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

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Reference laboratories

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Sampling and laboratory methods

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

#### CHAPTER C

#### Definition of categories

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

#### CHAPTER D

#### Minimal surveillance requirements

- 1. Surveillance types
- 2. Surveillance strategy
  - The surveillance strategy shall be designed to ensure that samples... 2.1.
  - 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
    - All bovine animals over 24 months of age shall be... 2.1.
    - 2.2. All healthy bovine animals over 30 months of age slaughtered...
  - Monitoring in animals not slaughtered for human consumption 3.
    - 3.1. All bovine animals over 24 months of age which have...
    - 3.2. Point 3.1 does not prevent the exercise by the appropriate...
  - Monitoring in animals purchased for destruction pursuant to Regulation (EC)... 4.
  - Monitoring in other animals 5.
  - Measures following testing 6.
    - Where an animal slaughtered for human consumption has been 6.1.
    - 6.2. The appropriate authority need not comply with point 6.1 where...
    - All parts of the body of an animal tested for... 6.3.
    - All parts of the body of an animal found positive... 6.4.

- 6.5. Where an animal slaughtered for human consumption is found positive...
- The appropriate authority may decide not to destroy the carcases... 6.6.
- 7. Revision of the annual monitoring programmes concerning BSE (BSE monitoring...

#### II. MONITORING IN OVINE AND CAPRINE ANIMALS

- General 1.
- 2. Monitoring in ovine and caprine animals slaughtered for human consumption...
  - The appropriate authorities shall test a minimum annual sample of...
  - (b)
  - (c) The Secretary of State, with the consent of the other...
- 3. Monitoring in ovine and caprine animals not slaughtered for human...
- Sampling rules applicable to the animals referred to in points... 4.
- 5. Monitoring in holdings under TSE control and eradication measures
- Monitoring in other animals 6.
- Measures following testing of ovine and caprine animals 7.
  - Where an ovine or caprine animal slaughtered for human 7.1. consumption...
  - 7.2. The appropriate authority may decide not to comply with point...
  - 7.3. All parts of the body of a tested animal, including...
  - 7.4. All parts of the body of an animal found positive...
- 8. Genotyping

#### III. MONITORING IN CERVIDS

Three-year monitoring programme for chronic wasting disease (CWD) Α

B. Monitoring in cervids

#### IV. MONITORING IN OTHER ANIMAL SPECIES

#### CHAPTER B

#### REPORTING AND RECORDING REQUIREMENTS

#### I. REOUIREMENTS ON APPROPRIATE AUTHORITIES

- Information to be presented by appropriate authorities in their annual... A.
  - The number of suspected cases placed under official movement 1. restrictions...
  - 2. The number of suspected cases subject to laboratory examination in...
  - The number of flocks where suspected cases in ovine and... 3.
  - 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...
  - In animals other than bovine, ovine and caprine animals, as... 7.
  - 8. The genotype, and, where possible, the breed, of each ovine...
- B. Reporting periods

#### II. INFORMATION TO BE PRESENTED IN THE UNION SUMMARY REPORT

#### III. RECORDS

- 1. The competent authority shall keep, for 7 years, records of...
- 2. The investigating laboratory shall keep, for 7 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 and storage of feed materials and compound feed intended...

- 1. The following products intended to be used for feeding non-ruminant...
- 2. By way of derogation from point 1, vehicles, containers and...
- 3. Storage plants storing in accordance with point 2 feed materials...
- 4. Bulk processed animal protein derived from non-ruminants, including processed animal...
- 5. By way of derogation from point 4, vehicles, containers and...

#### 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...

#### **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...

#### SECTION F

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

#### CHAPTER V

General requirements

#### SECTION A

#### Listing

- 1. The appropriate authority shall keep up-to-date and make publicly available...
- 2. Member States shall keep up-to-date lists of home compounders registered...

#### **SECTION B**

Transport and storage of feed materials and compound feed containing...

