

This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

► **B** REGULATION (EC) No 1774/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 3 October 2002

laying down health rules concerning animal by-products not intended for human consumption

(OJ L 273, 10.10.2002, p. 1)

Amended by:

	Official Journal		
	No	page	date
► <b><u>M1</u></b> Commission Regulation (EC) No 808/2003 of 12 May 2003	L 117	1	13.5.2003



**REGULATION (EC) No 1774/2002 OF THE EUROPEAN  
PARLIAMENT AND OF THE COUNCIL**

**of 3 October 2002**

**laying down health rules concerning animal by-products not  
intended for human consumption**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE  
EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and  
in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the Economic and Social  
Committee <sup>(2)</sup>,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of  
the Treaty <sup>(3)</sup>, in the light of the joint text approved by the Conciliation  
Committee on 12 September 2002.

Whereas:

- (1) Council Directive 90/667/EEC of 27 November 1990 laying 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 feedingstuffs of animal or fish origin and amending Directive 90/425/EEC <sup>(4)</sup> established the principle that all animal waste, regardless of its source, may be used for the production of feed material following appropriate treatment.
- (2) The Scientific Steering Committee has adopted a number of opinions since the adoption of that Directive. Their main conclusion is that animal by-products derived from animals not fit for human consumption following health inspection should not enter the feed chain.
- (3) In the light of those scientific opinions, a distinction should be drawn between the measures to be implemented, depending on the nature of animal by-products used. The possible uses of certain animal materials should be limited. Rules should be laid down for the use of animal by-products other than in feed and for their disposal.
- (4) In the light of the experience gained in recent years, it is appropriate to clarify the relationship between Directive 90/667/EEC and Community environmental legislation. This Regulation should not affect the application of existing environmental legislation or hinder the development of new rules on environmental protection, particularly as regards biodegradable waste. In this regard, the Commission has given a commitment that by the end of the year 2004 a Directive on biowaste, including catering waste, will be prepared with the aim of establishing rules on safe use, recovery, recycling and disposal of this waste and of controlling potential contamination.
- (5) The International Scientific Conference on Meat-and-Bone Meal organised by the Commission and the European Parliament, held in Brussels on 1 and 2 July 1997, initiated a debate concerning

<sup>(1)</sup> OJ C 96 E, 27.3.2001, p. 40.

<sup>(2)</sup> OJ C 193, 10.7.2001, p. 32.

<sup>(3)</sup> Opinion of the European Parliament of 12 June 2001 (OJ C 53 E of 28.2.2002, p. 84), Council Common Position of 20 November 2001 (OJ C 45 E of 19.2.2002, p. 70) and Decision of the European Parliament of 13 March 2002 (not yet published in the Official Journal). Decision of the European Parliament of 24 September 2002 and Council Decision of 23 September 2002.

<sup>(4)</sup> OJ L 363, 27.12.1990, p. 51. Directive as last amended by the 1994 Act of Accession.

**▼B**

the production and feeding of meat-and-bone meal. The Conference called for further reflection on the future policy in this area. In November 1997, to launch the widest possible public debate about the future of the Community's feed legislation, the Commission finalised a consultation paper on meat-and-bone meal. Following that consultation, it appears that there is a general recognition of the need to amend Directive 90/667/EEC to bring it in line with the new scientific information.

- (6) The European Parliament, in its resolution of 16 November 2000 on BSE and safety of animal feed <sup>(1)</sup>, called for a ban on the use of animal protein in feed until the present Regulation enters into force.
- (7) Scientific advice suggests that the practice of feeding an animal species with proteins derived from the bodies, or parts of bodies, of the same species presents a risk of spreading disease. As a precautionary measure, this practice should therefore be prohibited. Implementing rules should be adopted to ensure the necessary separation of animal by-products destined for use in feed at every stage of processing, storage and transport. However, there should be scope to establish derogations from this general prohibition in relation to fish and fur animals if justified by scientific advice.
- (8) Catering waste containing products of animal origin can also be a vector for the spread of disease. All catering waste generated from means of transport operating internationally should be disposed of safely. Catering waste produced within the Community should not be used for the feeding of farmed animals other than fur animals.
- (9) From October 1996, the Food and Veterinary Office of the Commission (FVO) carried out a number of rounds of inspections in Member States, to assess the presence and management of main risk factors and surveillance procedures with regard to BSE. Part of the assessment covered the systems of commercial rendering and other methods of animal waste disposal. General conclusions and a number of recommendations were drawn up following those inspections, with particular reference to the traceability of animal by-products.
- (10) To avoid any risk of dispersal of pathogens and/or residues, animal by-products should be processed, stored and kept separated in an approved and supervised plant designated by the Member State concerned or be disposed of in a suitable manner. In certain circumstances, especially when it is justified by distance, time of transport, or capacity problems, the designated processing, incineration or co-incineration plant could be located in another Member State.
- (11) Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste <sup>(2)</sup> does not apply to incineration plants if the waste treated consists solely of animal carcasses. It is necessary to lay down minimum requirements for such incineration plants to protect animal and public health. Pending the adoption of Community requirements, Member States may adopt environmental legislation for such plants. Less strict requirements should apply to low-capacity incineration plants, such as those located on farms and at pet crematoria, to reflect the lower risk posed by the material treated and to avoid unnecessary transport of animal by-products.
- (12) Specific rules should be laid down on controls for processing plants, with particular reference to detailed procedures for the validation of processing methods and for self-supervision of production.

