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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laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the Economic and Social Committee[(2)],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

Whereas:

(1) Several distinct transmissible spongiform encephalopathies (TSEs) have for a number of years been recognised as occurring separately in humans and animals. Bovine spongiform encephalopathy (BSE) was first recognised in bovine animals in 1986 and in the following years was recognised as occurring in other species of animal. A new variant of Creutzfeldt-Jakob Disease (CJD) was described in 1996. Evidence continues to grow of the similarity between the BSE agent and that of the new variant of Creutzfeld-Jakob Disease.

(2) Since 1990 the Community has adopted a series of measures to protect human and animal health from the risk of BSE. Those measures have been based on the safeguard provisions of Directives on animal-health measures. It is appropriate, in view of the magnitude of the risk posed to human and animal health by certain TSEs, to adopt specific rules for their prevention, control and eradication.

(3) This Regulation directly concerns public health and is relevant to the functioning of the internal market. It covers products which are included in Annex I to the Treaty as well as products which are not. Consequently, it is appropriate to choose Article 152(4)(b) of the Treaty as the legal basis.

(4) The Commission has obtained scientific opinions, in particular from the Scientific Steering Committee and the Scientific Committee on Veterinary Measures relating to Public Health, on several aspects of TSEs. Those opinions include advice on measures

to reduce the potential risk for humans and animals resulting from exposure to infected animal products.

(5) These rules should apply to the production and placing on the market of live animals and products of animal origin. However, it is not necessary for them to apply to cosmetic or medicinal products, medical devices or their starting materials or intermediate products, for which other specific rules, in particular on the non-use of specified risk material, apply. Nor should they apply to products of animal origin which do not pose a risk to animal or human health since they are intended for purposes other than the production of food, feed or fertiliser. It is appropriate to ensure that products of animal origin excluded from the scope of this Regulation are kept separate from those covered by it unless they meet at least the same health standards as the latter.

(6) Provision should be made for safeguard measures to be taken by the Commission in cases where a risk from a TSE has not been adequately addressed by the competent authority of a Member State or third country.

(7) A procedure should be established for the determination of the epidemiological status of a Member State, a third country and of one of their regions, hereinafter referred to as 'countries or regions' with respect to BSE, on the basis of the incident propagation and human exposure risk, using information available. Member States and third countries which choose not to apply for their status to be determined should be classified in a category by the Commission on the basis of all the information available to it.

(8) Member States should institute education programmes for those involved in the prevention and control of TSEs, as well as for veterinarians, farmers and workers involved in the transportation, marketing and slaughter of farm animals.

[[F1](8a) The feeding to non-ruminants of certain processed animal proteins originating from non-ruminants should be allowed taking into account the prohibition on intra-species recycling as laid down in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[(4)] and the control aspects in particular linked to the differentiation of processed animal proteins specific to certain species as laid down in the Communication on the TSE Road map adopted by the Commission on 15 July 2005.**]**

(9) Member States should carry out an annual programme for monitoring BSE and scrapie and should inform the Commission and the other Member States of the results and of the emergence of any other TSE.

(10) Certain ruminant tissues should be designated as specified risk material on the basis of the pathogenesis of TSEs and the epidemiological status of the country or region of origin or residence of the animal concerned. The specified risk material should be removed and disposed of in a manner which avoids any risk to human or animal health. In particular, it should not be placed on the market to be used in the production of food, feed or fertiliser. However, provision should be made for an equivalent level of health protection by means of a screening test for TSEs carried out on individual animals as soon as it has been fully validated. Slaughter techniques presenting a risk of

causing brain material to contaminate other tissues should not be permitted in countries or regions other than those presenting the lowest risk of BSE.

(11) Measures should be taken to prevent the transmission of TSEs to humans or animals by prohibiting the feeding of certain categories of animal protein to certain categories of animal, and by prohibiting the use of certain ruminant materials in food. Those prohibitions should be proportionate to the risks involved.

[F1(11a) In its resolution of 28 October 2004(5), the European Parliament expressed concerns about feeding animal proteins to ruminants as they do not form part of the natural nutrition of adult cattle. In the wake of the BSE crisis and the foot-and-mouth disease crisis it has increasingly become accepted that the best way to ensure human and animal health is to keep and nourish animals in a way that respects the particularities of each species. Pursuant to the precautionary principle and in keeping with the natural diet and living conditions of ruminants, it is therefore necessary to maintain the prohibition on the feeding of animal proteins to ruminants in forms not normally constituting part of their natural diet.

