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

| | CHAPTER I |
|---|--|
| | GENERAL PROVISIONS |
| Article 1 Article 2 Article 3 Article 4 | Scope Separation of live animals and of products of animal origin Definitions Safeguard measures |
| | CHAPTER II |
| | DETERMINATION OF BSE STATUS |
| Article 5 | Classification |
| | CHAPTER III |
| | PREVENTION OF TSE |
| Article 6 Article 6a Article 7 Article 8 Article 9 Article 10 | Monitoring system Breeding Programmes Prohibitions concerning animal feeding Specified risk material Products of animal origin derived from or containing ruminant material Education programmes |
| | CHAPTER IV |
| | CONTROL AND ERADICATION OF TSEs |
| Article 11 Article 12 Article 13 Article 14 | Notification Measures with respect to suspect animals Measures following confirmation of the presence of a TSE Contingency plan |
| | CHAPTER V |
| | PLACING ON THE MARKET AND EXPORT |
| Article 15 Article 16 Article 17 Article 18 | Live animals, their semen, embryos and ova Placing on the market of products of animal origin Under the procedure referred to in Article 24(2), the health The appropriate health certificates relating to imports provided for by |

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. (See end of Document for details)

CHAPTER VI

REFERENCE LABORATORIES, SAMPLING, TESTING AND CONTROLS

| Article 19 | Reference laboratories |
|------------|---------------------------------|
| Article 20 | Sampling and laboratory methods |
| Article 21 | Community controls |

CHAPTER VII

TRANSITIONAL AND FINAL PROVISIONS

| Article 22 | Transitional measures concerning specified risk material |
|-------------|--|
| Article 23 | Amendment of the annexes and transitional measures |
| Article 23a | The following measures which are designed to amend non- |
| | essential elements |
| Article 24 | Committees |
| Article 24a | Decisions to be adopted in accordance with one of the |
| Article 25 | Consultation of the scientific committees |
| Article 26 | Entry into force |
| | Signature |
| | |

ANNEX I

SPECIFIC DEFINITIONS

- 1. For the purpose of this Regulation, the following definitions set...
- 2. For the purpose of this Regulation, the following definitions shall...

ANNEX II DETERMINATION OF BSE STATUS

CHAPTER A

Criteria

CHAPTER B

Risk analysis

- 1. Structure of the risk analysis
- 2. Entry assessment (external challenge)
 - 2.1. The entry assessment shall consist of assessing the likelihood that...
 - 2.2. Special eradication schemes, surveillance and other epidemiological investigations (especially surveillance...
- 3. Exposure assessment

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. (See end of Document for details)

CHAPTER C

Definition of categories

- I. COUNTRY OR REGION WITH A NEGLIGIBLE BSE RISK
- II. COUNTRY OR REGION WITH A CONTROLLED BSE RISK
- III. COUNTRY OR REGION WITH UNDETERMINED BSE RISK

CHAPTER D

Minimal surveillance requirements

- 1. Surveillance types
- 2. Surveillance strategy
 - 2.1. The surveillance strategy shall be designed to ensure that samples...
 - 2.2. In order to implement the surveillance strategy for BSE, a...
- 3. Points values and point targets
- 4. Specific targeting
- 5. BSE surveillance model
- 6. Maintenance surveillance

ANNEX III

MONITORING SYSTEM

CHAPTER A

- I. MONITORING IN BOVINE ANIMALS
 - 1. General
 - 2. Monitoring in animals slaughtered for human consumption
 - 2.1. All bovine animals over 24 months of age shall be...
 - 2.2. All healthy bovine animals over 30 months of age slaughtered...
 - 3. Monitoring in animals not slaughtered for human consumption
 - 3.1. All bovine animals over 24 months of age which have...
 - 3.2. Member States may decide to derogate from the provisions of...
 - 4. Monitoring in animals purchased for destruction pursuant to Regulation (EC)...
 - 5. Monitoring in other animals
 - 6. Measures following testing
 - 6.1. Where an animal slaughtered for human consumption has been selected
 - 6.2. Member States may derogate from the provisions of point 6.1...
 - 6.3. All parts of the body of an animal tested for...
 - 6.4. All parts of the body of an animal found positive...

