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COMMISSION DECISION

of 29 June 2000

regulating the use of material presenting risks as regards transmissible spongiform encephalopathies and amending Decision 94/474/EC

(notified under document number C(2000) 1735)

(Text with EEA relevance)

(2000/418/EC)

(OJ L 158, 30.6.2000, p. 76)

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►M2	Commission Decision 2001/233/EC of 14 March 2001	L 84	59	23.3.2001
►M3	Commission Decision 2001/270/EC of 29 March 2001	L 94	29	4.4.2001

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(Text with EEA relevance)

(2000/418/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in infra-Community trade with a view to the completion of the internal market [1], as last amended by Directive 92/118/EEC [2], and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in infra-Community trade in certain live animals and products with a view to the completion of the internal market [3], as last amended by Directive 92/118/EEC, and in particular Article 10(4) thereof,

Having regard to 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 [4], and in particular Article 22 thereof,

Whereas:

(1) Several distinct transmissible spongiform encephalopathies (TSEs) have been recognised for many years as occuring separately in humans and animals. Bovine Spongiform Encephalopathy (BSE) was first recognised in bovine animals in 1986 and in following years was recognised as occurnng in other species of animals. A new variant of Creutzfeldt-Jakob Disease (v-CJD) was described in 1996. Evidence is accumulating that the agent causing BSE is identical to that causing v-CJD.

(2) The Scientific Veterinary Committee in its opinion of 21 October 1996, recommended on the basis of its risk assessment that specified risk materials, defined as brain, spinal cord and eyes from cattle, sheep and goats over one year of age and spleens from sheep and goats over six months of age, should be removed from all human food and animal feed chains in countries or regions where a potential risk was identified. It also recommended that, in the case of fallen bovine animals, sheep and goats, either the specified risk materials should be removed so that they do not enter any human food or animal feed chain, or the whole carcass should be destroyed.

(3) The Scientific Steering Committee (SSC) adopted an opinion on 9 December 1997. It suggested a new and enlarged list of specified risk materials and proposed that those materials should be excluded temporarily from human and animal consumption depending on the geographical source. It added dura mater, pituitary, dorsal root ganglia, vertebral column, intestine and lung when animals are killed by certain slaughter techniques, to the list recommended by the above opinion of the Scientific Veterinary Committee of 21 October 1996. The SSC adopted on 14 April 2000 an opinion on the United Kingdom decision to lift the ban on the consumption of meat on the bone. It concluded that the risk from meat on the bone is negligible if the bones are not from the vertebral column or skull. It furthermore concluded that the combined effect of several protection measures in the United Kingdom results in an extremely small risk of human exposure to BSE from vertebral column and dorsal root ganglia. This Committee adopted on the same date an opinion on specified risk materials of small

(1) OJ L 395, 30.12.1989, p. 13.
(2) OJ L 62, 15.3.1993, p. 49.
(3) OJ L 224, 18.8.1990, p. 29.
(4) OJ L 24, 30.1.1998, p. 9.

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ruminants. It stated that skull (head excluding skin and tongue) and spinal cord of all small ruminants above 12 months and the spleen of small ruminants of all ages pose the highest risk. It also stated that certain unprocessed meat products, such as mechanically recovered meat derived from the vertebral column of small ruminants constitutes a significant potential risk.

(4) The Commission adopted on 18 November 1998 a proposal based on Article 152(4) of the Treaty (COM(1998) 623 final) for a Regulation of the European Parliament and of the Council laying down rules for the prevention and control of certain transmissible spongiform encephalopathies [1]. That proposal was submitted to the European Parliament and the Council on 7 January 1999. That proposal includes rules on the removal and disposal of specified risk materials. The provisions of this Decision will be repealed when that Regulation enters into force.

(5) Rules should be laid down concerning the production and placing on the market of products of animal origin with respect to removal of, or absence of, specified risk material. In particular, they should not be placed on the market for human food, animal feed or fertiliser. However, those rules should not apply to cosmetic or medicinal products or medical devices, or their starting materials or intermediate products, for which other specific rules apply. They should also not 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 human food, animal feed or fertiliser. It is appropriate to ensure that products of animal origin outside the scope of this Decision are kept separate from those within it unless they meet at least the same health standards as the latter.