(11b) Mechanically separated meat is obtained by removing meat from bones in such a way that the muscle fibre structure is destroyed or modified. It can contain parts of the bones and the periosteum (bone skin). Thus, mechanically separated meat is not comparable with regular meat. Consequently its use for human consumption should be reviewed.**]**

(12) The suspected presence of any TSE in any animal should be notified to the competent authority, which should immediately take all appropriate measures, including placing the suspect animal under movement restrictions while awaiting the results of the investigation or having it slaughtered under official supervision. If the competent authority cannot exclude the possibility of a TSE, it should have the appropriate investigations carried out and should keep the carcasse under official supervision until a diagnosis has been made.

(13) In the event of official confirmation of the presence of a TSE, the competent authority should take all the necessary measures, including having the carcasse destroyed, carrying out an investigation in order to identify all animals at risk and placing movement restrictions on the animals and the products of animal origin identified as such. Owners should be compensated, as soon as possible, for the loss of animals and products of animal origin destroyed pursuant to this Regulation.

(14) Member States should draw up contingency plans for the national measures to be implemented in the event of an outbreak of BSE. Those plans should be approved by the Commission. Provision should be made for extending this provision to TSEs other than BSE.

(15) Provisions should be laid down covering the placing on the market of certain live animals and products of animal origin. Existing Community rules on the identification and registration of bovine animals provide for a system enabling the animals to be traced back to the dam and herd of origin in accordance with international standards. Equivalent guarantees should be provided for bovine animals imported from third countries. The animals and products of animal origin covered by Community

rules, moving in intra-Community trade or imported from third countries, should be accompanied by the certificates required by the said rules, supplemented as appropriate in accordance with this Regulation.

(16) The placing on the market of certain products of animal origin derived from bovine animals in high risk regions should be prohibited. However, that prohibition should not apply to certain products of animal origin produced under controlled conditions from animals which can be demonstrated not to pose a high risk of infection with a TSE.

(17) It is necessary, in order to ensure that the rules concerning the prevention, control and eradication of TSEs are observed, for samples to be taken for laboratory testing on the basis of an established protocol which would give a full epidemiological picture of the situation as regards TSE. In order to guarantee uniform testing procedures and results, national and Community Reference Laboratories and reliable scientific methods, including rapid tests specifically for TSEs, should be established. Rapid tests should be used as far as possible.

(18) Community inspections should be carried out in the Member States in order to ensure uniform implementation of the requirements concerning the prevention, control and eradication of TSEs and provision should also be made for the implementation of audit procedures. In order to ensure that guarantees equivalent to those applied by the Community are provided by third countries upon import into the Community of live animals and products of animal origin, Community on-the-spot inspections and audits should be carried out in order to verify that the import conditions are met by exporting third countries.

(19) Trade measures for TSEs should be based on international standards, guidelines or recommendations, where they exist. However, scientifically justified measures resulting in a higher level of health protection may be adopted if measures based on the relevant international standards, guidelines or recommendations would not achieve the appropriate level of health protection.

(20) This Regulation should be re-examined as new scientific information becomes available.

(21) The necessary transitional measures in particular for regulating the use of specified risk material should be provided for in the framework of this Regulation.

(22) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedure for the exercise of implementing powers conferred on the Commission[(6)].

(23) In order to implement this Regulation, procedures should be laid down establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee, the Standing Committee on Feedingstuffs, and the Standing Committee on Foodstuffs.

(24) Given that the provisions for the implementation of this Regulation are general measures within the meaning of Article 2 of Decision 1999/468/EC, they should be

adopted in accordance with the regulatory procedure laid down in Article 5 of that Decision,

HAVE ADOPTED THIS REGULATION:

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).

(**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**) **[**[F1]OJ 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**) **[**[F1]OJ C 174 E, 14.7.2005, p. 178.;**]**

(**6**) OJ L 184, 17.7.1999, p. 23.

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Status:
Point in time view as at 02/11/2007.

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, Introductory Text.