

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*

**Scope**

- 1 This Regulation lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It shall apply to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.
- 2 This Regulation shall not apply to:
  - a cosmetic or medicinal products or medical devices, or to their starting materials or intermediate products;
  - b products which are not intended for use in human food, animal feed or fertilisers, or to their starting materials or intermediate products;
  - c products of animal origin intended for exhibition, teaching, scientific research, special studies or analysis, provided those products are not eventually consumed or used by humans or by animals other than those kept for the research projects concerned;
  - d live animals used in or intended for research.

*Article 2*

**Separation of live animals and of products of animal origin**

In order to avoid cross-contamination or substitution between the live animals or of the products of animal origin referred to in Article 1(1) and the products of animal origin referred to in Article 1(2)(a), (b) and (c), or the live animals referred to in Article 1(2) (d), they shall be kept separate at all times unless such live animals or products of animal origin are produced under at least the same conditions of health protection in respect of TSEs.

Rules for the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 24(2).

*Article 3*

**Definitions**

- 1 For the purposes of this Regulation the following definitions shall apply:
  - a TSEs: all transmissible spongiform encephalopathies with the exception of those occurring in humans;

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- b placing on the market: any operation the purpose of which is to sell live animals or products of animal origin covered by this Regulation to a third party in the Community, or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;
- c products of animal origin: any product derived from or containing a product derived from any animal covered by the provisions of Directive 89/662/EEC<sup>(1)</sup> or Directive 90/425/EEC<sup>(2)</sup>;
- d starting materials: raw materials or any other product of animal origin out of which, or with the help of which, the products referred to in Article 1(2)(a) and (b) are produced;
- e competent authority: the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that central authority has delegated that competence, in particular for the control of feedingstuffs; it shall also include, where appropriate, the corresponding authority of a third country;
- f category: one of the classification categories referred to in Chapter C of Annex II;
- g specified risk material: the tissues specified in Annex V; unless otherwise indicated, it does not include products containing or derived from those tissues;
- h animal suspected of being infected by a TSE: live, slaughtered or dead animals, which show or have shown neurological or behavioural disorders or a progressive deterioration of the general condition linked to impairment of the central nervous system and for which the information gathered on the basis of a clinical examination, response to treatment, a post-mortem examination or an ante or post-mortem laboratory analysis do not allow an alternative diagnosis to be established. Bovine spongiform encephalopathies (BSE) shall be suspected in bovine animals which have produced a positive result from a rapid test specifically for BSE;
- i holding: any place in which animals covered by this Regulation are held, kept, bred, handled or shown to the public;
- j sampling: the taking of samples, ensuring a statistically correct representation, from animals or their environment, or from products of animal origin, for the purpose of establishing a disease diagnosis, familial relationships, for health surveillance, or for the monitoring of the absence of microbiological agents or of certain materials in products of animal origin;
- k fertilisers: any substance containing products of animal origin utilised on land to enhance growth of vegetation; it may include digestion residues from bio-gas production or composting;
- [<sup>F1</sup> rapid tests: the screening methods listed in Annex X, for which the results are known within 24 hours;]
- m alternative test: the tests referred to in Article 8(2) which are used as an alternative to the withdrawal of specified risk material[<sup>F1</sup>];]
- [<sup>F2</sup>n mechanically separated meat or 'MSM': the product obtained by removing meat from flesh-bearing bones after boning, using mechanical means resulting in the loss or modification of the muscle fibre structure;
- o passive surveillance: the reporting of all animals suspected of being infected by a TSE and, where TSE cannot be excluded by clinical investigation, the laboratory testing of such animals;
- p active surveillance: the testing of animals not reported as suspected of being infected by a TSE, such as emergency slaughtered animals, animals with observations at ante mortem inspection, fallen stock, healthy slaughtered animals and animals culled in connection with a TSE case, in particular in order to determine the evolution and prevalence of TSE in a country or region thereof.]

2 The specific definitions set out in Annex I shall also apply.

3 Where the terms in this Regulation are not defined in paragraph 1 or Annex I, the relevant definitions given in Regulation (EC) No 1760/2000<sup>(3)</sup> and those given in or pursuant to Directives 64/432/EEC<sup>(4)</sup>, 89/662/EEC, 90/425/EEC and 91/68/EEC<sup>(5)</sup> shall apply insofar as reference is made to them in this text.

#### **Textual Amendments**

- F1** Substituted 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).
- F2** 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).

### *Article 4*

#### **Safeguard measures**

1 With regard to the implementation of safeguard measures, the principles and provisions set out in Article 9 of Directive 89/662/EEC, Article 10 of Directive 90/425/EEC, Article 18 of Directive 91/496/EEC<sup>(6)</sup> and Article 22 of Directive 97/78/EC<sup>(7)</sup> shall apply.

2 The safeguard measures shall be adopted in accordance with the procedure referred to in Article 24(2) and shall be notified at the same time to the European Parliament, stating the reasons.

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- (1) Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ L 395, 30.12.1989, p. 13). Directive as last amended by Council Directive 92/118/EEC (OJ L 62, 15.3.1993, p. 49).
- (2) Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29). Directive as last amended by Council Directive 92/118/EEC.
- (3) Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).
- (4) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 121 29.7.1964, p. 1977/64). Directive as last amended by Directive 2000/20/EC of the European Parliament and of the Council (OJ L 163, 4.7.2000, p. 35).
- (5) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Commission Decision 94/953/EC (OJ L 371, 31.12.1994, p. 14).
- (6) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ L 268, 24.9.1991, p. 56). Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).
- (7) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

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