<sup>(1)</sup> OJ C 223, 8.8.2001, p. 281.

<sup>(2)</sup> OJ L 332, 28.12.2000, p. 91.

**▼B**

- (13) Derogations from the rules on the use of animal by-products may be appropriate to facilitate the feeding of animals not destined for human consumption. The competent authorities should control such uses.
- (14) Derogations may also be appropriate to permit the disposal of animal by-products on site in controlled circumstances. The Commission should receive the information necessary to enable it to monitor the situation and to lay down implementing rules if appropriate.
- (15) Community inspections should be carried out in the Member States to ensure uniform implementation of the health requirements. Such inspections should also include audit procedures.
- (16) The basis for Community legislation on health issues is sound science. To this end, the relevant scientific committees set up by Commission Decisions 97/404/EC <sup>(1)</sup> and 97/579/EC <sup>(2)</sup> should be consulted wherever necessary. In particular, further scientific advice is required on the use of products of animal origin in organic fertilisers and soil improvers. Pending the adoption of Community rules in the light of this advice, Member States may maintain or adopt national rules that are stricter than those envisaged in this Regulation, provided that such rules comply with other applicable Community legislation.
- (17) A wide variety of approaches exists in Member States as regards the financial support for processing, collection, storage and disposal of animal by-products. To ensure that the conditions of competition between agricultural products are not affected, it is necessary to carry out an analysis and, if necessary, to take appropriate measures at Community level.
- (18) In the light of the above, a fundamental revision of the Community rules applicable to animal by-products appears to be necessary.
- (19) Animal by-products not destined for human consumption (in particular processed animal protein, rendered fats, petfood, hides and skins and wool) are included in the list of products in Annex I to the Treaty. The placing on the market of such products constitutes an important source of income for part of the farming population. To ensure rational development in this sector and increase productivity, animal health and public health rules for the products in question should be laid down at Community level. Given the significant risks of the spread of diseases to which animals are exposed, particular requirements should apply to the placing on the market of certain animal by-products, particularly in regions with a high health status.
- (20) To ensure that products imported from non-member countries are of a hygiene standard which is at least equal or equivalent to the hygiene standard applied by the Community, a system of approval should be introduced for non-member countries and their establishments, together with a Community inspection procedure to ensure that the conditions for such approval are observed. The importation from third countries of petfood and raw material for petfood can take place subject to conditions different from those applicable to such material produced in the Community, in particular as regards the guarantees required concerning the residues of substances prohibited in accordance with Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC <sup>(3)</sup>. To ensure that such petfood and raw material are used

<sup>(1)</sup> OJ L 169, 27.6.1997, p. 85. Decision as amended by Decision 2000/443/EC (OJ L 179, 18.7.2000, p. 13).

<sup>(2)</sup> OJ L 237, 28.8.1997, p. 18. Decision as amended by Decision 2000/443/EC.

<sup>(3)</sup> OJ L 125, 23.5.1996, p. 3.

▼B

only for their intended purpose, it is necessary to lay down appropriate control measures on importation of material covered by such derogations.