(6) Existing Community Directives provide for the protection of public health in respect of the use of specified risk material in cosmetic or medicinal products and medical devices placed on the market in the Community. Therefore, those products may be excluded from the scope of this Decision.

(7) Commission Decision 98/272/EC of 23 April 1998 on epidemio-surveillance for transmissible spongiform encephalopathies [2] lays down the rules for measures to be taken by Member States where a transmissible spongiform encephalopathy (TSE) is suspected in an animal, the minimum requirements for the monitoring of bovine spongiform encephalopathy (BSE) and scrapie and the rules for sampling and laboratory testing for the presence of a TSE. The Commission has undertaken to amend Decision 98/272/EC with the objective to improve the efficacy of the monitoring for BSE in bovine animals by use of tests targeting in particular dead-onfarm (fallen stock) and emergency slaughtered animals. These measures are expected to provide a better insight into the regional epidemiological situation.

(8) Certain ruminant tissues should be designated as specified risk materials 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 materials should be removed and disposed of in a manner that avoids any risk to human or animal health. It is necessary for practical and precautionary reasons to exclude the use of spleens from sheep and goats irrespective of age, and mechanically recovered meat from the skull and vertebral column of bovine animals, sheep and goats.

(9) The SSC and the Scientific Committee on Veterinary Measures relating to Public Health recommended on the safety of certain slaughter techniques in their opinions adopted on 9 December 1997 and on 25 June 1999, and on 17 February 1998 respectively. They concluded that certain slaughter techniques, notably pneumatic stunning by gas injection and laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into cranial cavity ('pithing') could cause the dissemination of potentially contaminated central nervous tissue throughout the body during slaughter. Council Directive 93/119/EC of 22 December 1993 on the

(1) OJ C 45, 19.2.1999, p. 2.
(2) OJ L 122, 24.4.1998, p. 59.

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protection of animals at the time of slaughter or killing [1], prohibits the use of these techniques for the stunning and killing of animals. Therefore, the use of those techniques should not be permitted for other purposes in the Community, and upon import from countries or regions with a risk of BSE.

(10) The Commission will review the provisions to take into account the effectiveness of the feed ban and the need to remove vertebral column from certain cattle subpopulations, as soon as possible in the light of new scientific information and assessments, as well as the development of the recommendations of the World Organisation for Animal Health (Office International des Epizooties), or any other relevant information available to the Commission. The review with respect to the effective enforcement of the prohibition on the feeding of ruminants with meat-and bone meal and greaves derived from ruminants envisages confining the provisions of this Decision to animals born before the date of the effectiveness of that ban.

(11) The SSC, in its opinion of 23 January 1998, has established the list of factors determining the geographical risk in a given geographical zone, and, in its opinion of 19 and 20 February 1998, the contents of a complete dossier for epidemiological status with respect to TSEs. On the basis of these opinions the Commission issued Recommendation 98/477/EC [2] of 22 July 1998 concerning information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiform encephalopathies and inviting Member States and non-member countries to submit dossiers according to this recommendation for recognition of their epidemiological status. The Commission will review the provisions for the import of products of animal origin as soon as possible in the light of scientific assessments using the information submitted in accordance with Recommendation 98/477/EC, as well as the development of the recommendations of the World Organisation for Animal Health (Office International des Epizooties). It therefore repeats its invitation to submit a dossier in accordance with that Recommendation for those countries that have not yet done so and will make every effort to obtain a scientific assessment within 12 months of the dossier submission.

(12) Commission Decision 94/474/EC of 27 July 1994 concerning certain protection measures relating to bovine spongiform encephalopathy and repealing Decisions 89/469/EEC and 90/200/EEC [3], as last amended by Decision 98/272/EEC, should be amended accordingly.

(13) On the basis of the advice of the Scientific Veterinary Committee of 21 October 1996, in accordance with the risk assessment carried out by that Committee, the Commission adopted Decision 97/534/EC of 30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies [4], which was last amended by Council Decision 1999/881/EC [5]. In the light of the new scientific advice, the development of international standards and progress on the legislative process on adopting primary legislation in this area, the definition of specified risk materials laid down in Decision 97/534/EC and the rules it lays down are no longer appropriate. This Decision should therefore be repealed.

(14) Separate rules may be adopted on the treatment and disposal of animal by-products.

