COMMISSION DECISION

of 25 March 1997

laying down the animal health requirements and the veterinary certification for the import of processed animal protein from certain third countries which use alternative heat treatment systems and amending Decision 94/344/EC

(Text with EEA relevance)

(97/198/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, in Directive 90/425/EEC [1], as last amended by Directive 96/90/EC [2], and in particular Article 10 (2) (c) and (3) (a) thereof,

Whereas Chapter 6 of Annex I to Directive 92/118/EEC lays down requirements for the importation of processed animal protein;

Whereas Commission Decision 94/278/EC [3], as last amended by Decision 96/344/EC [4], has laid down a list of third countries from which Member States shall authorize the importation of processed animal protein not intended for human consumption;

Whereas Commission Decision 94/344/EC [5] has laid down the import requirements for processed animal protein including products containing these proteins intended for animal consumption;

Whereas the implementation of the latter Decision was last postponed by Commission Decision 96/106/EC [6] because the application would have led to difficulties as regards the importation of processed animal protein that has been produced by using alternative heat-treatment systems;

Whereas following scientific results on the inactivation of the agent of BSE and scrapie, Commission Decision 96/449/EC [7] has laid down rules of approval of alternative heat-treatment systems for the processing of mammalian waste in the Community; whereas it is appropriate to apply these rules to processed mammalian protein imported from third countries;

Whereas it is appropriate to authorize the imports of processed animal protein, derived form high risk material produced by using alternative heat-treatment systems;

Whereas Decision 96/449/EC, amongst others, requires animal protein derived from mammalian waste to be subjected to a heat-treatment of at least 133 °C throughout its substance for a minimum of 20 minutes at a pressure of 3 bar, with a particle size prior to processing of not more than 5 cm; whereas it is therefore appropriate to limit the import of processed animal protein to those derived from non-mammalian waste only;

Whereas Decision 94/344/EC has to be amended accordingly;

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

HAS ADOPTED THIS DECISION:

Article 1

1. Member States shall authorize the importation of processed animal protein, and products containing these proteins, intended for animal consumption from third countries listed in Annex A, if it is accompanied by a health certificate as set out in Annex B.

The first subparagraph shall not apply to:

— petfood in hermetically sealed containers containing processed animal protein,

and

— processed non-mammalian protein derived from low risk material and products containing this protein.

[1] OJ No L 62, 15. 3. 1993, p. 49.
[2] OJ No L 13, 16. 1. 1997, p. 24.
[3] OJ No L 120, 11. 5. 1994, p. 44.
[4] OJ No L 133, 4. 6. 1996, p. 28.
[5] OJ No L 154, 21. 6. 1994, p. 54.
[6] OJ No L 24, 31. 1. 1996, p. 34.
[7] OJ No L 184, 24. 7. 1996, p. 43.

2. The health certificate referred to in paragraph 1 shall consist of one sheet and shall be completed in at least one official language of the Member State carrying out import checks.

Article 2

1. Processed animal protein mentioned in Article 1 (1) must have been produced according to the following standards:

(a) — the raw material is heated to at least 133 °C throughout its substance for a minimum of 20 minutes at a pressure of 3 bars, with a particle size prior to processing of not more than 5 cm, or

— if the raw material is not of mammalian origin, a system or a combination of systems described in the Annex to Commission Decision 92/562/EEC [1] may be used. Such systems may be used under condition that the process has been sampled on a daily basis over a period of one month in compliance with the microbiological standards laid down in Annex II Chapter III (1) and (2) to Council Directive 90/667/EEC [2];

(b) details of the critical control points are recorded and maintained so that the owner, operator or his representative and, as necessary, the competent authority can monitor the operation of the plant. The information to be recorded and monitored shall include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed-rate and fat recycling rate.

2. Processed animal protein mentioned in Article 1 (1) must have been produced in a plant which is approved by the competent authority of a Member State or a third country listed in Annex A to fulfil the conditions set out in paragraph 1.