- (21) Animal by-products that pass through the Community in transit, and those originating in the Community and destined for export, can create a risk for animal and public health within the Community. Certain requirements laid down by this Regulation should therefore apply to such movements.
- (22) The accompanying document for products of animal origin is the best way of satisfying the competent authority of the place of destination that a consignment complies with the provisions of this Regulation. The health certificate should be maintained for the purposes of verifying the destination of certain imported products.
- (23) Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade 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, to Directive 90/425/EEC <sup>(1)</sup> pursues the abovementioned objectives.
- (24) The Council and the Commission have adopted several Decisions implementing Directives 90/667/EEC and 92/118/EEC. Furthermore, Directive 92/118/EEC has been substantially amended and further amendments are to be made. Consequently, a great number of Community acts currently regulate the animal by-products sector and there is a need for simplification.
- (25) Such simplification will lead to more transparency with regard to specific health rules for products of animal origin not destined for human consumption. Simplification of the specific health legislation must not lead to deregulation. It is therefore necessary to maintain and, to ensure public and animal health protection, to tighten the detailed health rules for products of animal origin not destined for human consumption.
- (26) The products concerned should be subject to the rules for veterinary checks, including checks by experts from the Commission, and any protective measures laid down by 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>(2)</sup>.
- (27) Effective checks should be carried out on products imported into the Community. This can be achieved by implementing the controls laid down in 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 non-member countries <sup>(3)</sup>.
- (28) Directive 90/667/EEC, Council Decision 95/348/EC of 22 June 1995 laying down the veterinary and animal health rules applicable in the United Kingdom and Ireland to the treatment of certain types of waste intended to be marketed locally as feed-stuffs for certain animal categories <sup>(4)</sup> and Council Decision 1999/534/EC 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 <sup>(5)</sup> should therefore be repealed.

<sup>(1)</sup> OJ L 62, 15.3.1993, p. 49. Directive as last amended by Commission Decision 2001/7/EC (OJ L 2, 5.1.2001, p. 27).

<sup>(2)</sup> OJ L 224, 18.8.1990, p. 29. Directive as last amended by Directive 92/118/EEC.

<sup>(3)</sup> OJ L 24, 30.1.1998, p. 9.

<sup>(4)</sup> OJ L 202, 26.8.1995, p. 8.

<sup>(5)</sup> OJ L 204, 4.8.1999, p. 37.

**▼B**

- (29) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>(1)</sup>.
- (30) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(2)</sup>,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

**GENERAL PROVISIONS**

*Article 1*

**Scope**

1. This Regulation lays down animal and public health rules for:
  - (a) the collection, transport, storage, handling, processing and use or disposal of animal by-products, to prevent these products from presenting a risk to animal or public health;
  - (b) the placing on the market and, in certain specific cases, the export and transit of animal by-products and those products derived therefrom referred to in Annexes VII and VIII.
2. This Regulation shall not apply to:
  - (a) raw petfood originating from retail shops or in premises adjacent to sale points, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot;
  - (b) liquid milk and colostrum disposed of or used on the farm of origin;
  - (c) entire bodies or parts of wild animals not suspected of being infected with diseases communicable to humans or animals, except for fish landed for commercial purposes and bodies or parts of wild animals used to produce game trophies;
  - (d) raw petfood for use on site derived from animals slaughtered on the farm of origin for use as foodstuffs by the farmer and his family only, in accordance with national legislation;
  - (e) catering waste, unless:
    - (i) from means of transport operating internationally,
    - (ii) destined for animal consumption, or
    - (iii) destined for use in a biogas plant or for composting;
  - (f) ova, embryos and semen intended for breeding purposes; and
  - (g) transit by sea or by air.
3. This Regulation shall not affect veterinary legislation having as its objective the eradication and control of certain diseases.

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1.

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.

▼B*Article 2***Definitions**

1. For the purpose of this Regulation, the following definitions shall apply:
  - (a) animal by-products: entire bodies or parts of animals or products of animal origin referred to in Articles 4, 5 and 6 not intended for human consumption, including ova, embryos and semen;
  - (b) Category 1 material: animal by-products referred to in Article 4;
  - (c) Category 2 material: animal by-products referred to in Article 5;
  - (d) Category 3 material: animal by-products referred to in Article 6;
  - (e) animal: any vertebrate or invertebrate animal (including fish, reptiles and amphibians);
  - (f) farmed animal: any animal that is kept, fattened or bred by humans and used for the production of food (including meat, milk and eggs), wool, fur, feathers, skins or any other product of animal origin;
  - (g) wild animal: any animal not kept by humans;
  - (h) pet animal: any animal belonging to species normally nourished and kept, but not consumed, by humans for purposes other than farming;
  - (i) competent authority: the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that central authority has delegated that competence, in particular for the control of feedingstuffs; it shall also include, where appropriate, the corresponding authority of a non-member country;
  - (j) placing on the market: any operation the purpose of which is to sell animal by-products, or products derived therefrom covered by this Regulation, to a third party in the Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;
  - (k) trade: trade between Member States in goods within the meaning of Article 23(2) of the Treaty;
  - (l) transit: a movement through the Community from one non-member country to another;
  - (m) producer: any person whose activity produces animal by-products;
  - (n) TSEs: all transmissible spongiform encephalopathies, except those occurring in humans;
  - (o) specified risk material: material referred to in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies <sup>(1)</sup>.
2. The specific definitions set out in Annex I shall also apply.

