II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 11 June 1996

amending Decision 96/239/EC on emergency measures to protect against bovine spongiform encephalopathy

(Text with EEA relevance)

(96/362/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], as last amended by Directive 92/118/EEC [2], and in particular Article 10 (4) thereof,

Having regard to 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 [3], as last amended by Directive 92/118/EEC, and in particular Article 9 (4) thereof,

Whereas, to protect animal and human health in the Community, the Commission adopted 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 [4], as last amended by Decision 95/287/EC [5], Decision 92/290/EEC of 14 May 1992 concerning certain protection measures relating to bovine embryos in respect of bovine spongiform encephalopathy (BSE) in the United Kingdom [6], as amended by the Act of Accession of Austria, Finland and Sweden, Decision 94/381/EC of 27 June 1994 concerning certain protection measures with regard to bovine spongiform encephalopathy and the feeding of mammalian derived protein [7], as amended by Decision 95/60/EC [8], and Decision 94/382/EC of 27 June 1994 on the approval of alternative heat treatment systems for processing animal waste of ruminant origin, with a view to the inactivation of spongiform encephalopathy agents [9], as amended by Decision 95/29/EC [10];

Whereas the Council, at its meeting on 1 to 3 April 1996, concluded that a Commission decision in accordance with the Standing Veterinary Committee procedure should be adopted to require that all animal waste of mammalian origin in the Community shall be processed by a method that has been demonstrated as being *de facto* effective for the inactivation of the agents of scrapie and BSE;

[1] OJ No L 224, 18. 8. 1990, p. 29.
[2] OJ No L 62, 15. 3. 1993, p. 49.
[3] OJ No L 395, 30. 12. 1989, p. 13.
[4] OJ No L 194, 29. 7. 1994, p. 96.
[5] OJ No L 181, 1. 8. 1995, p. 40.
[6] OJ No L 152, 4. 6. 1992, p. 37.
[7] OJ No L 172, 7. 7. 1994, p. 23.
[8] OJ No L 55, 11. 3. 1995, p. 43.
[9] OJ No L 172, 7. 7. 1994, p. 25.
[10] OJ No L 38, 18. 2. 1995, p. 17.

Whereas the United Kingdom has taken additional measures as a result of the publication of new information on certain cases of Creutzfeldt-Jakob Disease in that Member State;

Whereas the United Kingdom has banned the use of mammalian meat- and bonemeal for feeding of farm animals;

Whereas the United Kingdom has enlarged the list of bovine tissues which must be destroyed (Specified Bovine Material Order);

Whereas the Commission has adopted Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy [1]; whereas that Decision has prohibited the dispatch to the other Member States and to third countries, in particular, of bovine semen, and certain other products from the UK obtained from bovine animals slaughtered in the United Kingdom which are liable to enter the animal feed or human food chains and materials destined for use in medicinal products, cosmetics or pharmaceutical products;

Whereas the Scientific Veterinary Committee was consulted on 18 April 1996 and on 26 April 1996; whereas in the opinion of this Committee, bovine semen is considered to be safe for animal health with respect to BSE;

Whereas the Scientific Committee on Cosmetology was consulted on the safety of certain bovine products on 11 April 1996; whereas the Liaison Committee of European Associations of the Perfume, Cosmetics Products and Toiletries Industries (Colipa) recommended several years ago to its members not to use source materials from United Kingdom bovine animals; whereas this Committee has declared that its members follow this recommendation;

Whereas the Scientific Committee for Food was consulted on the safety of certain bovine products on 15 April 1996;

Whereas the Committee for Proprietary Medicinal Products was consulted on 16 April 1996; whereas the pharmaceutical sector had already introduced measures relating to the sourcing of materials and their treatment; whereas every medicinal product undergoes a pre-marketing approval before it is placed on the market, by virtue of which the treatment process of any raw material is evaluated; whereas at the request of the European Medicines Evaluation Agency, all Community marketing authorization holders, or applicants with a positive opinion from the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products, have confirmed that the products concerned do not contain bovine tissue of United Kingdom origin;

Whereas subsequently, additional information has been made available in order to facilitate a more complete risk assessment; whereas, on this basis, the Scientific Veterinary Committee on 26 April 1996 concluded that a combination of appropriate sourcing of bovine materials used and the application of minimum processing standards which have been shown to effectively inactivate the BSE agent, together give good reassurances about the safety of these products for food or cosmetic use; whereas, consequently, the Scientific Veterinary Committee has recommended safety parameters for the production of these products which are therefore considered to be safe; whereas, furthermore, specific rules for the veterinary control of establishments should be put in place;

Whereas, therefore, the Commission considers that the products covered by the Annex to this Decision (such as gelatin and tallow) are safe;

Whereas these products and bovine semen may therefore be exempted from the prohibition provided for by Decision 96/239/EC;

Whereas in 1988 the United Kingdom introduced a requirement for animals affected with BSE to be completely destroyed; whereas the Council, at its meeting on 1 to 3 April 1996, concluded that bovine animals over the age of 30 months shall not enter the human food or animal food chains or be used for cosmetic or pharmaceutical products; whereas such animals must not be used as source materials for certain bovine products as referred to above;

Whereas furthermore, certain bovine tissues must not be used as source materials for these products;

Whereas it is necessary to lay down appropriate guarantees for the dispatch from the United Kingdom of products obtained from bovine animals which were not slaughtered in the United Kingdom;

Whereas the Commission should carry out Community inspections in the United Kingdom to verify the application of the measures provided for in this Decision;

Whereas the United Kingdom has presented a proposal for measures to control and eradicate BSE in the United Kingdom, in particular selective compulsory slaughter of animals and/or herds identified as being most likely to have been exposed to infected meat- and bonemeal and an improved system of individual identification of bovine animals to ensure effective control of movements and traceability of animals (animal passport system);

Whereas the Standing Veterinary Committee has not given an opinion; whereas the Commission has therefore proposed these measures to the Council on 23 May 1996 in accordance with Article 17 of Directive 89/662/EEC, the Council being required to adopt measures within 15 days;

[1] OJ No L 78, 28. 3. 1996, p. 47.

