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(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 19 July 1999

on measures applying to the processing of certain animal waste to protect against transmissible spongiform encephalopathies and amending Commission Decision 97/735/EC

(1999/534/EC)

THE COUNCIL OF THE EUROPEAN UNION,

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⁾, and in particular Article 10(4) thereof,

Having regard to the proposal of the Commission,

Whereas:

(1) Council Directive 90/667/EEC ⁽²⁾, lays down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin;

(2) Commission Decision 92/562/EEC ⁽³⁾, defined alternative systems of heat treatment as provided for in paragraph 6(c) of Chapter II of Annex II to Directive 90/667/EEC;

(3) In 1994, phase 1 of a scientific study into the physical parameters which must be applied in order to inactivate the agents of bovine spongiform encephalopathy (BSE) and scrapie identified the minimum parameters necessary for inactivation of the BSE agent; it also identified certain processes which were not effective;

(4) The result of phase 2 of that study showed that only one system tested was capable of fully inactivating the scrapie agent in meat-and-bone meal;

(5) It is therefore necessary to ensure that systems which have been shown to be ineffective are not used for the processing of mammalian animal waste in order to protect animals from the hazard of spongiform encephalopathy agents in animal feed, unless an effective sterilisation phase is added to the process;

(6) At its meeting from 1 to 3 April 1996, the Council concluded that a Commission Decision should be adopted under the Standing Veterinary Committee procedure in order to require all animal waste of mammalian origin in the Community to be processed by a method that has been demonstrated as being *de facto* effective for the inactivation of the agents of scrapie and BSE; the only such method at present is the application of heat in a rendering system which achieves a minimum 133 °C at 3 bar for a minimum period of 20 minutes; that method may be applied as the sole process or as a pre- or post-process sterilisation phase;

(7) The Scientific Steering Committee adopted an opinion on the safety of meat-and-bone meal from mammalian animals, naturally or experimentally susceptible to transmissible spongiform encephalopathies (TSEs) on 26 and 27 March 1998; that opinion has been updated by a scientific report on the safety of meat-and-bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals adopted by the Scientific Steering Committee on 24 and 25 September 1998;

⁽¹⁾ OJ L 224, 18.8.1990, p.29. Directive as last amended by Directive 92/118/EEC (OJ L 62, 15.3.1993, p.49).

⁽²⁾ OJ L 363, 27.12.1990, p.51. Directive as last amended by the 1994 Act of Accession.

⁽³⁾ OJ L 359, 9.12.1992, p. 23. Directive as last amended by the 1994 Act of Accession.

- (8) It is necessary to define the maximum particle size and the minimum time and temperature to be applied in approved systems, in order to ensure that such systems are running in accordance with procedures which have been shown to be effective;
- (9) Specific rules should be laid down on controls on establishments;
- (10) On 12 December 1994 the Scientific Veterinary Committee recommended detailed procedures for the validation of rendering processes; pending a scientific review of those procedures, it is necessary to lay down a list of indicators based, where appropriate, on that scientific recommendation, to be used for the validation of rendering processes in order to ensure that the parameters laid down in this Decision are achieved on a plant-by-plant basis;
- (11) Commission Decision 96/449/EC of 18 July 1996 on the approval of alternative heat treatment systems for processing animal waste with a view to the inactivation of spongiform encephalopathy agents⁽¹⁾ provided that, from 1 April 1997, certain mammalian animal waste which had not been processed in accordance with the standards set out therein should not be fed to animals; recent Community inspections have revealed that there are problems of implementation of that Decision due to difficulties of legal interpretation;
- (12) The Scientific Steering Committee adopted an opinion on the safety of tallow derived from ruminant tissues on 26 and 27 March 1998; in order to take account of that scientific opinion, it is necessary to lay down requirements for the production of rendered fats derived from ruminant tissue; a period of time should be provided for the implementation of those requirements;
- (13) A revision of the Animal Health Code of the *Office International des Epizooties* (OIE) on BSE was adopted in the general assembly of the OIE in Paris on 29 May 1998; Article 3.2.13.3 of that Code recommends that if protein-free tallow (maximum level of impurities of 0,15 % in weight) is derived from healthy animals, veterinary administrations should be able to authorise, without restriction, its import and transit through their territories, regardless of the status of the exporting countries; Article 3.12.13.16 of that Code recommends sourcing and processing conditions which are to be complied with before tallow (other than protein-free tallow) and tallow derivatives (other than protein-free tallow derivatives) can be traded;
- (14) Special uses of animal waste may be exempted from the requirements of this Decision; furthermore, products which will be used for industrial purposes, where it can be assured that they will not be used in any animal feed chain or as fertilisers, may also be exempted from the requirements of this Decision;
- (15) A fundamental reworking of Decision 96/449/EC therefore appears necessary; in the interests of clarity, that Decision should be replaced;
- (16) Commission Decision 97/735/EC of 21 October 1997 concerning certain protection measures with regard to trade in certain types of mammalian animal waste⁽²⁾ should be amended to take account of the provisions of this Decision;
- (17) This Decision should apply without prejudice to Council Decision 98/256/EC⁽³⁾, and Commission Decision 98/653/EC⁽⁴⁾, which lay down specific conditions for the production of amino acids, peptides, tallow and products derived from tallow in the United Kingdom and Portugal;
- (18) This Decision should be without prejudice to the adoption of rules for the organisation of the prevention and control of TSEs;
- (19) The Commission has, by Decision 97/534/EC⁽⁵⁾, prohibited the use of material presenting risks as regards TSEs;
- (20) The Commission has, by Decision 98/272/EC⁽⁶⁾, laid down measures to be applied in cases of animals suspected of having a TSE;
- (21) The Standing Veterinary Committee has not given a favourable opinion,