Article 3

1. Third countries that use the certificate referred to in Annex B shall inform the Commission of:

(a) the legal power of the veterinary service to inspect and approve the plants producing processed animal protein;

(b) the approval procedures that have been followed;

(c) the list of the approved plants.

2. The Commission shall carry out inspection in the third countries listed in Annex A to verify the application of the provisions of this Decision.

Article 4

Decision 94/344/EC is amended as follows:

(a) in Article 1 (1), first subparagraph, 'derived from high risk material' is deleted and the following is inserted after 'third countries': 'not listed in Annex A to Commission Decision 97/198/EC.';

(b) in Article 1 (1), second subparagraph, the following is inserted after 'material': 'and to products mentioned in paragraph 2, first subparagraph';

(c) in Article 1 (2), 'animal protein' is replaced by 'non-mammalian protein';

(d) in the heading of Annex A, 'derived from high risk material' is deleted and the following is inserted after 'Community': 'from certain third countries not listed in Annex A to Commission Decision 97/198/EC.';

(e) in Annex A, IV (a), 'derived from high risk material' is deleted;

(f) the animal health certificate in Annex B is replaced by Annex C to this Decision.

Article 5

This Decision shall apply from 1 April 1997.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 25 March 1997.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ No L 359, 9. 12. 1992, p. 23.
[2] OJ No L 363, 27. 12. 1990, p. 51.

ANNEX A

All third countries laid down in Part II A of the Annex to Commission Decision 94/278/EC.

ANNEX B

ANIMAL HEALTH CERTIFICATE

for processed animal protein intended for animal consumption and products, including mixtures, other than petfood in hermetically sealed containers, containing these proteins, intended for dispatch to the European Community from third countries listed in Annex A to Commission Decision 97/198/EC

Note for the importer:

This certificate is for veterinary purposes only and the original must accompany the consignment until it reaches the border inspection post.

Country of destination: .....

Reference number of the health certificate: .....

Exporting country: .....

Responsible ministry: .....

Certifying department: .....

I. Identification of the protein or product

Nature of the protein or product: .....

Protein or product obtained from raw material of the following species: .....

.....

Nature of packaging: .....

Number of packages (1): .....

Net weight: .....

II. Origin of protein or product

Address and veterinary registration number of the approved establishment: .....

.....

.....

III. Destination of protein or product

The protein or product will be sent

from: .....

(place of loading)

to: .....

(country and place of destination)

by the following means of transport: .....

Number of the seal (1): .....

Name and address of consignor: .....

.....

Name and address of consignee: .....

.....

(1) Optional.

IV. **Attestation**

The undersigned official veterinarian, certifies that:

(a) the protein or product described above contains exclusively or partially processed animal protein not intended for human consumption which has been processed in a plant registered and approved in accordance with Council Directive 90/667/EEC and Article 2 of Commission Decision 97/198/EC

and has been heated:

— to at least 133 °C throughout its substance for a minimum of 20 minutes at pressure of 3 bars, with a particle size prior to processing of not more than 5 cm (1), or

— in case of non-mammalian protein, according to the system laid down in Chapter ... of Commission Decision 92/562/EEC (1),

and

the random sample complies with the following standards (2):

— *clostridium perfringens*: absence in 1 g (3),

— *salmonella*: absence in 25 g, n = 5, c = 0, m = 0, M = 0 (4),

— *enterobacteriaceae*: n = 5, c = 2, m = 10, M = 3×10^2 in 1 g (4);

(b) a random sample of the end product was examined immediately prior to dispatch by a competent authority and found to comply with the following standard (2):

Salmonella: absence in 25 g, n = 5, c = 0, m = 0, M = 0;

(c) the protein or product described above:

— was produced by using ruminant protein (1),

— was produced without using ruminant protein (1);

(d) the end product:

— was packed in new packaging material,

or

— in case of dispatch as bulk transport, containers or any other means of transport were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use (1);

(e) the end product was stored in enclosed storages;

(f) the end product has undergone all precautions to avoid recontamination with pathogenic agents after heat treatment.

Done at ....., on .....