1. Bulk feed materials and bulk compound feed containing products derived...

2. By way of derogation from point 1, vehicles, containers and...

#### SECTION C

Production of compound feed intended for fur animals or for...

- 1. Compound feed intended for fur animals or for pet animals...
- 2. Compound feed intended for fur animals or for pet animals,...

#### 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, or...
- 2. Without prejudice to point 1, the export of products containing...
- 3. The export of processed animal protein derived from non-ruminants, or...
- 4. By way of derogation from point 3, the conditions laid...
- 5. The export of organic fertilisers or soil improvers that contain...

#### 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 countries 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, the appropriate authority...
  - The rules on the removal of specified risk material set... 4.4.

- 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. The appropriate authority may allow dispatch of heads or of...
  - 10.2. By way of derogation from point 10.1, carcasses, half carcasses...
  - 10.3. Exports outside the European Union of heads and of fresh...
- 11. Controls
  - 11.1. The appropriate authority shall carry out frequent official controls to...
  - 11.2. The appropriate authority shall in particular set up a system...
  - 11.3. A control system shall be put in place for the...

#### 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...
- A system of uniform certification shall be established in which... 3.
- 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 ... may assist breed societies, to establish...
- 7. Breeding programmes shall be drawn up for each breed, taking...
- 8. Where the appropriate authority allows, in accordance with the second...

#### PART 2

#### Specific rules for participating flocks

- 1. The breeding programme shall be aimed at increasing the frequency...
- 2. The minimum requirements for participating flocks shall be the following:...
- 3. Nothing in these Regulations prevents the appropriate authority from deciding...
- 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...

- The framework for the recognition of the TSE-resistant status of... 1.
- 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 ... 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...
- 2. A constituent nation of an appropriate authority or a zone...
  - 2.1. Where an appropriate authority considers that its territory or part...
  - 2.2. ..
  - 2.3. ...
- 3. National control programme for classical scrapie:
  - 3.1. each constituent nation must have a national control programme for...
  - 3.2. Within the European Union the national scrapic control programmes for...
- 4. ...

#### 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

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**Products** 

SECTION B

Requirements

CHAPTER D

Conditions applicable to exports

#### ANNEX IX

#### IMPORTATION INTO GREAT BRITAIN OF LIVE ANIMALS, EMBRYOS, OVA AND PRODUCTS OF ANIMAL ORIGIN

#### CHAPTER B

#### Imports of bovine animals

#### SECTION A

Imports from a country or a region with a negligible...

#### SECTION B

Imports from a country or a region with a controlled...

#### SECTION C

Imports from a country or a region with undetermined BSE...

#### CHAPTER C

Imports of products of animal origin from bovine, ovine or...

#### **SECTION A**

#### **Products**

#### SECTION B

Imports from a country or a region with a negligible...

#### SECTION C

Imports from a country or a region with a controlled...

- 1. Imports of products of bovine, ovine and caprine animal origin...
- 2. For products of bovine animal origin, by way of derogation...
- 3. When the removal of the vertebral column is 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...

Imports of products of bovine, ovine and caprine animal origin... 1.

- 2. For products of bovine animal origin, by way of derogation...
- 3. When removal of the vertebral column is required, carcasses or...
- 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...

#### SECTION A

Animal by-products

#### SECTION B

Health certificate requirements

#### CHAPTER E

Imports of ovine and caprine animals

### CHAPTER F

Imports of products of animal origin from farmed and wild...

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

#### 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

B.

1.

Concerning statistical surveys

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

	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 (ii) Secondary molecular testing with additional molecular testing methods (iii) Mouse bioassay
	3.3. Laboratory testing for the presence of TSEs in species other
<ol> <li>4.</li> <li>5.</li> </ol>	Rapid tests Alternative tests
3.	Alternative tests
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	TRANSITIONAL MEASURES REFERRED TO IN ARTICLES 22 AND 23
A.	Concerning specified risk material, mechanically recovered meat and slaughtering techniques
	1.

	2
C.	Concerning prohibitions on animal feeding
D.	Concerning placing on the market and export  1

- (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).

### **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.