HAS ADOPTED THIS DECISION:

Article 1

1. This Decision shall apply to the processing of low-risk and high-risk mammalian animal waste within the scope of Directive 90/667/EEC, including mammalian by-products not intended for human consumption derived from the production of products intended for human consumption.
2. Member States shall ensure that all waste to which this Decision applies is processed in accordance with the requirements laid down in Annex I.
3. Paragraph 2 shall not apply to the processing of the following:
 - (a) low-risk material within the meaning of Directive 90/667/EEC for the production of petfood;

⁽²⁾ OJ L 294, 28.10.1997, p. 7.

⁽³⁾ OJ L 113, 15.4.1998, p.32. Decision as last amended by Decision 98/692/EC (OJ L 328, 4.12.1998, p. 28).

⁽⁴⁾ OJ L 311, 20.11.1998, p. 23.

⁽⁵⁾ OJ L 216, 8.8.1997, p. 95. Decision as last amended by Decision 98/745/EC (OJ L 358, 31.12.1998, p. 113).

⁽⁶⁾ OJ L 122, 24.4.1998, p. 59.

⁽¹⁾ OJ L 184, 24.7.1996, p. 43.

- (b) animal waste referred to in Article 7(ii) of Directive 90/667/EEC for the feeding of zoo, circus or fur animals, recognised packs of hounds and maggot farming for fishing bait;
 - (c) degreased bones for the production of gelatine;
 - (d) hides and skins for the production of gelatine, collagen and hydrolysed proteins, hooves, horns, hair;
 - (e) glands, tissues and organs for pharmaceutical use;
 - (f) blood and blood products;
 - (g) milk and milk products;
 - (h) non-ruminant waste for the production of rendered fats, excluding greaves derived from such production;
 - (i) low-risk ruminant waste for the production of rendered fats excluding greaves derived from such production;
 - (j) animal waste for the production of products for which it can be assured that they will not enter any human food or animal feed chain and will not be used as fertilisers;
- and, until 1 July 2000,
- (k) high-risk ruminant waste for the production of rendered fats, excluding greaves derived from such production;
 - (l) bones fit for human consumption.

4. Member States which already impose requirements for the processing of waste to which this Decision applies which are more stringent than those provided for in Annex I may maintain their existing requirements.

Article 2

1. Member States shall ensure that all rendered fats derived from ruminant waste are purified in such a way that the maximum levels of remaining total insoluble impurities does not exceed 0,15 % in weight.

2. Article 1(2) and paragraph 1 of this Article shall not apply to the production of rendered fats derived from ruminant waste if they are to be processed by a method which at least meets the standards of one of the processes described in Annex II or it can be assured that they will not enter any human food or animal feed chain.

Article 3

By way of derogation from Article 1(2) and Article 2, Member States may authorise:

- (a) the processing of waste to which this Decision applies by a method which does not meet the requirements set out in Annex I if such processing is followed by a process which meets those requirements or if the resulting proteinaceous

material is destroyed by burial, incineration, burning as fuel or a similar method which ensures safe disposal;

- (b) the production of rendered animal fat derived from high-risk mammalian ruminant waste by a method which does not meet the requirements set out in Annex I or the standards set out in Annex II, if such processing is followed by a process which meets those requirements or standards, or if the resulting rendered fat is destroyed by burial, incineration, burning as fuel or a similar method which ensures safe disposal.

Member States which authorise a method provided for in the first subparagraph shall put in place a system of control to ensure that waste to which this Decision applies which has not been processed in accordance with the requirements set out in Annex I or the standards set out in Annex II cannot enter the animal feed chain and is not used as fertiliser.

