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**COMMISSION DECISION**

**of 29 December 2000**

**concerning control measures required for the implementation of Council Decision 2000/766/EC concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein**

*(notified under document number C(2000) 4412)*

**(Text with EEA relevance)**

**(2001/9/EC)**

**(OJ L 2, 5.1.2001, p. 32)**

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► <b><u>M1</u></b> Commission Decision 2001/165/EC of 27 February 2001	L 58	43	28.2.2001

**COMMISSION DECISION****of 29 December 2000****concerning control measures required for the implementation of Council Decision 2000/766/EC concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein***(notified under document number C(2000) 4412)***(Text with EEA relevance)**

(2001/9/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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<sup>(1)</sup>, as last amended by Directive 92/118/EEC<sup>(2)</sup>, and in particular Article 9(4) thereof,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<sup>(3)</sup>, as last amended by Directive 92/118/EEC, and in particular Article 10(4) thereof,Having regard to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>(4)</sup>, and in particular Article 22 thereof,

Whereas:

- (1) Council Decision 2000/766/EC of 4 December 2000 concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein<sup>(5)</sup>, prohibits the feeding of processed animal proteins to certain farmed animals. This prohibition does not apply to certain processed animal proteins subject to conditions to be established.
- (2) On 26 June 1998, the Scientific Steering Committee (SSC) adopted an opinion on the safety of dicalcium phosphate precipitated from ruminant bones. That opinion was updated by the SSC on 26 and 27 October 2000. In order to take account of that scientific opinion, it is necessary to lay down requirements for the production of dicalcium phosphate.
- (3) On 22 and 23 October 1998, the Scientific Steering Committee (SSC) adopted an opinion on the safety of hydrolysed proteins produced from bovine hides. This opinion was updated by the SSC on 25 and 26 May 2000. In order to take account of that scientific opinion, it is necessary to lay down requirements for the production of hydrolysed proteins. The SSC stated that a maximum molecular weight of 10 000 Daltons, for the final product produced, may be used as an indicator of the effectiveness of the production process.
- (4) Decision 2000/766/EC establishes that placing on the market, trade, importation and exportation of processed animal proteins for animals not kept, fattened or bred for the production of food may be allowed by Member States. It is necessary to set conditions to ensure that such proteins cannot be used for non authorised purposes.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

<sup>(1)</sup> OJ L 395, 30.12.1989, p. 13.

<sup>(2)</sup> OJ L 62, 15.3.1993, p. 49.

<sup>(3)</sup> OJ L 224, 18.8.1990, p. 29.

<sup>(4)</sup> OJ L 24, 30.1.1998, p. 9.

<sup>(5)</sup> OJ L 306, 7.12.2000, p. 32.

**▼B**

HAS ADOPTED THIS DECISION:

*Article 1*

1. Member States shall authorise the feeding of fishmeal ►**M1** to farmed animals referred to in Article 2(1) of Decision 2000/766/EC ◀ other than ruminants, only in accordance with the conditions laid down in Annex I.
2. Member States shall authorise the feeding of dicalcium phosphate ►**M1** to farmed animals referred to in Article 2(1) of Decision 2000/766/EC ◀ other than ruminants only in accordance with the conditions laid down in Annex II.
3. Member States shall authorise the feeding of hydrolysed proteins ►**M1** to farmed animals referred to in Article 2(1) of Decision 2000/766/EC ◀ other than ruminants, only in accordance with the conditions laid down in Annex III.
4. Member States shall ensure that, for the purpose of trade, dicalcium phosphate and hydrolysed proteins are accompanied by an official certificate as laid down in Annex IV.
5. Member States shall forward to the other Member States and to the Commission the list of approved processing plants producing fishmeal, dicalcium phosphate and hydrolysed proteins, which operate in accordance with the conditions laid down by this Decision, within 15 days after the entry into force of this Decision. Any modification to the list shall be notified immediately to the other Member States and to the Commission.

**▼M1***Article 2*

Member States shall ensure that feedingstuffs, including pet food, destined to animals other than farmed animals referred to in Article 2(1) of Decision 2000/766/EC, which contain processed animal proteins as defined by that Decision are not manufactured in plants which prepare feed for farmed animals.

