Status: *Point in time view as at 01/09/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)*

[F1 ANNEX III

MONITORING SYSTEM

Textual Amendments

F1 Substituted by 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.

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

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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 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[(3)].

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.

[F2II. 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).

Status: *Point in time view as at 01/09/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)*

[F3 2. Monitoring in ovine and caprine animals slaughtered for human consumption

(a) *Ovine animals*

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 slaughtered for human consumption in accordance with the sampling rules set out in point 4[(4)].

(b) *Caprine animals*

Member States shall test healthy slaughtered caprine animals in accordance with the sampling rules set out in point 4 and the minimum sample sizes listed in Table A.

Where a Member State experiences difficulty in collecting sufficient numbers of healthy slaughtered caprine animals to reach its allotted minimum sample size, it may choose to replace a maximum of 50 % of its minimum sample size by testing dead caprine animals over the age of 18 months at the ratio of one to one and in addition to the minimum sample size set out in point 3.

TABLE A

Member State	**Minimum sample size in healthy slaughtered caprine animals**[a]
Spain	125 500
France	93 000
Italy	60 000
Greece	20 000
Cyprus	5 000
Austria	5 000
Other Member States	all

a Minimum sample sizes are set to take account of the size of the number of healthy slaughtered caprine animals and the prevalence of BSE in the individual Member State. They are also intended to provide achievable targets. The minimum sample sizes above 60 000 allow the detection of a prevalence of 0,0017 % with a 95 % confidence.

Textual Amendments

F3 Substituted by Commission Regulation (EC) No 214/2005 of 9 February 2005 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 caprine animals (Text with EEA relevance).

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

Member States shall test in accordance with the sampling rules set out in point 4 and the minimum sample sizes indicated in table B and table C, ovine and caprine animals which have died or been killed, but which were not:

— killed in the framework of a disease eradication campaign, or

— slaughtered for human consumption.

Status: *Point in time view as at 01/09/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)*

TABLE B

Member State population of ewes and ewe lambs put to the ram	**Minimum sample size of dead ovine animals[a]**
>750 000	10 000
100 000750 000	1 500
40 000100 000	500
<40 000	100

a Minimum 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 minimum 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 C

Member State population of goats which have already kidded and goats mated	**Minimum sample size of dead caprine animals[a]**
>750 000	10 000
250 000750 000	3 000
40 000250 000	1 000
<40 000	100 % up to 200

a Minimum 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 minimum sample sizes of 10 000, 3 000, 1 000 and 200 animals will allow the detection of a prevalence of 0,03 %, 0,1 %, 0,3 % and 1,5 % respectively with a 95 % confidence.**]**

4. Sampling rules applicable to the animals referred to in points 2 and 3

The animals shall be over 18 months of age or have more than two permanent incisors erupted through the gum.

The age of the animals shall be estimated on the basis of dentition, obvious signs of maturity, or any other reliable information.

The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, age, breed, production type or any other characteristic.

Multiple sampling in the same flock shall be avoided, wherever possible.

The Member States shall put in place a system to check, on a targeted or other basis, that animals are not being diverted from sampling.

The sampling shall be representative for each region and season.

However, Member States may decide to exclude from the sampling 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 shall submit a list of those remote areas where the derogation applies. The derogation shall not cover more than 10 % of the ovine and caprine population in the Member State concerned.

5. Monitoring in infected flocks

Status: *Point in time view as at 01/09/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)*

From 1 October 2003, animals over 12 months or which have a permanent incisor erupted through the gum, and which are killed for destruction 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 following table.

Number of animals over 12 months or which have a permanent incisor erupted through the gum, killed for destruction in the herd or flock	**Minimum sample size**
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

Where possible, the killing and subsequent sampling shall be delayed until the result of primary molecular testing carried out for the further examination of positive scrapie cases under the provisions of Annex X, Chapter C, point 3.2.(c)(i) is known.

6. 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.

7. Measures following testing of ovine and caprine animals

7.1. Where an ovine or caprine animal slaughtered for human consumption has been selected for TSE testing in accordance with point 2, its carcase shall not be marked with the health marking provided for in Chapter XI of Annex I to Directive 64/433/EEC until a negative result to the rapid test has been obtained.