Article 4

1. Member States shall ensure that establishments which are approved in accordance with Directive 90/667/EEC and process waste referred to in Article 1(2), other than those establishments which process waste pursuant to Article 1(3) and Article 3(a), operate in accordance with the requirements set out in Annex I and are validated according to the procedures laid down in Annex III.

Member States shall carry out checks on the operation of those establishments at regular intervals. Records of the temperature, pressure and particle size for the establishments must be maintained.

2. In accordance with Article 11 of Directive 90/667/EEC, Member States shall ensure that the list of approved establishments processing animal waste indicates the establishments which operate in accordance with the conditions laid down in this Decision.

Article 5

In Annex II to Decision 97/735/EC, the words 'defined by the Scientific Veterinary Committee' shall be replaced by 'laid down in Annex III to Decision 1999/534/EC'.

Article 6

1. Decision 96/449/EC shall be repealed.

2. References to Decision 96/449/EC shall be construed as references to this Decision. In particular, references to Article 1(2) of the said Decision shall be construed as references to Article 1(3) of this Decision and references to the Annex to Decision 96/449/EC shall be construed as references to Annex I to this Decision.

Article 7

This Decision shall apply from 1 July 1999.

However, Article 2(1) shall apply from 1 January 2000.

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 19 July 1999.

For the Council

The President

K. HEMILÄ

ANNEX I

REQUIREMENTS REFERRED TO IN ARTICLE 1(2)

Minimum requirements for the processing of mammalian animal waste:

- | | |
|--|---------------------------------|
| (a) Maximum particle size | 50 mm |
| (b) Temperature | > 133 °C |
| (c) Time | 20 minutes without interruption |
| Pressure (absolute) produced by saturated steam ⁽¹⁾ | ≥ 3 bar |

Processing may be carried out in a batch or a continuous system.

ANNEX II

STANDARDS REFERRED TO IN ARTICLE 2 (2)

1. Transesterification or hydrolysis at at least: 200 °C, under corresponding appropriate pressure for 20 minutes (glycerol, fatty acids and esters);
2. Saponification with NaOH 12M (glycerol and soap):
 - in a batch process: at 95 °C for three hours, or
 - in a continuous process: at 140 °C, 2 bars (2 000 hPa) for eight minutes or equivalent conditions.

⁽¹⁾ 'Saturated steam' means that all air is evacuated and replaced by steam in the whole sterilisation chamber.

ANNEX III

VALIDATION PROCEDURES FOR PLANTS PROCESSING MAMMALIAN ANIMAL WASTE

Validation procedures shall take into account at least the following indicators:

1. Description of the process (by a process flow diagram);
2. Identification of critical control points (CCPs) including the material process rate for continuous system;
3. Compliance with the following process requirements:
 - (a) Maximum particle size 50 mm maximum
 - (b) Temperature > 133 °C
 - (c) Time at least 20 minutes without interruption
 - (d) Pressure (absolute) produced by saturated steam at least 3 bar
4. Achievement of the requirements laid down in Annex I
 - (a) Particle size for batch-pressure and continuous processes: the particle size is defined by the mincer hole or the anvil gap size
 - (b) Temperature, pressure, processing time and material processing rate (for continuous system only):
 - (i) batch pressure system:
 - the temperature must be monitored with a permanent thermocouple and it must be plotted against real time;
 - the pressure stage must be monitored with a permanent pressure gauge; pressure must be plotted against real time;
 - the processing time must be shown by time/temperature and time/pressure diagrams.
 - At least once a year the thermocouple and the pressure gauge must be calibrated.
 - (ii) continuous pressure system:
 - the temperature and the pressure must be monitored with thermocouples, or an infrared temperature gun, and pressure gauges used at defined positions throughout the process system in such a way that temperature and pressure comply with the conditions set out in Annex I inside the whole continuous system or in a section of it; the temperature and pressure must be plotted against real time,
 - measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the conditions set out in the Annex I, must be provided to the competent authorities, using insoluble markers (i.e. manganese dioxide) or a method which offers equivalent guarantees; accurate measurement and control of the material process rate is essential and must be measured during the validation test in relation to a CCP that can be continuously monitored such as:
 - feed screw revolutions per minute (rev/min), or
 - electric power (amps at given voltage), or
 - evaporation/condensation rate, or
 - number of pump strokes per unit time.

All measuring and monitoring equipment must be calibrated at least once a year.

The validation procedures must be repeated periodically or when it is considered necessary by the competent authority and in any case each time any significant alterations are made to the process (i.e. modification of the machinery, change of raw materials etc.).