However, where those feedingstuffs are produced with no other processed animal proteins than fishmeal, dicalcium phosphate and hydrolysed proteins, they may be manufactured in plants which prepare feed for farmed animals other than ruminants in accordance with Annex I point 6, Annex II point 3 and Annex III point 2, as appropriate.

**▼B***Article 3*

1. Member States may send to other Member States processed animal proteins, as defined in Decision 2000/766/EC, provided they are destined for uses not prohibited by Article 3(1)(a) of that Decision, and only if the following additional conditions are fulfilled:
  - (a) the Member State of destination must have authorised the receipt of the processed animal proteins;
  - (b) the processed animal proteins shall be accompanied by an official certificate as laid down in Annex V;
  - (c) the processed animal proteins must be transported in sealed, covered containers or vehicles, in such a way as to prevent loss and conveyed directly to the petfood or feed plants;
  - (d) Member States which send processed animal proteins to other Member States must inform by means of the ANIMO system<sup>(1)</sup> the competent authority of the place of destination of each consignment sent. The words 'not for feed destined to animals which are kept, fattened or bred for the production of food' must be contained in the ANIMO message;
  - (e) Member States of destination must inform the competent authority of the place of origin, by means of the ANIMO system, of the arrival of each consignment; if such information is not provided, Member States of origin shall immediately take appropriate action;
  - (f) Member States of destination must ensure that the designated plants on their territory use the consignment only for the authorised purposes.

<sup>(1)</sup> Commission Decision 91/398/EEC (OJ L 221, 9.8.1991, p. 30).

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2. Member States may export to third countries processed animal proteins, as defined in Decision 2000/766/EC, provided they are destined for uses not prohibited by Article 3(1)(a) of that Decision, only if the following conditions are fulfilled:

- (a) a bilateral agreement with the third country shall be made prior to exportation, which includes an undertaking from the third country to respect the final use and not to export the processed animal protein unless incorporated in a product destined for uses not prohibited by Article 3(1)(a) of Decision 2000/766/EC;
- (b) the processed animal proteins shall be accompanied by an official certificate as laid down in Annex V.

Member States which allow such exportation shall inform the Commission and the other Member States of all terms and conditions as agreed with the third country concerned, for the effective implementation, of this Decision, in the context of the Standing Veterinary Committee.

3. Member States shall ensure that imported processed animal proteins, as defined in Decision 2000/766/EC, destined for uses not prohibited by Article 3(1)(a) of that Decision, shall be dealt with in accordance with the conditions laid down in Article 8 of Council Directive 97/78/EC<sup>(1)</sup>.

4. Member States shall carry out documentary checks and tests on feed materials and compound feedingstuffs throughout the production and distribution chain to ensure compliance with the provisions of this Decision and Decision 2000/766/EC. These checks and tests shall be carried out, *inter alia*, in farms in which ruminants are kept with other animal species.

Member States shall inform the Commission of the results of these checks by 31 May 2001.

5. The additional control measures set out in paragraphs 1, 2 and 3 shall not apply:

- to pet food referred to by Chapter 4 of Annex I to Directive 92/118/EEC, and
- to products exempted by Article 2(2) of Decision 2000/766/EC, from the prohibition established by Article 2(1) of that Decision, provided they fulfil, where applicable, the conditions set out in the Annexes I to III to the present Decision.

6. The additional control measures set out in paragraph 1 shall not apply to processed animal proteins referred to in Article 4 of Commission Decision 97/735/EC<sup>(2)</sup>, as last amended by Decision 1999/534/EC<sup>(3)</sup>.

#### *Article 4*

Article 2 of Decision 97/735/EC shall not apply to consignments of processed animal proteins which are accompanied by the health certificate referred to in Article 3(1)(b) of the present Decision.

#### *Article 5*

This Decision shall apply from 1 January 2001.

#### *Article 6*

This Decision is addressed to the Member States.

<sup>(1)</sup> OJ L 24, 30.1.1998, p. 9.

<sup>(2)</sup> OJ L 294, 28.10.1997, p. 7.

