COMMISSION DECISION

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

(Text with EEA relevance)

(94/382/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placind on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC (1), as amended by Directive 92/118/EEC (2), and in particular Annex II, Chapter II, paragraph 6 (c) thereof,

Whereas paragraph 6 (a) of Annex II, Chapter II of Directive 90/667/EEC requires that high-risk material must be heated to a core temperature of at least 113° C for 20 minutes at a pressure of 3 bar after the particle size of the raw material has been reduced to at least 50 mm;

Whereas, however, paragraph 6 (c) of Annex II, Chapter II of the said Directive, provides for approval of alternative systems of heat treatment; whereas therefore Commission Decision 92/562/EEC of 17 November 1992 on the approval of alternative heat treatment systems for processing high-risk material (3) has been adopted;

Whereas, however, no particle size or time and temperature parameters were defined for the approved systems; whereas, furthermore, no such parameters have been defined for the processing of low-risk material;

Whereas, as a result of a scientific study into the physical parameters which must be applied in order to inactive the agents of scrapie and bovine spongiform enephalopathy (BSE), it is now possible to identify certain processes in the rendering industry which do not inactivate those agents; whereas it is possible provisionally to identify the parameters used in other processes described in Decision 92/562/EEC which will inactivate those agents;

Whereas, therefore, it is necessary to ensure that systems which have been shown to be ineffective are not used for the processing of animal waste of ruminant origin, in order to protect animal healt from the hazard of spongiform encephalopathy agents in animal feed, unless another validated sterilisation phase is added to the process;

Whereas it is necessary to define the maximum particle size and the minimum time and temperature to be applied in other systems, in order to ensure that such systems are running in accordance with procedures have been validated scientifically;

Whereas these minimum standards should be considered to be provisional and may need to be amended in the light of the final results of the study and future scientific information, in order to ensure that all authorized processes lead to satisfactory inactivation of the agents;

Whereas Member States must ensure that processingt plants are individually checked to ensure that the minimum requirements are met;

Whereas Member States which already require maximum particle sizes and times and temperatures in excess of these minimum levels should continue to apply their original requirements;

Whereas certain specific animal products are not considered to present a risk in respect of BSE, because they are known notto be infective as a result of scientific tests; whereas those products are covered by Directive 92/118/EEC, and in particular Annex 1, Chapters 1, 3, 4, 5, 7, 9 and 10 thereof;

Whereas those products may be exempted from the requirements of this Decision;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

(1) OJ No L 363, 27. 12. 1990, p. 51.
(2) OJ No L 62, 15. 3. 1993, p. 49.
(3) OJ No L 359, 9. 12. 1992, p. 23.

HAS ADOPTED THIS DECISION:

Article 1

1. This Decision shall apply to the processing of animal waste within the scope of Council Directive 90/667/EEC where that waste is derived from ruminant tissues.

2. This Decision shall not apply to the production and processing of:

(i) pet food containing only low risk material within the meaning of Directive 90/667/EEC,

(ii) gelatin,

(iii) hides and skins,

(iv) glands and organs for pharmaceutical use,

(v) blood and blood products,

(vi) milk,

(vii) lards and reduced fats,

(viii) casings.

Article 2

1. Subject to the exclusions listed in Article 1 (2), Member States shall not authorize the processing of animal waste of ruminant origin by:

— the continuous vacuum added fat method as described in Chapter V of the Annex to Decision 92/562/EEC;

— any other system which is not in compliance with the provisions of paragraph 2 of this Article or Annex II, Chapter II, paragraph 6 (a) of Directive 90/667/EEC.

2. Subject to the exclusions listed in Article 1 (2), Member States shall not authorize the processing of animal waste of ruminant origin by those systems described in Chapters I to IV, VI and VII of the Annex to Decision 92/562/EEC unless the following minimum conditions are achieved:

CHAPTER I (Batch / Atmospheric / Natural Fat)
150 mm particle size maximum

Temperature	>100°C	>110°C	>120°C
Time	125 min	120 min	50 min

CHAPTER II (Batch / Pressure / Natural Fat)
50 mm particle size maximum

Temperature	>100°C	>133°C
Time	25 min	20 min
Pressure (Absolute)		3 bar

CHAPTER III (Continuous / Atmospheric / Natural Fat)
30 mm particle size maximum

Temperature	>100°C	>110°C	>120°C
Time	95 min	55 min	13 min

CHAPTER IV AND VI (Continuous / Atmospheric / Added Fat and continuous / pressure / added fat)
30 mm particle size maximum

Temperature	>100°C	>110°C	>120°C	>130°C
Time	16 min	13 min	8 min	3 min

CHAPTER VII (Continuous / Atmospheric / Defatted)
20 mm particle size maximum

Temperature	>80°C	>100°C
Time	120 min	60 min

The above should be preceded by coagulation at >80°C for 30 - 60 minutes.

The above temperature/time requirements may run concurrently.

3. Member States shall only authorize plants if they have been shown by methods laid down in the Annex to be operating in accordance with the conditions set out in paragraph 2.

4. Member States which already require conditions for the processing of animal waste of ruminant origin which exceed those provided for in paragraph 2 shall maintain their existing requirements.

5. Notwithstanding the provisions of paragraph 1, Member STates may authorize the processing of animal waste of ruminant origin by a process mentioned in that paragraph if such process is preceded or followed by one of the processes described in paragraph 2.

Article 3

The provisions of this Decision shall apply from 1 January 1995, except for Article 2 (1), which shall apply with effect from the ninetieth day following notification of this Decision.

Within 30 days of the notification of this Decision, Member States shall take all necessary measures to ensure that material which does not comply with this Decision and which has been obtained by methods mentioned in Article 2 (1) is used in a way which avoids the risk of transmitting spongiform encephalopathies.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 27 June 1994.

For the Commission

René STEICHEN

Member of the Commission

ANNEX

PROCEDURES FOR THE VALIDATION OF PLANTS FOR THE PROCESSING OF ANIMAL WASTE OF RUMINANT ORIGIN USING METHODS DESCRIBED IN THE ANNEX OF DECISION 92/562/EEC

1. **Temperature — continuous and batch systems**

   Temperature monitoring devices shall be situated regularly throughout the equipment in order to record temperature at different stages in the process. Records should be kept and calibrations completed at regular intervals.

2. **Pressure (Chapter II only)**

   Pressure monitoring devices shall be installed in order to record pressure at stages in the process. Records shall be kept and calibrations completed at regular intervals.

3. **Particle size — all systems**

   This shall be monitored regularly and corrected when wear or damage to breaking equipment is noted, that could allow larger particles than defined to enter the process.

4. For continuous systems (Chapter III — VII), a residence time test shall be completed under normal operating conditions. Such markers as Manganese dioxide (MnO_2) should be introduced into the continuous systems, (at time zero). Samples of products leaving the process shall be taken to monitor the recovery of the insoluble marker. Samples shall be taken from time zero until a time when the majority of marker is expected to have passed throughout the system.