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. (See end of Document for details)

- 6.5. Where an animal slaughtered for human consumption is found positive...
- 6.6. Member States may derogate from the provisions of point 6.5...
- 7. Revision of the annual monitoring programmes concerning BSE (BSE monitoring...
 - 7.1. Member States' applications
 - 7.2. Epidemiological criteria

II. MONITORING IN OVINE AND CAPRINE ANIMALS

- 1. General
- 2. Monitoring in ovine and caprine animals slaughtered for human consumption...
 - (a) Member States in which the population of ewes and ewe...
 - (b) Member States in which the population of goats which have...
 - (c) A Member State may choose to replace a maximum of:...
- 3. Monitoring in ovine and caprine animals not slaughtered for human...
- 4. Sampling rules applicable to the animals referred to in points...
- 5. Monitoring in holdings under TSE control and eradication measures
- 6. Monitoring in other animals
- 7. Measures following testing of ovine and caprine animals
 - 7.1. Where an ovine or caprine animal slaughtered for human consumption...
 - 7.2. Member States may derogate from point 7.1. where a system...
 - 7.3. All parts of the body of a tested animal, including...
 - 7.4. Except for the material to be retained in conjunction with...
- 8. Genotyping
 - 8.1. The prion protein genotype for the codons 136, 154 and...
 - 8.2. In addition to the animals genotyped in accordance with point...

III. MONITORING IN OTHER ANIMAL SPECIES

CHAPTER B

REPORTING AND RECORDING REQUIREMENTS

I. REQUIREMENTS ON MEMBER STATES

- A. Information to be presented by Member States in their annual...
 - 1. The number of suspected cases placed under official movement restrictions...
 - 2. The number of suspected cases subject to laboratory examination in...
 - 3. The number of flocks where suspected cases in ovine and...
 - 4. The number of bovine animals tested within each subpopulation referred...
 - 5. The number of ovine and caprine animals and flocks tested...
 - 6. The geographical distribution, including the country of origin if not...
 - 7. In animals other than bovine, ovine and caprine, the number...
 - 8. The genotype, and where possible the breed, of each ovine...
- B. Reporting periods

II. INFORMATION TO BE PRESENTED BY THE COMMISSION IN ITS SUMMARY...

III. RECORDS

1. The competent authority shall keep, for seven years, records of:...

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. (See end of Document for details)

2. The investigating laboratory shall keep, for seven years, all records...

ANNEX IV ANIMAL FEEDING

CHAPTER I

Extensions of the prohibition provided for in Article 7(1)

CHAPTER II

Derogations from the prohibitions provided for in Article 7(1) and...

CHAPTER III

General conditions for the application of certain derogations provided for...

SECTION A

Transport of feed materials and compound feed intended to be...

- 1. The following products intended to be used for feeding non-ruminant...
- 2. By way of derogation from point 1, vehicles and containers...
- 3. Bulk processed animal protein derived from non-ruminants and bulk compound...
- 4. By way of derogation from point 3, vehicles and containers...

SECTION B

Production of compound feed intended to be used for feeding...

- 1. Compound feed intended to be used for feeding non-ruminant farmed...
- 2. By way of derogation from point 1, the production of...
- 3. By way of derogation from point 1, a specific authorisation...

SECTION C

Import of feed materials and compound feed intended to be...

SECTION D

Use and storage on farms of feed intended to be...

- 1. The use and storage of the following feed shall be...
- 2. By way of derogation from point 1, the competent authority...

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. (See end of Document for details)

CHAPTER IV

Specific conditions for the application of derogations provided for in...

SECTION A

Specific conditions applicable to the production and the use of...

SECTION B

Specific conditions applicable to the use of dicalcium phosphate and...

SECTION C

Specific conditions applicable to the production and use of blood...

SECTION D

Specific conditions applicable to the production and use of processed...

SECTION E

Specific conditions applicable to the production, placing on the market...

CHAPTER V

General requirements

SECTION A

Listing

SECTION B

Transport of feed materials and compound feed containing products derived...

- 1. Bulk feed materials and bulk compound feed containing products derived...
- 2. By way of derogation from point 1, vehicles and containers...

SECTION C

Production of compound feed containing products derived from ruminants

SECTION D

Use and storage on farms of feed materials and compound...

SECTION E

Export of processed animal protein and products containing such protein...

1. The export of processed animal protein derived from ruminants, and...

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. (See end of Document for details)

- 2. The export of processed animal protein derived from non-ruminants, and...
- 3. Written agreements concluded in accordance with point 2(b) above shall...
- 4. Points 2 and 3 shall not apply to the export...

SECTION F

Official controls

- 1. Official controls carried out by the competent authority in order...
- 2. The competent authority shall verify on a regular basis the...