*Article 3***General obligations**

1. Animal by-products, and products derived therefrom, shall be collected, transported, stored, handled, processed, disposed of, placed on the market, exported, carried in transit and used in accordance with this Regulation.
2. However, Member States may regulate under national law the importation and placing on the market of products not referred to in Annexes VII and VIII, pending the adoption of a decision in accor-

<sup>(1)</sup> OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1326/2001 (OJ L 177, 30.6.2001, p. 60).

▼B

dance with the procedure referred to in Article 33(2). They shall immediately inform the Commission of the use that they make of this possibility.

3. Member States shall, either individually or cooperatively, ensure that adequate arrangements are in place, and that a sufficient infrastructure exists, to ensure compliance with the requirement of paragraph 1.

## CHAPTER II

**CATEGORISATION, COLLECTION, TRANSPORTATION,  
DISPOSAL, PROCESSING, USE AND INTERMEDIATE  
STORAGE OF ANIMAL BY-PRODUCTS**

*Article 4***Category 1 material**

1. Category 1 material shall comprise animal by-products of the following description, or any material containing such by-products:

- (a) all body parts, including hides and skins, of the following animals:
  - (i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed,
  - (ii) animals killed in the context of TSE eradication measures,
  - (iii) animals other than farmed animals and wild animals, including in particular pet animals, zoo animals and circus animals,
  - (iv) experimental animals as defined by Article 2 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes <sup>(1)</sup>, and
  - (v) wild animals, when suspected of being infected with diseases communicable to humans or animals;
- (b) (i) specified risk material, and
  - (ii) where, at the time of disposal, specified risk material has not been removed, entire bodies of dead animals containing specified risk material;
- (c) products derived from animals to which substances prohibited under Directive 96/22/EC have been administered and products of animal origin containing residues of environmental contaminants and other substances listed in Group B(3) of Annex I to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC <sup>(2)</sup>, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;
- (d) all animal material collected when treating waste water from Category 1 processing plants and other premises in which specified risk material is removed, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises, unless such material contains no specified risk material or parts of such material;
- (e) catering waste from means of transport operating internationally; and
- (f) mixtures of Category 1 material with either Category 2 material or Category 3 material or both, including any material destined for processing in a Category 1 processing plant.

<sup>(1)</sup> OJ L 358, 18.12.1986, p. 1.

<sup>(2)</sup> OJ L 125, 23.5.1996, p. 10.



**▼B**

2. Category 1 material shall be collected, transported and identified without undue delay in accordance with Article 7 and, except as otherwise provided in Articles 23 and 24, shall be:

- (a) directly disposed of as waste by incineration in an incineration plant approved in accordance with Article 12;
- (b) processed in a processing plant approved under Article 13 using any of processing methods 1 to 5 or, where the competent authority so requires, processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and finally disposed of as waste by incineration or by co-incineration in an incineration or co-incineration plant approved in accordance with Article 12;
- (c) with the exclusion of material referred to in paragraph 1(a)(i) and (ii), processed in a processing plant approved in accordance with Article 13 using processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and finally disposed of as waste by burial in a landfill approved under Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste <sup>(1)</sup>;
- (d) in the case of catering waste referred to in paragraph 1(e), disposed of as waste by burial in a landfill approved under Directive 1999/31/EC; or
- (e) in the light of developments in scientific knowledge, disposed of by other means that are approved in accordance with the procedure referred to in Article 33(2), after consultation of the appropriate scientific committee. These means may either supplement or replace those provided for in subparagraphs (a) to (d).

3. Intermediate handling or storage of Category 1 material shall take place only in Category 1 intermediate plants approved in accordance with Article 10.

4. Category 1 material shall not be imported or exported except in accordance with this Regulation or with rules laid down under the procedure referred to in Article 33(2). However, the import or export of specified risk material shall take place only in accordance with Article 8(1) of Regulation (EC) No 999/2001.

*Article 5*

**Category 2 material**

1. Category 2 material shall comprise animal by-products of the following description, or any material containing such by-products:

- (a) manure and digestive tract content;
- (b) all animal materials collected when treating waste water from slaughterhouses other than slaughterhouses covered by Article 4(1)(d) or from Category 2 processing plants, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises;
- (c) products of animal origin containing residues of veterinary drugs and contaminants listed in Group B(1) and (2) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation;
- (d) products of animal origin, other than Category 1 material, that are imported from non-member countries and, in the course of the inspections provided for in Community legislation, fail to comply with the veterinary requirements for their importation into the Community, unless they are returned or their importation is accepted under restrictions laid down under Community legislation;

<sup>(1)</sup> OJ L 182, 16.7.1999, p. 1.