<sup>(3)</sup> OJ L 204, 4.8.1999, p. 37.



## ANNEX I

## CONDITIONS REFERRED TO IN ARTICLE 1(1)

1. Fishmeal shall be produced in processing plants dedicated only to fishmeal production, which are approved for this purpose by the competent authority in accordance with Article 5(2) of Directive 90/667/EEC.
2. Before release for free circulation in Community territory, each consignment of imported fishmeal shall be analysed in accordance with Commission Directive 98/88/EC<sup>(1)</sup>.
3. Fishmeal shall be transported directly from the processing plants to the establishments manufacturing animal feed, by means of vehicles which at the same time do not transport other feed materials. If the vehicle is subsequently used for the transport of other products, it shall be thoroughly cleaned and inspected before and after the transport of fishmeal.
4. Fishmeal shall be transported directly from the border inspection post to the establishments manufacturing animal feed, in accordance with the conditions laid down in Article 8 of Directive 97/78/EC, by means of vehicles which at the same time do not transport other feed materials. If the vehicle is subsequently used for the transport of other products, it shall be thoroughly cleaned and inspected before and after the transport of fishmeal.
5. By way of derogation from points 3 and 4, intermediate storage of fishmeal may be allowed only if it is carried out in dedicated storage plants which are authorised for this purpose by the competent authority.
6. Feedingstuffs containing fishmeal can be produced only in establishments manufacturing animal feed which do not prepare feedingstuffs for ruminant animals and which are authorised for this purpose by the competent authority.  
By way of derogation from this provision, the production of feedingstuffs for ruminant animals in establishments which also produce feedingstuffs containing fishmeal for other animal species may be permitted by the competent authority on condition that:
  - the transport and storage of feed materials destined to ruminant animals is completely separate from feed material prohibited for feeding to ruminant animals, and
  - the storage, transport, manufacturing and packaging facilities for the compound feedingstuffs destined to ruminant animals are completely separate, and
  - records detailing the purchases and uses of fishmeal and the sales of feedingstuff containing fishmeal are made available to the competent authority, and
  - routine tests are carried out on feedingstuffs destined to ruminant animals to ensure that prohibited processed animal proteins as defined by Article 1 of Decision 2000/766/EC are not present.
7. The labelling of feedingstuffs containing fishmeal shall clearly indicate the words 'it contains fishmeal — cannot be fed to ruminant animals'.
8. Bulk feedingstuffs containing fishmeal shall be transported by means of vehicles which at the same time do not transport feed for ruminant animals. If the vehicle is subsequently used for the transport of other products, it shall be thoroughly cleaned and inspected before and after the transport of bulk feedingstuffs containing fishmeal.
9. The use and storage of feedingstuffs, other than pet food referred to by Chapter 4 of Annex I to Directive 92/118/EEC, containing fishmeal shall be prohibited in farms where ruminant animals are kept, fattened or bred for the production of food.  
By way of derogation from this provision, the competent authority may permit the use and storage of feedingstuffs containing fishmeal in farms where ruminant animals are kept, if they are satisfied that on-farm measures are implemented to prevent that feedingstuffs containing fishmeal is fed to ruminant animals.

<sup>(1)</sup> OJ L 318, 27.11.1998, p. 45.



## ANNEX II

## CONDITIONS REFERRED TO IN ARTICLE 1(2)

1. Dicalcium phosphate shall be produced in processing plants approved by the competent authority in accordance with Article 5(2) of Directive 90/667/EEC.
2. Dicalcium phosphate from defatted bones shall:
  - be derived from bones fit for human consumption following ante- and post-mortem inspection,
  - be produced by a process which ensures that all bone-material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and pH < 1,5) over a period of at least two days followed by a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7, which is finally air dried with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C to 65 °C or by an equivalent process approved in accordance with the procedure of Article 17 of Directive 89/662/EEC.
3. Feedingstuffs containing dicalcium phosphate from defatted bones can be produced only in establishments manufacturing animal feed which do not prepare feedingstuffs for ruminant animals and which are authorised for this purpose by the competent authority.
 