Status: *Point in time view as at 01/09/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)*

7.2. Member States may derogate from point 7.1. where a system approved by the competent authority is in place in the slaughterhouse ensuring that all parts of an animal can be traced and that no parts of the animals tested bearing the health mark can leave the slaughterhouse until a negative result to the rapid test has been obtained.

7.3. All parts of the body of a tested animal, including the hide, shall be retained under official control until a negative result has been obtained to the rapid test, except for animal by-products directly disposed of in accordance with Articles 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

7.4. Except for the material to be retained in conjunction with the records provided for in Chapter B, Part III of this Annex, all parts of the body of an animal found positive to the rapid test, including the hide, shall be directly disposed of in accordance with Articles 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

8. Genotyping

8.1. 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 alanine on both alleles at codon 136, arginine on both alleles at codon 154 and arginine 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 kept shall be subjected to enhanced monitoring with a view to finding other TSE cases for strain-typing.

8.2. In addition to the animals genotyped under the provisions of point 8.1., the prion protein genotype of a minimum 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 minimum sample shall consist of at least 600 animals. In the case of other Member States the minimum 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.

Textual Amendments

F2 Substituted by Commission Regulation (EC) No 36/2005 of 12 January 2005 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemio-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals (Text with EEA relevance).

III. MONITORING IN OTHER ANIMAL SPECIES

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

[F2CHAPTER B

Reporting and recording requirements

I. REQUIREMENTS ON MEMBER STATES

Status: *Point in time view as at 01/09/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)*

A. Information to be presented by Member States in their annual report as provided for in Article 6(4)

1. The number of suspected cases placed under official movement restrictions in accordance with Article 12(1), per animal species.

2. The number of suspected cases subject to laboratory examination in accordance with Article 12(2), per animal species, including the results of the rapid and confirmatory tests (number of positives and negatives) and, with regard to bovine animals, an estimation of the age distribution of all tested animals. The age distribution should be grouped whenever possible as follows: 'below 24 months', distribution per 12 months between 24 and 155 months, and 'above 155 months' of age.

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 number of bovine animals tested within each subpopulation referred to in Chapter A, Part (I), points 2.1., 2.2., 2.3., 3.1., 4.1., 4.2., 4.3. and 5. The method for the sample selection, the results of the rapid and confirmatory tests and an estimation of the age distribution of the tested animals grouped as set out in point 2 shall be provided.

5. The number of ovine and caprine animals and flocks tested within each subpopulation referred to in Chapter A, Part II, points 2, 3 and 5 together with the method for sample selection and the results of the rapid and confirmatory tests.

6. The geographical distribution, including the country of origin if not the same as the reporting country, of positive cases of BSE and scrapie. The year, and where possible the month of birth shall be given for each TSE case in bovine, ovine and caprine animals. TSE cases which have been considered atypical and the reasons why shall be indicated. For scrapie cases, the results of the primary molecular testing with a discriminatory immuno-blotting, referred to in Annex X, Chapter C, point 3.2.(c)(i), shall be reported.

7. In animals other than bovine, ovine and caprine, the number of samples and confirmed TSE cases per species.

8. The genotype, and where possible the breed, of each ovine animal either found positive to TSE or sampled in accordance with Chapter A, Part II, points 8.1. and 8.2.

B. Reporting periods

The compilation of reports containing the information referred to in A and forwarded to the Commission on a monthly basis or, with regard to the information referred to in point 8 on a quarterly basis, may constitute the annual report as required by Article 6(4), provided that the information is updated whenever additional information becomes available.**]**

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),

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— 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.**]**

Status: *Point in time view as at 01/09/2005.*
Changes to legislation: *There are currently no known outstanding effects for the Regulation (EC) No 999/2001 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)*

(1) **[**[F1]OJ 121, 29.7.1964, p. 2012/64.**]**

(2) **[**[F1]OJ L 99, 20.4.1996, p. 14.**]**

(3) **[**[F1]OJ L 273, 10.10.2002, p. 1.**]**

(4) **[**[F1]**[**[F2]**[**[F3]The minimum sample size has been calculated to detect a prevalence in slaughtered animals of 0,03 % with a 95 % confidence.**]]]**

Textual Amendments

F1 Substituted by 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.

F2 Substituted by Commission Regulation (EC) No 36/2005 of 12 January 2005 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemio-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals (Text with EEA relevance).

F3 Substituted by Commission Regulation (EC) No 214/2005 of 9 February 2005 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 caprine animals (Text with EEA relevance).

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