**▼B**

- (e) animals and parts of animals, other than those referred to in Article 4, that die other than by being slaughtered for human consumption, including animals killed to eradicate an epizootic disease;
  - (f) mixtures of Category 2 material with Category 3 material, including any material destined for processing in a Category 2 processing plant; and
  - (g) animal by-products other than Category 1 material or Category 3 material.
2. Category 2 material shall be collected, transported and identified without undue delay in accordance with Article 7 and, except as otherwise provided in Articles 23 and 24, shall be:
- (a) directly disposed of as waste by incineration in an incineration plant approved in accordance with Article 12;
  - (b) processed in a processing plant approved in accordance with Article 13 using any of processing methods 1 to 5 or, where the competent authority so requires, processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and:
    - (i) disposed of as waste either by incineration or by coincineration in an incineration or co-incineration plant approved in accordance with Article 12, or
    - (ii) in the case of rendered fats, further processed into fat derivatives for use in organic fertilizers or soil improvers or for other technical uses, other than in cosmetics, pharmaceuticals and medical devices, in a Category 2 oleochemical plant approved in accordance with Article 14;
  - (c) processed in a processing plant approved in accordance with Article 13 using processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and:
    - (i) in the case of resulting proteinaceous material, used as an organic fertilizer or soil improver in compliance with requirements, if any, laid down in accordance with the procedure referred to in Article 33(2), after consultation of the appropriate scientific committee,
    - (ii) transformed in a biogas plant or in a composting plant approved in accordance with Article 15, or
    - (iii) disposed of as waste by burial in a landfill approved under Directive 1999/31/EC;
  - (d) in the case of material of fish origin, ensiled or composted in compliance with rules adopted in accordance with the procedure referred to in Article 33(2);
  - (e) in the case of manure, digestive tract content separated from the digestive tract, milk and colostrum, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease:
    - (i) used without processing as raw material in a biogas plant or in a composting plant approved in accordance with Article 15 or treated in a technical plant approved for this purpose in accordance with Article 18,
    - (ii) applied to land in accordance with this Regulation, or
    - (iii) transformed in a biogas plant or composted in accordance with rules laid down under the procedure referred to in Article 33(2);
  - (f) in the case of entire bodies or parts of wild animals not suspected of being infected with diseases communicable to humans or animals, used to produce game trophies in a technical plant approved for this purpose in accordance with Article 18; or
  - (g) disposed of by other means, or used in other ways, in accordance with rules laid down under the procedure referred to in Article 33(2), after consultation of the appropriate scientific committee.

**▼B**

These means or ways may either supplement or replace those provided for in subparagraphs (a) to (f).

3. Intermediate handling or storage of Category 2 material, other than manure, shall take place only in Category 2 intermediate plants approved in accordance with Article 10.
4. Category 2 material shall not be placed on the market or exported except in accordance with this Regulation or with rules laid down under the procedure referred to in Article 33(2).

*Article 6***Category 3 material**

1. Category 3 material shall comprise animal by-products of the following description, or any material containing such by-products:

- (a) parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;
- (b) parts of slaughtered animals, which are rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that are fit for human consumption in accordance with Community legislation;
- (c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;
- (d) blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;
- (e) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;
- (f) former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals;
- (g) raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals;
- (h) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;
- (i) fresh by-products from fish from plants manufacturing fish products for human consumption;
- (j) shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals;
- (k) blood, hides and skins, hooves, feathers, wool, horns, hair and fur originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals; and
- (l) catering waste other than as referred to in Article 4(1)(e).

2. Category 3 material shall be collected, transported and identified without undue delay in accordance with Article 7 and, except as otherwise provided in Articles 23 and 24, shall be:

- (a) directly disposed of as waste by incineration in an incineration plant approved in accordance with Article 12;
- (b) processed in a processing plant approved in accordance with Article 13 using any of processing methods 1 to 5, in which case the resulting material shall be permanently marked, where techni-

▼**B**

- cally possible with smell, in accordance with Annex VI, Chapter I, and disposed of as waste either by incineration or by co-incineration in an incineration or co-incineration plant approved in accordance with Article 12 or in a landfill approved under Directive 1999/31/EC;
- (c) processed in a processing plant approved in accordance with Article 17;
  - (d) transformed in a technical plant approved in accordance with Article 18;
  - (e) used as raw material in a petfood plant approved in accordance with Article 18;
  - (f) transformed in a biogas plant or in a composting plant approved in accordance with Article 15;
  - (g) in the case of catering waste referred to in paragraph 1(1), transformed in a biogas plant or composted in accordance with rules laid down under the procedure referred to in Article 33(2) or, pending the adoption of such rules, in accordance with national law;
  - (h) in the case of material of fish origin, ensiled or composted in accordance with rules laid down under the procedure referred to in Article 33(2); or
  - (i) disposed of by other means, or used in other ways, in accordance with rules laid down under the procedure referred to in Article 33(2), after consultation of the appropriate scientific committee. These means or ways may either supplement or replace those provided for in subparagraphs (a) to (h).
3. Intermediate handling or storage of Category 3 material shall take place only in Category 3 intermediate plants approved in accordance with Article 10.