By way of derogation from this provision, the production of feedingstuffs for ruminant animals in establishments which also produce feedingstuffs containing dicalcium phosphate from defatted bones for other animal species may be permitted by the competent authority on condition that:

  - the transport and storage of feed materials destined for ruminant animals is completely separate from feed material prohibited for feeding to ruminant animals, and
  - the storage, transport, manufacturing and packaging facilities for the compound feedingstuffs destined for ruminant animals are completely separate, and
  - records detailing the purchases and uses of dicalcium phosphate from defatted bones and the sales of feedingstuff containing dicalcium phosphate from defatted bones are made available to the competent authority, and
  - routine tests are carried out on feedingstuffs destined for ruminant animals to ensure that prohibited processed animal proteins as defined by Article 1 of Decision 2000/766/EC are not present.
4. The labelling of the feedingstuffs containing dicalcium phosphate from defatted bones shall clearly indicate the words 'it contains dicalcium phosphate from defatted bones — cannot be fed to ruminant animals'.
5. Bulk feedingstuffs containing dicalcium phosphate from defatted bones shall be transported by mean of vehicles which at the same time do not transport feed for ruminant animals. If the vehicle is subsequently used for the transport of other products, it shall be thoroughly cleaned and inspected before and after the transport of bulk feedingstuffs containing dicalcium phosphate from defatted bones,
6. The use and storage of feedingstuffs, other than pet food referred to by Chapter 4 of Annex I to Directive 92/118/EEC, containing dicalcium phosphate from defatted bones shall be prohibited in farms where ruminant animals are kept, fattened or bred for the production of food.
 

By way of derogation from this provision, the competent authority may permit the use and storage of feedingstuffs containing dicalcium phosphate from defatted bones in farms where ruminant animals are kept, if they are satisfied that on-farm measures are implemented to prevent that feedingstuffs containing dicalcium phosphate from defatted bones is fed to ruminant animals.

**▼B***ANNEX III***CONDITIONS REFERRED TO IN ARTICLE 1(3)****▼M1**

1. Hydrolysed proteins derived from fish, feather and hides and skins shall:
  - be produced in a processing plant dedicated only to hydrolysed proteins production, which are approved for this purpose by the competent authority in accordance with Article 5(2) of Directive 90/667/EEC;
  - be sampled after processing and found to have a molecular weight below 10 000 Dalton.

In addition, hydrolysed proteins from hides and skins shall:

- be derived from hides and skins obtained from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante and post mortem inspection;
- be produced by a production process which involves appropriate measures to minimise contamination of hides and skins, preparation of the raw material by brining, liming and intensive washing followed by exposure of the material to a pH of > 11 for more than three hours at a temperature of more than 80 °C and followed by heat treatment at a temperature of more than 140 °C for 30 minutes at more than 3,6 bar; or by an equivalent production process approved in accordance with the procedure of Article 17 of Directive 89/662/EEC.

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2. Feedingstuffs containing hydrolysed proteins can be produced only in plants manufacturing animal feedingstuffs which do not prepare feedingstuffs for ruminant animals and which are authorised for this purpose by the competent authority,

By way of derogation from this provision, the production of feedingstuffs for ruminant animals in establishments which also produce feedingstuffs containing hydrolysed proteins for other animal species may be permitted by the competent authority on condition that:

- the transport and storage of feed materials destined to ruminant animals is completely separate from feed material prohibited for feeding to ruminant animals, and
- the storage, transport, manufacturing and packaging facilities for the compound feedingstuffs destined to ruminant animals are completely separate, and
- records detailing the purchases and uses of hydrolysed proteins and the sales of feedingstuff containing hydrolysed proteins are made available to the competent authority, and
- routine tests are carried out on feedingstuffs destined to ruminant animals to ensure that prohibited processed animal proteins as defined by Article 1 of Decision 2000/766/EC are not present.

