COMMISSION REGULATION (EC) No 1139/2003

of 27 June 2003

amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring programmes and specified risk material

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], as last amended by Commission Regulation (EC) No 1003/2003 [2], and in particular 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, including monitoring of a sample of animals not slaughtered for human consumption. It is necessary to clarify the definition of this group of animals, in order to avoid the inappropriate targeting of samples.

(2) Regulation (EC) No 999/2001 provides for eradication measures following the confirmation of TSE in ovine and caprine animals. Targeted testing should be carried out on animals destroyed under these measures, in order to gather epidemiological information.

(3) There is a theoretical possibility that BSE may exist in the ovine and caprine population. It is not possible using routine methods to distinguish between BSE and scrapie infection in these animals. The level of infectivity in the ileum in both diseases is significant from an early stage of infection. As a precautionary measure, the ileum of ovine and caprine animals of all ages should be added to the list of specified risk materials.

(4) In its opinion of 7 and 8 November 2002 on TSE infectivity distribution in ruminant tissues, the Scientific Steering Committee (SSC) recommended that tonsils of bovine animals of any age should be regarded as posing a risk of bovine spongiform encephalopathy (BSE).

(5) The SSC has stated that contamination with central nervous tissue and tonsil material are to be avoided when harvesting head meat and tongues of bovine animals for human consumption, to avoid any risk of BSE.

(6) As the condition of heads depends mainly on their careful handling and a safe sealing of the frontal shot hole and the foramen magnum, control systems must be in place in the slaughterhouses and in the specifically authorised cutting plants.

(7) The rules to dispatch carcases, half carcases and quarter carcases containing no specified risk material other than vertebral column to other Member States without the latter's prior agreement should be expanded to half carcases cut into no more than three wholesale cuts reflecting the actual trade between Member States.

(8) Regulation (EC) No 1774/2002 of the European Parliament and of the Council [3], amended by Commission Regulation (EC) No 808/2003 [4], lays down animal and public health rules for the collection, transport, storage, handling, processing and use or disposal of all animal by-products not intended for human consumption, including their placing on the market and, in certain specific cases, their export and transit. Special rules on removal and disposal of such products provided for in Annex XI to Regulation (EC) No 999/2001 should therefore be deleted.

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

(10) 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 XI 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 20th day following that of its publication in the *Official Journal of the European Communities*.

It shall apply from 1 October 2003.

[1] OJ L 147, 31.5.2001, p. 1.
[2] OJ L 152, 20.6.2003, p. 8.
[3] OJ L 273, 10.10.2002, p. 1.
[4] OJ L 117, 13.5.2003, p. 1.

The new provision of Annex XI, Part A, point 1(a)(ii) to Regulation (EC) No 999/2001, as set out in point 2 of the Annex to this Regulation, shall apply to animals slaughtered from 1 October 2003 onwards.

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

Done at Brussels, 27 June 2003.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Annexes III and XI are amended as follows:

1. Annex III 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.

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 points 4.1 or 4.2 shall be tested for BSE.

([1]) OJ 121, 29.7.1964, p. 2012/64
([2]) OJ L 99, 20.4.1996, p. 14.

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 destroyed in accordance with Annex V, point 3 or 4.

6.4. All parts of the body of an animal found positive to the rapid test including the hide shall be destroyed in accordance with Annex V, point 3 or 4, apart from material to be retained in conjunction with the records provided for in Chapter B, section 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 animals slaughtered for human consumption**

Animals over 18 months of age or which have more than two permanent incisors erupted through the gum and which are slaughtered for human consumption shall be tested in accordance with the sample size indicated in the table. The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, species, 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.

Member State	Minimum annual sample size Slaughtered animals (1)
Belgium	3 750
Denmark	3 000
Germany	60 000
Greece	60 000
Spain	60 000
France	60 000
Ireland	60 000
Italy	60 000
Luxembourg	250
Netherlands	39 000

Member State	Minimum annual sample size Slaughtered animals (1)
Austria	8 200
Portugal	22 500
Finland	1 900
Sweden	5 250
United Kingdom	60 000

(1) The sample size has been calculated to detect a prevalence of 0,005 % with a 95 % confidence in slaughtered animals in Member States which slaughter a large number of adult sheep. In those Member States which slaughter a smaller number of adult sheep, the sample size is calculated as 25 % of the estimated or recorded number of cull ewes slaughtered in 2000.

A Member State may test a number of animals less than that indicated in the table if the most recent official slaughter statistics indicate that this number is equivalent to 25 % of cull ewes slaughtered annually in the Member State.

3. **Monitoring in animals not slaughtered for human consumption**

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 size indicated in the table. The sampling shall be representative for each region and season. The sample selection shall be designed with a view to avoid the over-representation of any group as regards the origin, species, 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.

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.

Member State	Minimum annual sample size Dead animals (1)
Belgium	450
Denmark	400
Germany	6 000
Greece	6 000
Spain	6 000
France	6 000
Ireland	6 000
Italy	6 000
Luxembourg	30
Netherlands	5 000
Austria	1 100
Portugal	6 000
Finland	250
Sweden	800
United Kingdom	6 000

(1) The sample size has been calculated to detect a prevalence of 0,05 % with a 95 % confidence in dead animals in Member States with a large sheep population. In those Member States with a smaller sheep population, the sample size is calculated as 50 % of the estimated number of dead animals (estimated mortality 1%).