*Article 7***Collection, transportation and storage**

1. Animal by-products and processed products, with the exception of Category 3 catering waste shall be collected, transported and identified in accordance with Annex II.
2. During transportation, a commercial document or, when required by this Regulation, a health certificate, shall accompany animal by-products and processed products. Commercial documents and health certificates shall satisfy the requirements, and be kept for the period, specified in Annex II. They shall, in particular, include information concerning the quantity and a description of the material and its marking.
3. Member States shall ensure that adequate arrangements exist to guarantee the collection and transportation of Category 1 and Category 2 material in accordance with Annex II.
4. In accordance with Article 4 of Council Directive 75/442/EEC of 15 July 1975 on waste <sup>(1)</sup>, Member States shall take the necessary measures to ensure that Category 3 catering waste is collected, transported and disposed of without endangering human health and without harming the environment.
5. The storage of processed products shall take place only in storage plants approved in accordance with Article 11.
6. However, Member States may decide not to apply the provisions of this Article to manure transported between two points located on the same farm or between farms and users located in the same Member State.

<sup>(1)</sup> OJ L 194, 25.7.1975, p. 39. Directive as last amended by Commission Decision 96/350/EC (OJ L 135, 6.6.1996, p. 32).



*Article 8*

**Dispatch of animal by-products and processed products to other Member States**

1. Animal by-products and processed products shall be sent to other Member States only subject to the conditions laid down in paragraphs 2 to 6.
2. The Member State of destination must have authorised the receipt of Category 1 material, Category 2 material, processed products derived from Category 1 or Category 2 material and processed animal protein. Member States may make the application of processing method 1 prior to dispatch a condition of authorisation.
3. Animal by-products, and processed products referred to in paragraph 2, shall be:
  - (a) accompanied by a commercial document or, when required by this Regulation, a health certificate, and
  - (b) conveyed directly to the plant of destination, which must have been approved in accordance with this Regulation.
4. When Member States send Category 1 material, Category 2 material, processed products derived from Category 1 or Category 2 material and processed animal protein to other Member States, the competent authority of the place of origin shall inform the competent authority of the place of destination of each consignment by means of the ANIMO system, or by another method by mutual agreement. The message shall contain the information specified in Annex II, Chapter I, paragraph 2.
5. When informed of its dispatch in accordance with paragraph 4, the competent authority of the place of destination shall inform the competent authority of the place of origin of the arrival of each consignment by means of the ANIMO system, or by another method by mutual agreement.
6. Member States of destination shall ensure, through regular checks, that the designated plants on their territory use consignments only for authorised purposes and keep full records demonstrating compliance with this Regulation.

*Article 9*

**Records**

1. Any person consigning, transporting or receiving animal by-products shall keep a record of consignments. Records shall contain the information, and be kept for the period, specified in Annex II.
2. However, this Article shall not apply to manure transported between two points located on the same farm or locally between farms and users located in the same Member State.

CHAPTER III

**APPROVAL OF INTERMEDIATE, STORAGE, INCINERATION AND CO-INCINERATION, CATEGORY 1 AND 2 PROCESSING, CATEGORY 2 AND CATEGORY 3 OLEOCHEMICAL, BIOGAS AND COMPOSTING PLANTS**

*Article 10*

**Approval of intermediate plants**

1. Category 1, 2 and 3 intermediate plants shall be subject to approval by the competent authority.
2. To be approved, Category 1 or Category 2 intermediate plants must:
  - (a) meet the requirements of Annex III, Chapter I;

**▼B**

- (b) handle and store Category 1 or Category 2 material in accordance with Annex III, Chapter II, Part B;
  - (c) undergo the plant's own checks provided for in Article 25; and
  - (d) be checked by the competent authority in accordance with Article 26.
3. To be approved, Category 3 intermediate plants must:
- (a) meet the requirements of Annex III, Chapter I;
  - (b) handle and store Category 3 material in accordance with Annex III, Chapter II, Part A;
  - (c) undergo the plant's own checks provided for in Article 25; and
  - (d) be checked by the competent authority in accordance with Article 26.

