

Status: Point in time view as at 09/07/2006.

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, Division II.. (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

[^{F2}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).

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

(a) Ovine animals

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

TABLE A

Member State	Minimum sample size in healthy slaughtered ovine animals ^a
Germany	37 500
Greece	23 000
Spain	41 800
France	42 400
Ireland	40 500
Italy	43 700
the Netherlands	23 300
Austria	14 300
Poland	23 300
Portugal	14 300
United Kingdom	44 000
Other Member States	all

^a Minimum sample sizes are set to take account of the size of the number of healthy slaughtered ovine animals and are intended to provide achievable targets. The minimum sample sizes above 30 000 allow the detection of a prevalence of 0,003 % with a 95 % confidence.

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By way of derogation from the minimum sample sizes listed in Table A Cyprus may decide to test only a minimum of two ovine animals sent for slaughter for human consumption from every flock where no TSE cases have been registered.

(b) Caprine animals

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

TABLE B

Member State	Minimum sample size in healthy slaughtered caprine animals ^a
Greece	20 000
Spain	125 500
France	93 000
Italy	60 000
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.

- (c) Where a Member State experiences difficulty in collecting sufficient numbers of healthy slaughtered ovine or caprine animals to reach its allotted minimum sample size established in points (a) and (b), it may choose to replace a maximum of 50 % of its minimum sample size 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. In addition a Member State may choose to replace a maximum of 10 % of its minimum sample size 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.

Textual Amendments

F3 Substituted by [Commission Regulation \(EC\) No 1041/2006 of 7 July 2006 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 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 C and Table D, 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.

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TABLE C

Member State population of ewes and ewe lambs put to the ram	Minimum sample size of dead ovine animals^a
> 750 000	20 000
100 000750 000	3 000
40 000100 000	100 % up to 1 000
< 40 000	100 % up to 200

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

TABLE D

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	100 % up to 1 000
< 40 000	100 % up to 200

a Minimum sample sizes are set to take account of the size of the ovine and caprine populations 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.

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

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

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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 carcass 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.
- 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

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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 epidemic-surveillance for transmissible spongiform encephalopathies in bovine, ovine and caprine animals \(Text with EEA relevance\).](#)

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