ANNEX V

SPECIFIED RISK MATERIAL

- 1. Definition of specified risk material
- 2. Specific requirements for Member States with negligible BSE risk status...
- 3. Marking and disposal
- 4. Removal of specified risk material
 - 4.1. Specified risk material shall be removed at:
 - 4.2. By way of derogation from point 4.1, the use of...
 - 4.3. By way of derogation from point 4.1, Member States may...
 - 4.4. The rules on removal of specified risk material laid down...
- 5. Measures concerning mechanically separated meat
- 6. Measures concerning laceration of tissues
- 7. Harvesting of tongues from bovine animals
- 8. Harvesting of bovine head meat
 - 8.1. Head meat of bovine animals above 12 months of age...
 - 8.2. By way of derogation from the requirements of point 8.1,...
 - 8.3. If the harvesting is performed without removing the bovine head...
- 9. Harvesting of bovine head meat in authorised cutting plants
- 10. Rules on trade and export
 - 10.1. Member States may allow dispatch of heads or of un-split...
 - 10.2. By way of derogation from point 10.1, carcasses, half carcasses...
 - 10.3. Exports outside the Community of heads and of fresh meat...
- 11. Controls
 - 11.1. Member States shall carry out frequent official controls to verify...
 - 11.2. Member States shall in particular set up a system to...
 - 11.3. A control system shall be put in place for the...

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. (See end of Document for details)

ANNEX VI

PRODUCTS OF ANIMAL ORIGIN DERIVED FROM OR CONTAINING RUMINANT MATERIAL, AS REFERRED TO IN ARTICLE 9(1)

ANNEX VII

CONTROL AND ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

CHAPTER A

Measures following the suspicion of the presence of a TSE...

CHAPTER B

Measures following confirmation of the presence of a TSE in...

- 1. The inquiry referred to in Article 13(1)(b) must identify:
- 2. The measures laid down in Article 13(1)(c) shall comprise at...
- 3. Following the killing and complete destruction or slaughtering for human...
- 4. Following the decision to implement option 3 laid down in...

CHAPTER C

Minimum requirements for a breeding programme for resistance to TSEs...

PART 1

General requirements

- 1. The breeding programme shall concentrate on flocks of high genetic...
- 2. A database shall be established containing at least the following...
- 3. A system of uniform certification shall be established in which...
- 4. A system for the identification of animals and samples, the...
- 5. Genotyping of blood or other tissues collected for the purposes...
- 6. The competent authority of the Member State may assist breed...
- 7. Breeding programmes shall be drawn up for each breed, taking...

PART 2

Specific rules for participating flocks

1. The breeding programme shall be aimed at increasing the frequency...

Document Generated: 2024-07-15

Status: Point in time view as at 05/08/2015.

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. (See end of Document for details)

- 2. The minimum requirements for participating flocks shall be the following:...
- 3. Member States may decide to grant derogations from the requirements...
- 4 Member States shall inform the Commission of any derogation granted...

PART 3

Specific rules for breeding rams sampled in flocks not participating...

- 1. Rams to be sampled shall be individually identified using secure...
- 2. Any ram found to carry the VRQ allele shall not...

PART 4

The framework for the recognition of the TSE-resistant status of...

- 1. The framework for the recognition of the TSE-resistant status of...
- 2. Regular random sampling of ovine animals from TSE-resistant flocks shall...

PART 5

Reports to be provided to the Commission by the Member...

ANNEX VIII PLACING ON THE MARKET AND EXPORT

CHAPTER A

Conditions for intra-Union trade in live animals, semen and embryos

SECTION A

Conditions which apply to ovine and caprine animals and semen and embryos thereof

- 1. Holdings with a negligible risk of classical scrapie and a...
 - 1.1. Member States may establish or supervise an official scheme for...
 - A holding of ovine animals having the TSE-resistance level I... 1.2.
 - 1.3. A holding of ovine and/or caprine animals may be recognised...
 - 1.4. If a case of classical scrapie is confirmed in a...
- Member States or zones of a Member State with a... 2.
 - 2.1. Where a Member State considers that its territory or part...
 - 2.2. The negligible risk status for classical scrapie of the Member...
 - The Member States or zone of the Member State with... 2.3.
- 3. National control programme for classical scrapie:
 - 3.1. a Member State which has a national control programme for...
 - 3.2. The national scrapie control programmes of the following Member States...
- 4. Intra-Union trade in ovine and caprine animals and semen and...

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. (See end of Document for details)

SECTION B

Conditions which apply to bovine animals

CHAPTER B

Conditions relating to progeny of TSE suspect or confirmed animals...

CHAPTER C

Conditions for intra-Community trade in certain products of animal origin

SECTION A

Products

SECTION B

Requirements

CHAPTER D

Conditions applicable to exports

ANNEX IX

IMPORTATION INTO THE COMMUNITY OF LIVE ANIMALS, EMBRYOS, OVA AND PRODUCTS OF ANIMAL ORIGIN

CHAPTER A

CHAPTER B

Imports of bovine animals

SECTION A

Imports from a country or a region with a negligible BSE risk

SECTION B

Imports from a country or a region with a controlled BSE risk

SECTION C

Imports from a country or a region with undetermined BSE risk

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. (See end of Document for details)

CHAPTER C

Imports of products of animal origin from bovine, ovine or caprine animals

SECTION A

Products

SECTION B

Imports from a country or a region with a negligible BSE risk

SECTION C

Imports from a country or a region with a controlled BSE risk

- 1. Imports of products of bovine, ovine and caprine animal origin...
- 2. By way of derogation from point 1(d) carcasses, half carcasses...
- 3. When removal of the vertebral column is not required, carcasses...
- 4. The number of bovine carcasses or wholesale cuts of carcasses,...
- 5. In the case of intestines originally sourced from a country...

