[F1ANNEX 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).

[F2 2. Monitoring in animals slaughtered for human consumption

2.1. All bovine animals over 24 months of age shall be tested for BSE where they have undergone:

— emergency slaughter in accordance with point 1 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004[(1)], or

— an ante mortem inspection with observations concerning accidents, or serious physiological and functional problems, or signs in accordance with point 2 of Part B of Chapter II of Section I of Annex I to Regulation (EC) No 854/2004[(2)].

2.2. All healthy bovine animals over 30 months of age slaughtered normally for human consumption shall be tested for BSE.]

Textual Amendments

F2 Substituted by Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

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[(3)],

— 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.

[F3 4. Monitoring in animals purchased for destruction pursuant to Regulation (EC) No 716/96

All animals born between 1 August 1995 and 1 August 1996 killed for destruction pursuant Regulation (EC) No 716/96 shall be tested for BSE.]

Textual Amendments

F3 Substituted by Commission Regulation (EC) No 657/2006 of 10 April 2006 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the United Kingdom and repealing Council Decision 98/256/EC and Decisions 98/351/EC and 1999/514/EC (Text with EEA relevance).

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.

[F4 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), (b) or (e) of Regulation (EC) No 1774/2002 of the European Parliament and of the Council.

Textual Amendments

F4 Substituted by Commission Regulation (EC) No 162/2009 of 26 February 2009 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

6.4. All parts of the body of an animal found positive or inconclusive to the rapid test including the hide shall be disposed of in accordance with Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002, apart from material to be retained in conjunction with the records provided for in Chapter B(III).]

[F5 6.5. Where an animal slaughtered for human consumption is found positive or inconclusive to the rapid test, at least the carcase immediately preceding and the two carcases immediately following the tested positive or inconclusive animal on the same

slaughter line shall be destroyed in accordance with point 6.4. By way of derogation, Member States may decide to destroy the aforementioned carcases only if the result of the rapid test is confirmed to be positive or inconclusive by confirmatory examinations referred to in Annex X, Chapter C, point 3.1(b).**]**

Textual Amendments

F5 Substituted by Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

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.

[F6 7. Revision of the annual monitoring programmes concerning BSE (BSE monitoring programmes), as provided for in Article 6(1b)

7.1. Member States' applications

Applications submitted to the Commission by Member States for revision of their annual BSE monitoring programme shall include at least the following:

(a) information on the annual BSE monitoring system in place during the previous six-year period within the territory of the Member State, including detailed documentation proving compliance with the epidemiological criteria set out in point 7.2;

(b) information on the bovine identification and traceability system, as referred to in point (b) of the third subparagraph of Article 6(1b), in place during the previous six-year period within the territory of the Member State, including a detailed description of the functioning of the computerised database as referred to in Article 5 of Regulation (EC) No 1760/2000 of the European Parliament and of the Council[(4)]

(c) information on prohibitions concerning animal feeding during the previous six-year period within the territory of the Member State, including a detailed description of the enforcement of the feed ban for farmed animals, as referred to in point (c) of the third subparagraph of Article 6(1b), including the sampling plan and the number and type of infringements found and the follow-up results;

(d) a detailed description of the proposed revised BSE monitoring programme that includes the geographical area in which the programme is to be implemented and a description of subpopulations of bovine animals to be covered by the BSE revised monitoring programme, including indications of the age limits and the sample sizes for testing;

(e) the result of a comprehensive risk analysis showing that the revised BSE monitoring programme will ensure the protection of human and animal health. This risk analysis shall include a birth cohort analysis or other relevant studies aiming to demonstrate that the TSE risk reducing measures, including the feeding prohibitions as referred to in point (c) of the third subparagraph of Article 6(1b), have been implemented in an efficient way.