(15) The Standing Veterinary Committee has not given an opinion; the Commission has therefore proposed these measures to the Council on 16.6.2000 in accordance with Article 17 of Directive 89/662/EEC, the Council being required to act within 15 days.

(16) However, the Council has not acted within the required time limit; the Council has not decided against the proposed measures by simple majority within the same time limit; these measures should now be adopted by the Commission,

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[1] OJ L 340, 31.12.1993, p. 21.
[2] OJ L 212, 30.7.1998, p. 58.
[3] OJ L 194, 29.7.1994, p. 96.
[4] OJ L 216, 8.8.1997, p. 95.
[5] OJ L 331, 23.12.1999, p. 78.

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HAS ADOPTED THIS DECISION:

Article 1

Scope

1. This Decision regulates the use of material presenting risks as regards certain transmissible spongiform encephalopathies (TSEs). It shall apply to the production and placing on the market of products of animal origin derived from or containing material of the bovine, ovine or caprine animal species.

2. Articles 3 to 8 shall not apply to:

(a) cosmetic or medicinal products or medical devices, together with their starting materials or intermediate products;

(b) products not destined for use in human food, animal feed or fertilisers, together with their starting materials or intermediate products;

(c) products of animal origin destined for exhibition, teaching, research, special studies or analysis, provided those products are not eventually consumed by humans or by animals other than those kept for the research projects concerned.

3. In order to avoid cross-contamination or substitution, products of animal origin referred to in Article 1(1) shall be kept separate at all times from those referred to in Article 1(2), unless the latter are handled or produced under at least the same conditions of health protection in respect of TSEs.

Article 2

Definitions

For the purposes of this Decision, the following definitions shall apply:

1. 'transmissible spongiform encephalopathies or TSEs': all TSEs with the exception of those occurring in humans;

2. 'placing on the market': any operation the purpose of which is to sell products of animal origin covered by this Decision to a third party, or any other form of supply against payment or free of charge to a third party, or storage with a view to supply to a third party;

3. 'products of animal origin': any products derived from or containing a product derived from any animal;

4. 'starting materials': raw materials or any other product of animal origin from which, or with the help of which, the products referred to in Article 1(2)(a) and (b) are produced;

5. '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;

6. 'competent authority': the central authority of a Member State competent to ensure compliance with the requirements of this Decision or any authority to which that central authority has delegated such competence;

7. 'specified risk material': the tissues referred to in Annex I; unless otherwise specified, it does not include products containing or derived from those tissues;

8. 'landfill site': landfill site as defined by Council Directive 1999/31/EC ([1]).

Article 3

Specified risk material

1. Member States shall ensure that after 1 October 2000 the specified risk materials referred to in Annex I, point 1(a), and as appropriate point 1(b), are removed and destroyed in accordance with Annex I, points 2 to 5.

([1]) OJ L 182, 16.7.1999, p. 1.

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2. The specified risk materials or the processed material thereof may be dispatched only for arrangements of eventual incineration in accordance with Annex I, point 5, and, as appropriate, Article 7, paragraph (b).

Article 4

Mechanically recovered meat

Member States shall ensure that bones ►M2 ——————— ◄ of bovine, ovine and caprine animals shall not be used for the production of mechanically recovered meat after 1 October 2000.

Article 5

Slaughter techniques

Member States shall ensure that the laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into cranial cavity shall not be used after 31 December 2000 on their territory on bovine, ovine or caprine animals whose meat is destined for human or animal consumption.

▼M3

Article 6

Import into the Community

1. The specified risk materials referred to in Annex I, point 1(a) shall not be imported into the Community after 31 March 2001.

2. (a) Where the products of animal origin listed in Annex II, containing material derived from bovine, ovine or caprine animals, are imported into the Community after 31 March 2001 from third countries or regions thereof, the appropriate health certificate shall be supplemented by a declaration signed by the competent authority of the country of production, worded as follows:

'The product of animal origin does not contain, and is not derived from, specified risk material as defined in Annex I, point 1(a) of Decision 2000/418/EC, produced after 31 March 2001, or mechanically recovered meat obtained from the bones of bovine, ovine or caprine animals, produced after 31 March 2001. The animals have not been slaughtered, after 31 March 2001, after stunning by means of a gas injected into the cranial cavity or killed instantaneously by the same method, or slaughtered after laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.'