Whereas, however, the Council has not acted within the required time limit; whereas the Council has not decided against the proposed measures by simple majority within the same time limit; whereas these measures should now be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Decision 96/239/EC is amended as follows:

1. Article 1 is replaced by the following:

'Article 1

1. Pending an overall examination of the situation, and notwithstanding Community provisions adopted to protect against bovine spongiform encephalopathy, the United Kingdom shall not dispatch from its territory to other Member States or to third countries:

— live bovine animals and bovine embryos,

— meat of bovine animals slaughtered in the United Kingdom,

— products obtained from bovine animals slaughtered in the United Kingdom which are liable to enter the human food chain, with the exception of those products listed in the Annex,

— products obtained from bovine animals slaughtered in the United Kingdom which are liable to enter the animal feed chain, with the exception of those products listed in the Annex,

— materials obtained from bovine animals slaughtered in the United Kingdom which are destined for use in cosmetics products, with the exception of those listed in the Annex,

— materials obtained from bovine animals slaughtered in the United Kingdom which are destined for use in medical or pharmaceutical products, with the exception of those listed in the Annex,

— meat meal, bonemeal and meat- and bonemeal derived from mammals.

2. The United Kingdom shall authorize the production of products as referred to in paragraph 1, third, fourth, fifth and sixth indent and mentioned in the Annex only in establishments under official veterinary control which have been shown to be operating in accordance with the conditions set out in the Annex.

3. The United Kingdom shall ensure that the products mentioned in the Annex are labelled or otherwise identified to show the method and establishment of production.

4. Before any dispatch pursuant to this Decision, the United Kingdom shall forward the list of establishments referred to in paragraph 2 which meet the conditions referred to therein to the Commission and the other Member States.'

2. The following Articles 1 (a), 1 (b) and 1 (c) are inserted:

'Article 1 (a)

1. The United Kingdom shall not dispatch:

— meat for human consumption,

— meat products for human consumption,

— meat preparations for human consumption,

— food for domestic carnivores

obtained from bovine animals which were not slaughtered in the United Kingdom unless they come from establishments in the United Kingdom under official veterinary control which have put in place a system of tracing of the raw material which will guarantee the origin of the material throughout the whole production chain.

2. The United Kingdom shall forward the list of establishments which meet the conditions referred to in paragraph 1 to the Commission and the other Member States.

3. The United Kingdom shall ensure that the products mentioned in paragraph 1 dispatched to other Member States are accompanied by a health certificate issued by an official veterinarian stating that they meet the conditions referred to in paragraph 1.

Article 1 (b)

The United Kingdom shall ensure that products mentioned in the Annex dispatched to other Member States in accordance with this Decision are accompanied by a health certificate issued by an official veterinarian stating that they conform to the conditions laid down in this Decision and attesting to the frequency of official controls carried out.

Article 1 (c)

1. The Commission shall carry out Community inspections on the spot in the United Kingdom to verify the application of the provisions of this Decision, in particular in relation to the implementation of official controls.

2. The inspections mentioned in paragraph 1 shall be carried out in respect of the products referred to in the Annex before the dispatch of those products recommences.

3. The Commission, after having consulted the Member States in the framework of the Standing Veterinary Committee, shall set the date on which dispatch may recommence.'

3. The Annex to this Decision is added.

Article 2

Member States shall amend the measures they apply so that they conform to this Decision. They shall immediately inform the Commission thereof.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 11 June 1996.

For the Commission

The President

Jacques SANTER

ANNEX

'ANNEX

1. Gelatin and di-calcium phosphate produced in a process which ensures that:
   - all bone material is subjected to degreasing, followed by an acid treatment at a pH < 1,5 for at least four days, followed by an alkaline treatment, which uses either lime at a pH > 12,5 for at least 45 days or 0,3 N Sodium Hydroxide for 10 to 14 days, followed by heating between 138 °C and 140 °C for four seconds,
   - other raw material (hides and skins, tendons and sinews) is subjected to an alkaline treatment as specified in the previous indent, followed by heating between 138 °C and 140 °C for four seconds.
2. Amino acids and peptides produced from hides and skins by a process which involves exposure of the material to a pH of 1 to 2, followed by a pH of > 11, followed by heat treatment at 140 °C for 30 minutes at 3 bars.
3. Tallow and tallow products produced from material from animals fit for human consumption which has been subjected to one of the processes described in Article 2 of Decision 94/382/EC.
4. Products derived from tallow which have been derived by hydrolysis at 250 °C or higher.
5. Products referred to in points 1, 2, 3 and 4 excluding di-calcium phosphate must be filtered after production.
6. In all cases provided for in points 1, 2, 3 and 4, bovine animals which are showing signs of BSE and animals over 30 months of age (as provided for by Commission Regulation (EC) No 716/96 (1)) must not be used as source materials. Furthermore, the following tissues may not be used: skull, vertebral column, brain, spinal cord, eye, tonsil, thymus, intestine or spleen.

(1) OJ No L 99, 20. 4. 1996, p. 14.'