE and to aid eradication of the disease. Member States should take measures to ensure that infected animals are not diverted away from sampling.

(6) Regulation (EC) No 999/2001 should therefore be amended accordingly. For practical reasons, it is appropriate to replace the amended Annex III as a whole.

(7) 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

Annex III to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2004.

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

Done at Brussels, 19 December 2003.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 147, 31.5.2001, p. 1; Regulation as last amended by Commission Regulation (EC) No 1915/2003 (OJ L 283, 31.10.2003, p. 29).

ANNEX

Annex III to Regulation (EC) No 999/2001 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.

([1]) OJ 121, 29.7.1964, p. 2012/64.
([2]) 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 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 point 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 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 disposed of in accordance with Article 4(2)(a) and (b) of Regulation (EC) No 1774/2002 of the European Parliament and of the Council [1].

6.4. All parts of the body of an animal found positive to the rapid test including the hide shall be disposed of in accordance with Article 4(2)(a) and (b) of Regulation (EC) No 1774/2002, apart from material to be retained in conjunction with the records provided for in Chapter B(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 ovine animals slaughtered for human consumption**

Member States in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals shall test a minimum annual sample of 10 000 ovine animals which are slaughtered for human consumption [2]. The animals shall be over 18 months of age or have more than two permanent incisors erupted through the gum. The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoiding the over-representation of any group as regards the origin, 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.

[1] OJ L 273, 10.10.2002, p. 1.
[2] The sample size has been calculated to detect a prevalence of 0,03 % with a 95 % confidence in slaughtered animals. The sample is restricted to Member States with a large sheep population.

3. **Monitoring in ovine and caprine animals not slaughtered for human consumption**

Ovine and caprine 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 sizes indicated in table A and table B respectively. The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoiding the over-representation of any group as regards the origin, 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. The Member State shall put in place a system to check, on a targeted or other basis, that animals are not being diverted from sampling

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.

Table A

Member State population of ewes and ewe lambs put to the ram	Minimum sample size of dead ovine animals (1)
> 750 000	10 000
100 000-750 000	1 500
40 000-100 000	500
< 40 000	100

(1) Sample sizes are set to take account of the size of the ovine populations in the individual Member States and are intended to provide achievable targets. The sample sizes of 10 000, 1 500, 500 and 100 animals will allow the detection of a prevalence of 0,03%, 0,2 %, 0,6 % and 3 % respectively with a 95 % confidence.

Table B

Member State population of goats which have already kidded and goats mated	Minimum sample size of dead caprine animals (1)
> 750 000	5 000
250 000-750 000	1 500
40 000-250 000	500
< 40 000	50

(1) Sample sizes are set to take account of the size of the caprine populations in the individual Member States and are intended to provide achievable targets. The sample sizes of 5 000, 1 500, 500 and 50 animals will allow the detection of a prevalence of 0,06 %, 0,2 %, 0,6 % and 6 % respectively with a 95 % confidence. Where a Member State experiences difficulty in collecting sufficient numbers of dead caprine animals to reach its allotted sample size, it may choose to supplement its sample by testing caprine animals slaughtered for human consumption over the age of 18 months at the ratio of three caprine animals slaughtered for human consumption to one dead caprine animal.

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,

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

6.1. Where an ovine or caprine 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 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 disposed of in accordance with Article 4.2(a) and (b) of Regulation (EC) No 1774/2002.

6.4. All parts of the body of an animal found positive to the rapid test including the hide shall be disposed of in accordance with Article 4.(2)(a) and (b) of Regulation (EC) No 1774/2002, apart from material to be retained in conjunction with the records provided for in Chapter B(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 sample of ovine animals shall be determined. In the case of Member States with an adult sheep population of more than 750 000 adult animals, this sample shall consist of at least 600 animals. In the case of other Member States the sample shall consist of at least 100 animals. The samples may be chosen from animals slaughtered for human consumption, from animals dead-on farm or from live animals. The sampling should be representative of the entire ovine population.

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(I)(3) and (4)
5. The number of bovine animals tested within each subpopulation referred to in Chapter A(I)(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(II)(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(II)(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(II)(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 workbooks and, where appropriate, paraffin blocks and photographs of western blots.'