SECTION D

Imports from a country or a region with an undetermined BSE risk

- 1. Imports of products of bovine, ovine and caprine animal origin...
- 2. By way of derogation from point 1(c), carcasses, half carcasses...
- 3. When removal of the vertebral column is not required, carcasses...
- 4. Specific information on the number of bovine carcasses or wholesale...
- 5. In the case of intestines originally sourced from a country...

CHAPTER D

Imports of animal by-products and derived products from bovine, ovine and caprine origin

SECTION A

Animal by-products

SECTION B

Health certificate requirements

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. (See end of Document for details)

CHAPTER E

Imports of ovine and caprine animals

CHAPTER F

Imports of products of animal origin from farmed and wild cervid animals

- 1. When fresh meat, minced meat, meat preparations and meat products...
- 2. When fresh meat, minced meat, meat preparations and meat products...

CHAPTER G

CHAPTER H

Import of ovine and caprine semen and embryos

ANNEX X

REFERENCE LABORATORIES, SAMPLING AND LABORATORY ANALYSIS METHODS

CHAPTER A

National reference laboratories

CHAPTER B

EU reference laboratory

CHAPTER C

Sampling and laboratory testing

- 1. Sampling
- 2. Laboratories
- 3. Methods and protocols
 - 3.1. Laboratory testing for the presence of BSE in bovine animals...
 - (a) Suspect cases
 - (b) BSE monitoring
 - (c) Further examination of positive BSE cases
 - 3.2. Laboratory testing for the presence of TSE in ovine and...
 - (a) Suspect cases
 - (b) TSE monitoring
 - (c) Further examination of positive TSE cases
 - (i) Primary molecular testing with a discriminatory Western blotting method

Document Generated: 2024-07-15

Status: Point in time view as at 05/08/2015.

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. (See end of Document for details)

| (ii) | Secondary mo | lecular tes | sting with | additional | molecul | ar testing |
|------|--------------|-------------|------------|------------|---------|------------|
| | methods | | | | | |

- (iii) Mouse bioassay
- 3.3. Laboratory testing for the presence of TSEs in species other...
- 4. Rapid tests
- 5. Alternative tests

ANNEX XI

| | | 200 (0.000) | | | | | |
|----|-------|--|--|--|--|--|--|
| | TRA | NSITIONAL MEASURES REFERRED TO IN ARTICLES 22 AND 23 | | | | | |
| A. | | erning specified risk material, mechanically recovered meat and slaughtering | | | | | |
| | techn | techniques | | | | | |
| | 1. | | | | | | |
| | 2. | | | | | | |
| | 3. | | | | | | |
| | 4. | | | | | | |
| | 5. | | | | | | |
| | 6. | | | | | | |
| | 7. | | | | | | |
| | 8. | | | | | | |
| | 9. | | | | | | |
| | 10. | | | | | | |
| | 11. | | | | | | |
| | 12. | | | | | | |
| | 13. | | | | | | |
| | 14. | | | | | | |
| | 15. | | | | | | |
| B. | Conc | Concerning statistical surveys | | | | | |
| | 1. | | | | | | |
| | 2. | | | | | | |
| C. | Conc | erning prohibitions on animal feeding | | | | | |
| D. | Conc | Concerning placing on the market and export | | | | | |
| | 1. | | | | | | |
| | 2. | | | | | | |
| | 3. | | | | | | |
| | 4. | | | | | | |
| | 4. | | | | | | |
| | 5. | | | | | | |

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. (See end of Document for details)

- (1) OJ C 45, 19.2.1999, p. 2 and OJ C 120 E, 24.4.2001, p. 89.
- (2) OJ C 258, 10.9.1999, p. 19.
- (3) Opinion of the European Parliament of 17 May 2000 (OJ C 59, 23.2.2001, p. 93), Common Position of the Council of 12 February 2001 (OJ C 88, 19.3.2001, p. 1) and Decision of the European Parliament of 3 May 2001.
- (4) [F1OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p. 25).]
- (5) [F1OJ C 174 E, 14.7.2005, p. 178.;]
- (**6**) OJ L 184, 17.7.1999, p. 23.

Textual Amendments

F1 Inserted by Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18

December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance).

Status:

Point in time view as at 05/08/2015.

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.