7.2. Epidemiological criteria

Applications for revision of a BSE monitoring programme may only be accepted if the Member State concerned can demonstrate that, in addition to the requirements laid down in points (a), (b) and (c) of the third subparagraph of Article 6(1b), the following epidemiological criteria are met within its territory:

(a) for a period of at least six consecutive years following the date of implementation of the Community BSE testing scheme as referred to in point (b) of the third subparagraph of Article 6(1b):

either

(i) the average decrease of the annual BSE incidence rate observed within the adult bovine animal population (over 24 months of age) was superior to 20 %, and the total number of BSE affected cattle born after the implementation of the Community total feed ban for farmed animals, as referred to in point (c) of the third subparagraph of Article 6(1b), did not exceed 5 % of the total number of confirmed BSE cases;

or

(ii) the annual observed BSE incidence rate within the adult bovine animal population (over 24 months of age) remained consistently less than 1/100 000;

or

(iii) as a further option for a Member State with an adult bovine animal population (over 24 months of age) of less than 1 000 000 animals, the cumulated number of confirmed BSE cases remained under five;

(b) following the six-year period referred to in point (a), there is no evidence that the BSE epidemiological situation is deteriorating.**]**

Textual Amendments

F6 Inserted by Commission Regulation (EC) No 571/2008 of 19 June 2008 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the criteria for revision of the annual monitoring programmes concerning BSE (Text with EEA relevance).

[F7[F5II. 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).

[F2 2. Monitoring in ovine and caprine animals slaughtered for human consumption

(a) Member States in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals shall test, in accordance with the sampling rules set out in point 4, a minimum annual sample of 10 000 ovine animals slaughtered for human consumption;

(b) Member States in which the population of goats which have already kidded and goats mated exceeds 750 000 animals shall test, in accordance with the sampling rules set out in point 4, a minimum annual sample of 10 000 caprine animals slaughtered for human consumption;

(c) A Member State may choose to replace a maximum of:

— 50 % of its minimum sample size of ovine and caprine animals slaughtered for human consumption set out in points (a) and (b) by testing dead ovine or 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;

— 10 % of its minimum sample size set out in points (a) and (b) by testing ovine or caprine animals killed in the framework of a disease eradication campaign over the age of 18 months at the ratio of one to one.**]**

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 A and Table B, 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.

TABLE A

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	100 % up to 500
< 40 000	100 % up to 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.

TABLE B

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	1 500
40 000250 000	100 % up to 500
< 40 000	100 % up to 100

a Minimum sample sizes are set to take account of the size of the caprine population in the individual Member States and are intended to provide achievable targets.

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.

The sampling shall be representative for each region and season. Multiple sampling in the same flock shall be avoided, wherever possible. Member States shall aim their monitoring programmes to achieve, wherever possible, that in successive sampling years all officially registered holdings with more than 100 animals and where TSE cases have never been detected are subject to TSE testing.

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.

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.

[F2 5. Monitoring in holdings under TSE control and eradication measures

Animals over 18 months of age which are killed for destruction in accordance with Annex VII, Chapter B, Part 2, point 2.2.1. and point 2.2.2.(b) or (c), shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.(b), based on the selection of a simple random sample, in accordance with the sample size set out in the following table.

Number of animals over 18 months of age 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**]**

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 Section I, Chapter III of Annex I to Regulation (EC) No 854/2004 until a negative result to the rapid test has been obtained.

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 Article 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 Article 4(2)(a), (b) or (e) of Regulation (EC) No 1774/2002.

8. Genotyping

8.1. The prion protein genotype for the codons 136, 154 and 171 shall be determined for each positive TSE case in sheep. TSE cases found in 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 the positive TSE case is an atypical scrapie case the prion protein genotype for the codon 141 shall be determined.

8.2. In addition to the animals genotyped in accordance with point 8.1, the prion protein genotype for the codons 136, 141, 154 and 171 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 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

F7 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.**]**

[F7CHAPTER B

REPORTING AND RECORDING REQUIREMENTS

I. REQUIREMENTS ON MEMBER STATES

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),

— 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.**]**

(1) **[F1[F2**OJ L 139, 30.4.2004, p. 55.**]]**

(2) **[F1[F2**OJ L 139, 30.4.2004, p. 206.**]]**

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

(4) **[F1[F6**OJ L 204, 11.8.2000, p. 1.**]]**

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 (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

F6 Inserted by Commission Regulation (EC) No 571/2008 of 19 June 2008 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the criteria for revision of the annual monitoring programmes concerning BSE (Text with EEA relevance).

Status:
Point in time view as at 01/07/2013.

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.