3. The labelling of feedingstuffs containing hydrolysed proteins shall clearly indicate the words 'it contains hydrolysed proteins — cannot be fed to ruminant animals'.
4. Bulk feedingstuffs containing hydrolysed proteins shall be transported by means of vehicles which at the same time do not transport feed for ruminant animals. If the vehicle is subsequently used for the transport of other products, it shall be thoroughly cleaned and inspected before and after the transport of bulk feedingstuffs containing hydrolysed proteins.
5. The use and storage of feedingstuffs, other than pet food referred to by Chapter 4 of Annex I to Directive 92/118/EEC, containing hydrolysed proteins shall be prohibited in farms where ruminants are kept, fattened or bred for the production of food.

By way of derogation for this provision, the competent authority may permit the use and storage of feedingstuffs containing hydrolysed proteins in farms where ruminant animals are kept, if they are satisfied that on-farm measures are implemented to prevent that feedingstuffs containing hydrolysed proteins is fed to ruminant animals.

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ANNEX IV

HEALTH CERTIFICATE

for hydrolysed proteins ▶<sup>(1)</sup> / dicalcium phosphate from defatted bones <sup>(1)</sup>, intended for intra-Community trade

Reference No of this health certificate: .....  
Member State of destination: .....  
Member State of origin: .....  
Responsible ministry: .....  
Certifying department: .....

I. Identification of the consignment

Hydrolysed proteins of/ dicalcium phosphate from defatted bones of <sup>(1)</sup>:  
.....  
(species)  
Nature of packaging: .....  
Number of packages: .....  
Net weight: .....  
Batch production reference No: .....

II. Origin of the consignment

Address and approval number of the processing plant: .....  
.....

III. Destination of the consignment

The hydrolysed proteins / The dicalcium phosphate from defatted bones <sup>(1)</sup> will be sent  
from: .....  
(place of loading)  
to: .....  
(country and place of destination)  
by the following means of transport:  
— type: .....  
— plate number or name of the vessel: .....  
No of seal: .....  
Name and address of consignor: .....  
Name and address of consignee: .....

<sup>(1)</sup> Delete as appropriate.

▶<sup>(1)</sup>M1



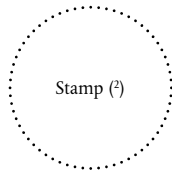
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**IV. Health attestation**

I the undersigned, official veterinarian, certify that the product described above:

- was produced in a plant approved in accordance with Directive 90/667/EEC,
- was produced in accordance with the conditions laid down in Annex II/Annex III <sup>(1)</sup> to Decision 2001/9/EC and cannot be used for the feeding of ruminant animals,
- was subjected to a sampling from each batch and the product was found to have a molecular weight below 10 000 Daltons <sup>(1)</sup>.

Done at .....  
(place) (date)



.....  
(signature of the official veterinarian) <sup>(2)</sup>

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

\_\_\_\_\_

<sup>(1)</sup> Delete as appropriate  
<sup>(2)</sup> The signature and the stamp must be in a different colour to that of the printing.



## ANNEX V

## HEALTH CERTIFICATE

for processed animal proteins as defined by Decision 2000/766/EC, other than pet food referred to in Annex I, Chapter 4 of Directive 92/118/EEC and processed animal protein listed in Article 2(2) of that Decision, destined for uses not prohibited by Article 3(1)(a) of Decision 2000/766/EC and intended for intra-Community trade or for export to third countries

Reference No of this health certificate: .....

Country of destination: .....

Member State of origin: .....

Responsible ministry: .....

Certifying department: .....

## I. Identification of the consignment

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

Processed animal protein of: .....  
(species)

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Batch production reference No: .....

## II. Origin of the consignment

Address and approval No of the processing plant: .....

.....

## III. Destination of the consignment

The processed animal proteins will be sent

from: .....  
(place of loading)

to: .....  
(country and place of destination)

by the following means of transport:

— type: .....

— plate number or name of the vessel: .....

No of seal: .....

Name and address of consignor: .....

Name and address of consignee: .....

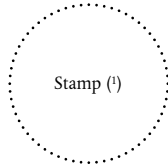
**▼B**

**IV. Health attestation**

I the undersigned, official veterinarian, certify that the product described above:

- was produced in a plant approved in accordance with Directive 90/667/EEC,
- contains processed animal proteins as defined by Decision 2000/766/EC and cannot be used for the feeding of farmed animals which are kept, fattened or bred for the production of food.

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



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

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

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