(b) Any reference to 'products of animal origin' in this Article is a reference to the products of animal origin listed in Annex II, not to other products of animal origin containing or derived from those products of animal origin.

3. The provisions of paragraphs 1 and 2 shall not apply to:

(a) the third countries listed in Annex III;

(b) without prejudice to the national measures in place before 31 March 2001, consignments which have left third countries prior to the entry into force of this Decision, and which are presented at the Community inspection post for importation before 15 April 2001.

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Article 7

Official controls

Member States shall carry out frequent official controls to verify the correct application of this Decision and ensure that measures are taken to avoid contamination, particularly in slaughterhouses, cutting plants, animal waste processing plants, high risk processing plants or premises authorised by the Member States in accordance with Article 7 of Council Directive 90/667/EEC [1], points of sale to the consumer, landfill sites and other

[1] OJ L 363, 27.12.1990, p. 51.

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facilities for storage or incineration. They shall in particular set up a system to ensure and check that:

(a) specified risk materials used in the production of products referred to in Article 1(2) are exclusively used for the authorised purpose;

(b) specified risk materials, in particular where the removal takes place at establishments or premises other than slaughterhouses, are completely separated from other waste not destined for incineration, are collected separately and are disposed of in accordance with Article 3 and Annex I. Member States may decide to allow dispatch of heads or carcasses containing specified risk material to another Member State after agreement with that other Member State both to receive the material and to the specific conditions to be applied to such movements.

▼M3

However, carcasses containing no specified risk material other than vertebral column, including dorsal root ganglia, may be imported into a Member State, or dispatched to another Member State without the latter's prior agreement.

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Article 8

Review

1. This Decision shall be reviewed regularly in the light of new scientific information with regard to the risk of exposure to TSEs.

2. This Decision shall be amended acting in accordance with the appropriate procedure:

(a) to take account of the dates of effective enforcement of the prohibition on the feeding of mammalian, or as appropriate, ruminant protein to ruminants, in each country or region thereof;

(b) to allow the use of vertebral column and dorsal root ganglia from bovine animals in or coming from the United Kingdom of Great Britain and Northern Ireland and Portugal or regions thereof;

(c) to exempt certain third countries from the provisions of Article 6, paragraphs 1 and 2.

Article 9

Amendments

Article 3(3) of Decision 94/474/EEC is hereby amended as follows:

(a) point (a) is deleted;

(b) in point (c), 'the implementation of (a) and (b)' is replaced by 'the implementation of (b)'.

Article 10

Repeal

1. Decision 97/534/EC is repealed on 30 June 2000.

2. References to Decision 97/534/EC shall be construed as references to this Decision.

Article 11

Application

This Decision shall apply from 30 June 2000.

Article 12

Addressees

This Decision is addressed to the Member States.

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ANNEX I

Specified risk material

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1. (a) The following tissues shall be designated as specified risk material in all Member States and regions thereof:

   (i) the skull including the brains and eyes, the tonsils, the vertebral column excluding the vertebrae of the tail, but including dorsal root ganglia and spinal cord of bovine animals aged over 12 months, and the intestines from the duodenum to the rectum of bovine animals of all ages;

   (ii) the skull including the brains and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over 12 months or that have a permanent incisor erupted through the gum, and the spleen of ovine and caprine animals of all ages.

   (b) In addition to the specified risk material listed in point (a), the following tissues shall be designated as specified risk material in the United Kingdom and in Portugal with the exception of the Autonomous Region of the Azores:

   — the entire head excluding the tongue, including the brains, eyes, trigeminal ganglia and tonsils; the thymus; the spleen and spinal cord of bovine animals aged over six months.

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2. Member States shall ensure that the specified risk materials are removed at:

   (a) slaughterhouses;

   (b) cutting plants, high risk processing plants or premises referred to in Article 3 and 7 of Directive 90/667/EEC, under the supervision of a designated agent appointed by the competent authority. Those establishments shall be approved for that purpose by the competent authority.

   Where specified risk materials are not removed from dead animals not slaughtered for human consumption, the parts of the body containing the specified risk materials or the entire body shall be treated as specified risk material.

   However, the vertebral column may be removed at the point of sale to the consumer ►M2 ——— ◄.

