



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.07.1999
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Proposal for a

COUNCIL DECISION

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

Decision 96/449/EC on the approval of alternative heat treatment systems for processing animal waste with a view to the inactivation of spongiform encephalopathy agents, establishes that from 1 April 1997 all mammalian animal waste to which this Decision applies has to be processed in accordance with the standards set out in the Annex to the Decision.

During recent community inspections, it appeared that there are problems of implementation of this Decision due to difficulties of legal interpretation.

Furthermore, on 26-27 March 1998, the Scientific Steering Committee adopted the following opinions:

- opinion on the safety of meat and bone meal from mammalian animals, naturally or experimentally susceptible to Transmissible Spongiform Encephalopathies which has been up-dated 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 24-25 September 1998,
- opinion on the safety of tallow derived from ruminant tissues.

In order to clarify the above mentioned problems of interpretation and to take into account these scientific opinions, it is necessary to amend Decision 96/449/EC.

On 12 December 1994 the Scientific Veterinary Committee recommended detailed procedures for the validation of rendering processes laid down in Decision 94/382/EC; Pending a scientific review of these procedures, it is necessary to lay down a list of indicators based, where appropriate, on the above 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.

The foregoing entails a fundamental reworking of Decision 96/449/EC. Therefore, in the interests of clarity, this Decision repeals Decision 96/449/EC.

Decision 97/735/EC concerning certain protection measures with regard to trade in certain types of mammalian animal waste need to be amended to be in line with the provision of this Decision.

The adoption of this Decision is without prejudice to the adoption of rules for the organisation of the prevention and control of transmissible spongiform encephalopathies.

This proposal has no impact on the Community budget.

On 31 May 1999, the College of Commissioners agreed to submit the proposal to the Standing Veterinary Committee for an opinion. On 2 June 1999 the SVC gave a negative opinion.

Germany opposed for the issue of 'bones fit for human consumption' Germany is claimed that there is not scientific justification for submitting this material to the pressure standards is it is destined to animal consumption.

Germany, Spain and Ireland opposed for the requirements of '20 minutes without interruption' in Annex I.

Germany, Austria, Spain and Ireland opposed on the double treatment of tallow derived from high risk material. These delegation stated that the recommendation that tallow derived from material not fit for human consumption must be purified such that the maximum level of impurities does not exceed 0.15% and treated to 133°C 20 Minutes 3 bar is scientifically unjustified.

Italy opposed to the proposal because of the requirement that material fit for human consumption derived from non-ruminant animals must be treated under pressure.

The result of the vote was:

In favour: 52 (B, DK, GR, FR, L, NL, P, FIN, SW, UK)

Against: 31 (DE, SP, IRL, IT)

Abstention: 4 (AT).

Proposal for a

COUNCIL DECISION

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

(Text with EEA relevance)

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 market¹, as last amended by Directive 92/118/EEC², and in particular Article 10(4) thereof,

Having regard to the proposal of the Commission,

- (1) Whereas Council Directive 90/667/EEC³, as last amended by the Act of Accession of Austria, Finland and Sweden, 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) Whereas Commission Decision 92/562/EEC⁴, as amended by the Act of Accession of Austria, Finland and Sweden, 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) Whereas 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; whereas it also identified certain processes which were not effective;
- (4) Whereas the results 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;

¹ OJ L 224, 18.8.1990, p. 29.

² OJ L 62, 15.3.1993, p. 49.

³ OJ L 363, 27.12.1990, p. 51.

⁴ OJ L 359, 9.12.1992, p. 23

- (5) Whereas, therefore, it is 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) Whereas, at its meeting on 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; whereas 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; whereas that may be applied as the sole process or as a pre- or post-process sterilisation phase;
- (7) Whereas 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; whereas that opinion has been up-dated 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;
- (8) Whereas 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) Whereas specific rules should be laid down on controls on establishments;
- (10) Whereas on 12 December 1994 the Scientific Veterinary Committee recommended detailed procedures for the validation of rendering processes; whereas, 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) Whereas 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 agents⁵ 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; whereas recent Community inspections have revealed that there are problems of implementation of that Decision due to difficulties of legal interpretation;

5 OJ L 184, 24.7.1996, p. 43.

- (12) Whereas the Scientific Steering Committee adopted an opinion on the safety of tallow derived from ruminant tissues on 26 and 27 March 1998; whereas, 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; whereas a period of time should be provided for the implementation of those requirements;
- (13) Whereas 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; whereas 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; whereas Article 3.12.13.16 of that Code recommends sourcing and processing conditions under which tallow (other than protein-free tallow) and tallow derivatives (other than protein-free tallow derivatives) can be traded;
- (14) Whereas special uses of animal waste may be exempted from the requirements of this Decision; whereas, 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) Whereas in view of the foregoing a fundamental reworking of Decision 96/449/EC is necessary; whereas, in the interests of clarity, that Decision should be replaced;
- (16) Whereas Commission Decision 97/735/EC of 21 October 1997 concerning certain protection measures with regard to trade in certain types of mammalian animal waste⁶ should be amended to take account of the provisions of this Decision;
- (17) Whereas this Decision should be without prejudice to Council Decision 98/256/EC⁷, as last amended by Commission Decision 98/692/EC⁸ and Commission Decision 98/653/EC⁹, 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) Whereas this Decision should be without prejudice to the adoption of rules for the organisation of the prevention and control of TSEs;
- (19) Whereas the Commission has, by Decision 97/534/EC¹⁰, as last amended by Council Decision 98/745/EC¹¹, prohibited the use of material presenting risks as regards TSEs;

6 OJ L 294, 28.10.1997, p. 7.

7 OJ L 113, 15.4.1998, p. 32.

8 OJ L 328, 4.12.1998, p. 28.

9 OJ L 311, 20.11.1998, p. 23.

10 OJ L 216, 8.8.1997, p. 95.

- (20) Whereas the Commission has, by Decision 98/272/EC¹², laid down measures to be applied in cases of animals suspected of having a TSE;
- (21) Whereas the Standing Veterinary Committee has not given a favourable opinion,

HAS ADOPTED THIS DECISION:

Article 1

1. This Decision applies to the processing of high-risk and low-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;
 - (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;

11 OJ L 358, 31.12.1998, p. 113.

12 OJ L 122, 24.4.1998, p. 59.

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 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 paragraph 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 approved 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" are replaced by "laid down in Annex III to Decision 1999/.../EC".

Article 6

1. Decision 96/449/EC is repealed.
2. References to the repealed Decision shall be construed as references to this Decision. In particular, references to Article 1(2) of the repealed Decision shall be construed as references to Article 1(3) of this Decision and references to the Annex to the repealed Decision 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 July 2000.

Article 8

This Decision is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I

PROCESSING REQUIREMENTS REFERRED TO IN ARTICLE 1(2)

Minimum requirements for the processing of mammalian animal waste:

Maximum particle size	50 mm
Temperature	>133°C
Time	20 minutes without interruption
Pressure (Absolute) produced by saturated steam ¹³	≥3 bar

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

¹³ 'saturated steam' means that all air is evacuated and replaced by steam in the whole sterilisation chamber.

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 (2000 hPa) for eight minutes or equivalent conditions

ANNEX III

VALIDATION PROCEDURES FOR PLANTS PROCESSING MAMMALIAN ANIMAL WASTE

Validation procedures shall take into accounts 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 shall 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.).