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)

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)

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 Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the monitoring of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals.

(2) In its opinion of 4 and 5 April 2002 on a strategy to investigate the possible presence of bovine spongiform encephalopathy (BSE) in small ruminants, the Scientific Steering Committee (SSC) recommended a strategy for such investigation concerning the Community's small ruminant population.

(3) A panel of experts on strain typing has been assembled by the Community Reference Laboratory (CRL) for TSEs for further defining the strategy recommended by the SSC. The strategy includes firstly implementing a screening method of all confirmed TSE cases in small ruminants at the level of the national reference laboratories. Secondly, a ring trial with at least three different methods in selected laboratories under the heading of the CRL to be carried out on all cases in which the first screening test could not exclude BSE. Finally, mouse strain typing is required if the outcome of the molecular typing methods needs confirmation.

(4) It is necessary to ensure that brain material of an optimal quality and in sufficient quantity from positive scrapie cases is delivered to the laboratories carrying out confirmatory examinations.

(5) When molecular typing of confirmed scrapie cases reveals a BSE-like or unusual isolate, it is desirable that the competent authority should have access to brain material from other infected animals on the holding, to further assist the investigation of the case.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 36/2005. (See end of Document for details)*

(6) Four laboratories have successfully participated in a ring trial conducted by the CRL between July 2003 and March 2004 to test their proficiency in using molecular typing methods. The CRL should organise proficiency testing for other laboratories in the use of one of these molecular typing methods before April 2005.

(7) In the meantime, in view of the necessity to extend and accelerate the monitoring of caprine animals following a suspect case found in a goat, and considering the information forwarded to the CRL panel of experts by the laboratories of certain Member States on their capacity to carry out molecular testing, those laboratories should be provisionally approved for such testing pending the results of the proficiency test.

(8) Member States are submitting monthly TSE reports on a voluntary basis in addition to the annual report required by Article 6(4) of Regulation (EC) No 999/2001. The information forwarded in the annual and monthly reports should be harmonised and additional information, in particular on the age distribution of tested bovine animals, should be provided in order to evaluate the prevalence of BSE in different age groups.

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

(10) In view of the increasing urgency to differentiate BSE from scrapie, the amendments made by this Regulation should enter into force without delay.

(11) 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 and X 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 day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 12 January 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 36/2005. (See end of Document for details)*

ANNEX

Annexes III and X to Regulation (EC) No 999/2001 are amended as follows:

1. In Annex III, Chapter A, Part II and III and Chapter B, Part I are replaced by the following:

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 in accordance with the sampling rules laid down in point 4 a minimum annual sample of 10 000 ovine animals slaughtered for human consumption[(2)].

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

Member States shall test in accordance with the sampling rules laid down in point 4 and the sample sizes indicated in table A and table B respectively, 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
100 000-750 000	1 500
40 000-100 000	500
< 40 000	100

a 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[a]**

a 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 36/2005. (See end of Document for details)*

> 750 000	5 000
250 000-750 000	1 500
40 000-250 000	500
< 40 000	50

a 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. 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 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.

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