3. Member States shall ensure that all specified risk material is stained with a dye and, as appropriate, marked with a marker immediately on removal, and is completely destroyed:

   (a) by incineration without pre-processing; or,

   (b) provided that the dye or marker remains detectable, after pre-processing:

   (i) in accordance with the systems described in Chapters I to IV, VI and VII of Annex to Commission Decision 92/562/EEC [1]:

   — by incineration;

   — by co-incineration;

   (ii) in accordance with at least the standards referred to in Annex I to Council Decision 1999/534/EC [2], by burial in an approved landfill site.

4. Member States may derogate from the provisions of points 2 and 3 to allow the incineration or burial of specified risk material or entire bodies, without prior staining, or, as appropriate, removal of the specified risk materials, in the circumstances set out in Article 3(2) of Directive 90/667/EEC and by a method, which precludes all risk of transmission of a TSE, and is authorised and supervised by the competent authority, in particular where animals have died, or have been killed in the context of disease control measures.

5. Member States may send specified risk material or the processed material thereof to other Member States for incineration under the conditions laid down in Article 4(2) of Commission Decision 97/735/EC [3], as applicable.

   This Decision may be amended on request of a Member State to allow the dispatch of specified risk material or the processed material thereof to third

(1) OJ L 359, 9.12.1992, p. 23.
(2) OJ L 204, 4.8.1999, p. 37.
(3) OJ L 294, 28.10.1997, p. 7.

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countries for incineration. The Commission shall at the same time adopt the conditions governing the exportation.

▼M2

6. By way of derogation from point 1(a)(i), a decision may be taken in accordance with the procedure referred to in Article 17 of Directive 89/662/EEC to allow the use of vertebral column and dorsal root ganglia from bovine animals:

(a) born, continuously reared and slaughtered in Member States for which a scientific evaluation established that the occurrence of BSE in native bovine animals is highly unlikely, or unlikely but not excluded; or,

(b) born after the date of effective enforcement of the prohibition on the feeding of mammalian protein to ruminants in Member States with reported BSE in native animals or for which a scientific evaluation established that the occurrence of BSE in native bovine animals is likely.

The United Kingdom, Portugal, Finland, Sweden and Austria may benefit from this derogation on the basis of previously submitted and evaluated evidence. Other Member States may apply for this derogation by submitting conclusive supporting evidence to the Commission regarding point (a) or (b), as appropriate.

Member States benefiting from this derogation shall, in addition to the requirements laid down in Decisions 98/272/EC and 2000/764/EC, ensure that one of the approved rapid tests listed in Annex IV(A) to Decision 98/272/EC is applied to all bovine animals over 30 months of age which:

(a) have died on the farm or in transport, but which have not been slaughtered for human consumption, with the exception of those dead animals in remote areas with a low animal density situated in Member States where the occurrence of BSE is unlikely;

(b) were subject to normal slaughter for human consumption;

(c) were born during the first year after the date of the effective enforcement of the prohibition on the feeding of mammalian protein to ruminants and were purchased for destruction in accordance with Commission regulations adopting exceptional support measures for the beef market.

This derogation shall not be granted to allow the use of vertebral column and dorsal root ganglia from bovine animals aged over 30 months from the United Kingdom or from Portugal with the exception of the Autonomous Region of the Azores.

Experts from the Commission may carry out on-the-spot checks to further verify the submitted evidence.

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ANNEX II

The following products of animal origin shall be subject to restrictions on import into the Community pursuant to Article 6(1):

(a) 'fresh meat': fresh meat as defined by Council Directive 64/433/EEC [1] on health problems affecting intra-Community trade in fresh meat;

(b) 'minced meat' and 'meat preparations': minced meat and meat preparations as defined by Council Directive 94/65/EC [2];

(c) 'meat products': meat products as defined by Council Directive 77/99/EEC [3];

(d) 'processed animal protein', as referred to by Directive 92/118/EEC;

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(e) 'bovine intestines' as referred to in Article 2(b)(v) of Directive 77/99/EEC.

[1] OJ L 121, 29.7.1964, p. 2012/64.
[2] OJ L 368, 31.12.1994, p. 10.
[3] OJ L 26, 31.1.1977, p. 85.

▼M3

ANNEX III

Third countries referred to in Article 6(3)

Australia
Argentina
Botswana
Chile
Namibia
New-Zealand
Nicaragua
Paraguay
Uruguay
Swaziland