(place) (date)

Stamp (5)

.....

(signature of the official veterinarian) (5)

.....

(name in capital letters, qualifications and title)

---

(1) Delete as appropriate.

(2) Where:

n = number of units comprising the sample;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is M or more;

c = number of sample units the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other sample units is m or less.

(3) Sample taken after treatment.

(4) Sample taken during storage at processing plant.

(5) The signature and the stamp must be in a colour different to that of the printing.

ANNEX C

'ANIMAL HEALTH CERTIFICATE

for processed non-mammalian protein intended for animal consumption derived from low-risk material and products, including mixtures, other than petfood, intended for dispatch to the European Community from third countries

Note for the importer:

This certificate is for veterinary purposes only and the original must accompany the consignment until it reaches the border inspection post.

Country of destination: .....

Reference number of the health certificate: .....

Exporting country: .....

Responsible ministry: .....

Certifying department: .....

I. **Identification of the protein or product**

The protein or product was produced from raw material of the following species: .....

.....

Nature of packaging: .....

Number of packages (1): .....

Net weight: .....

II. **Origin of protein or product**

Address and veterinary registration number of the approved or registered establishment: .....

.....

.....

.....

III. **Destination of protein or product**

The protein will be sent

from: .....

(place of loading)

to: .....

(country and place of destination)

by the following means of transport: .....

Number of the seal (2): .....

Name and address of consignor: .....

Name and address of consignee: .....

(1) Only appropriate if not in bulk.
(2) Optional.

IV. **Attestation**

1. The undersigned official veterinarian certifies that the protein or product described above contains exclusively non-mammalian protein derived from low risk material

   and:

   a) was produced in such a way that it has been subjected to a treatment throughout its substance, in order to meet the standards as described under (b);

   b) was examined by random sampling from each processed batch taken during storage at the processing plant, that complies with the following standards (1):

      — *Salmonella*: absence in 25 g, n = 5, c = 0, m = 0, M = 0,

      — *Enterobacteriaceae*: n = 5, c = 2, m = 10, M = 3×10^2 in 1 g;

   c) was not produced from:

      — non-mammalians kept for agricultural production, which died but were not slaughtered, including still-born and unborn animals and, without prejudice to instances of emergency slaughtering for reasons of welfare, farm animals which have died in transit,

      — non-mammalians which were killed in the context of disease control measures either on the farm or in any other place designated by the competent authority,

      — non-mammalians waste including blood originating from animals which showed, during the veterinary inspection carried out at the time of slaughtering, clinical signs of diseases communicable to man or other animals,

      — those parts of non-mammalians slaughtered in the normal way which were not presented for post mortem inspection, with the exception of feathers, blood and similar products,

      — meat of non-mammalians, non-mammalian game and foodstuffs of animal origin which were spoiled,

      — non-mammalians, non-mammalian meat and non-mammalian game which in the course of the inspection provided for in Community legislation failed to comply with the veterinary requirements for their importation into the Community,

      — non-mammalian waste containing residues of substances which posed a danger to human or animal health and non-mammalian meat or products of non-mammalian origin rendered unfit for human consumption by the presence of such residues.

2. The undersigned official veterinarian certifies that:

   (a) a random sample of the end product was examined immediately prior to dispatch by the competent authority and found to comply with the following standard (1):

   Salmonella: absence in 25 g, n = 5, c = 0, m = 0, M = 0;

   b) the end product:

      — was packed in new packaging material,

      or

      — in case of dispatch as bulk transport, containers or any other means of transport were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use;

   (c) the end product was stored in enclosed storages;

   (d) the end product has undergone all precautions to avoid recontamination with pathogenic agents after heat treatment.

(1) n = number of units comprising the sample;
m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed m;
M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is M or more;
c = number of sample units the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other sample units is m or less.

Done at ....., on .....
(place) (date)

Stamp (1)

.....
(signature of the official veterinarian) (1)

.....
(name in capital letters, qualification and title)

(1) The signature and the stamp must be in a colour different to that of the printing.'