*Article 11***Approval of storage plants**

1. Storage plants shall be subject to approval by the competent authority.
2. To be approved, storage plants must:
- (a) meet the requirements of Annex III, Chapter III; and
  - (b) be checked by the competent authority in accordance with Article 26.

*Article 12***Approval of incineration and co-incineration plants**

1. The incineration and co-incineration of processed products shall take place in accordance with the provisions of Directive 2000/76/EC. The incineration and co-incineration of animal by-products shall take place either in accordance with the provisions of Directive 2000/76/EC or, when that Directive does not apply, in accordance with the provisions of this Regulation. Incineration and co-incineration plants shall be approved under that Directive or in accordance with paragraph 2 or 3.
2. To be approved by the competent authority for the purpose of disposing of animal by-products, a high-capacity incineration or co-incineration plant to which Directive 2000/76/EC does not apply must fulfil:
- (a) the general conditions laid down in Annex IV, Chapter I;
  - (b) the operating conditions laid down in Annex IV, Chapter II;
  - (c) the requirements laid down in Annex IV, Chapter III, concerning water discharges;
  - (d) the requirements laid down in Annex IV, Chapter IV, concerning residues;
  - (e) the temperature measurement requirements laid down in Annex IV, Chapter V; and
  - (f) the conditions concerning abnormal operating laid down in Annex IV, Chapter VI.
3. To be approved by the competent authority for the purpose of disposing of animal by-products, a low-capacity incineration or co-incineration plant to which Directive 2000/76/EC does not apply must:

**▼M1**

- (a) be used only for the disposal of dead pet animals, animal by-products as referred to in Articles 4(1) (b), 5(1) and 6(1) to which Directive 2000/76/EC does not apply;

**▼B**

- (b) when located on a holding, be used only for the disposal of material from that particular holding;

**▼B**

- (c) fulfil the general conditions laid down in Annex IV, Chapter I;
- (d) fulfil the applicable operating conditions laid down in Annex IV, Chapter II;
- (e) fulfil the requirements laid down in Annex IV, Chapter IV, concerning residues;
- (f) fulfil the applicable temperature measurement requirements laid down in Annex IV, Chapter V;
- (g) fulfil the conditions concerning abnormal operating laid down in Annex IV, Chapter VI; and

**▼M1**

- (h) fulfil the conditions in Annex IV, Chapter VII when used for the disposal of animal by-products referred to in Article 4(1)(b).

**▼B**

4. Approval shall be suspended immediately if the conditions under which it was granted are no longer fulfilled.

5. The requirements of paragraphs 2 and 3 may be modified in the light of developments in scientific knowledge in accordance with the procedure referred to in Article 33(2), after consultation of the appropriate scientific committee.

*Article 13***Approval of Category 1 and Category 2 processing plants**

1. Category 1 and Category 2 processing plants shall be subject to approval by the competent authority.
2. To be approved, Category 1 and Category 2 processing plants must:
  - (a) meet the requirements of Annex V, Chapter I;
  - (b) handle, process and store Category 1 or Category 2 material in accordance with Annex V, Chapter II and Annex VI, Chapter I;
  - (c) be validated by the competent authority in accordance with Annex V, Chapter V;
  - (d) undergo the plant's own checks provided for in Article 25;
  - (e) be checked by the competent authority in accordance with Article 26; and
  - (f) ensure that, after processing, the products satisfy the requirements of Annex VI, Chapter I.
3. Approval shall be suspended immediately if the conditions under which it was granted are no longer fulfilled.

*Article 14***Approval of Category 2 and Category 3 oleochemical plants**

1. Oleochemical plants shall be subject to approval by the competent authority.
2. To be approved, Category 2 oleochemical plants must:
  - (a) process rendered fats derived from Category 2 material in accordance with the standards laid down in Annex VI, Chapter III;
  - (b) establish and implement methods of monitoring and checking the critical control points on the basis of the process used;
  - (c) keep a record of the information obtained pursuant to point (b) for presentation to the competent authority; and
  - (d) be checked by the competent authority in accordance with Article 26.
3. To be approved, Category 3 oleochemical plants must process rendered fats derived only from Category 3 material and meet the relevant requirements referred to in paragraph 2.

**▼B**

4. Approval shall be suspended immediately if the conditions under which it was granted are no longer fulfilled.

*Article 15***Approval of biogas plants and composting plants**

1. Biogas plants and composting plants shall be subject to approval by the competent authority.

2. To be approved, biogas plants and composting plants must:

- (a) meet the requirements of Annex VI, Chapter II, Part A;
- (b) handle and transform animal by-products in accordance with Annex VI, Chapter II, Parts B and C;
- (c) be checked by the competent authority in accordance with Article 26;
- (d) establish and implement methods of monitoring and checking the critical control points; and
- (e) ensure that digestion residues and compost, as appropriate, comply with the microbiological standards laid down in Annex VI, Chapter II, Part D.

3. Approval shall be suspended immediately if the conditions under which it was granted are no longer fulfilled.

## CHAPTER IV

**PLACING ON THE MARKET AND USE OF PROCESSED ANIMAL PROTEINS AND OTHER PROCESSED PRODUCTS THAT COULD BE USED AS FEED MATERIAL, PETFOOD, DOGCHEWS AND TECHNICAL PRODUCTS AND APPROVAL OF RELATED PLANTS**

*Article 16***General animal health provisions**

1. Member States shall take all necessary measures to guarantee that animal by-products, and products derived therefrom referred to in Annexes VII and VIII, are not dispatched from any holding situated in a zone subject to restrictions because of the occurrence of a disease to which the species from which the product is derived is susceptible, or from any plant or zone from which movements or trade would constitute a risk to the animal health status of the Member States or areas of Member States, except where products are treated in accordance with this Regulation.

2. The measures referred to in paragraph 1 shall guarantee that the products are obtained from animals that:

- (a) come from a holding, territory or part of a territory or, in the case of aquaculture products, from a farm, zone or part of a zone, not subject to animal health restrictions applicable to the animals and products concerned, and in particular restrictions under disease control measures imposed by Community legislation or by virtue of a serious transmissible disease listed in Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease <sup>(1)</sup>;
- (b) were not slaughtered in a plant in which animals infected, or suspected of being infected, with one of the diseases covered by the rules referred to in (a) were present at the time of slaughter.

3. Subject to compliance with the disease control measures referred to in paragraph 2(a), the placing on the market of animal by-products, and products derived therefrom referred to in Annexes VII and VIII,

<sup>(1)</sup> OJ L 62, 15.3.1993, p. 69. Directive as last amended by the 1994 Act of Accession.



**▼B**

that come from a territory or part of a territory subject to animal health restrictions but are not infected or suspected of being infected shall be permitted provided that, as appropriate, the products:

- (a) are obtained, handled, transported and stored separately from or at different times from products fulfilling all animal health conditions;
- (b) have undergone a treatment sufficient to eliminate the animal health problem concerned in accordance with this Regulation at a plant approved for that purpose by the Member State where the animal health problem occurred;
- (c) are properly identified;
- (d) comply with the requirements laid down in Annexes VII and VIII, or with detailed rules to be laid down in accordance with the procedure referred to in Article 33(2).

Conditions alternative to those set out in the first subparagraph may be laid down in specific situations by decisions adopted in accordance with the procedure referred to in Article 33(2). Such decisions shall take account of any measures concerning the animals or tests to be carried out on them and the specific characteristics of the disease in the species concerned and shall specify any measures needed to ensure the protection of animal health in the Community.

*Article 17***Approval of Category 3 processing plants**

1. Category 3 processing plants shall be subject to approval by the competent authority.
2. To be approved, Category 3 processing plants must:
  - (a) meet the requirements of Annex V, Chapter I, and Annex VII, Chapter I;
  - (b) handle, process and store only Category 3 material in accordance with Annex V, Chapter II, and Annex VII;
  - (c) be validated by the competent authority in accordance with Annex V, Chapter V;
  - (d) undergo the plant's own checks provided for in Article 25;
  - (e) be checked by the competent authority in accordance with Article 26; and
  - (f) ensure that, after processing, the products satisfy the requirements of Annex VII, Chapter I.
3. Approval shall be suspended immediately if the conditions under which it was granted are no longer fulfilled.

*Article 18***Approval of petfood plants and technical plants**

1. Petfood plants and technical plants shall be subject to approval by the competent authority.
2. To be approved, the petfood plant or the technical plant must:
  - (a) undertake, in the light of the specific requirements laid down in Annex VIII for the products the plant produces:
    - (i) to comply with the specific production requirements set out in this Regulation;
    - (ii) to establish and implement methods of monitoring and checking the critical control points on the basis of the process used;
    - (iii) depending on the products, to take samples for analyses in a laboratory recognised by the competent authority for the purposes of checking compliance with the standards established by this Regulation;
    - (iv) to keep a record of the information obtained pursuant to points (ii) and (iii) for presentation to the competent authority. The

**▼B**

results of the checks and tests shall be kept for at least two years;

- (v) to inform the competent authority, should the result of the laboratory examination referred to in point (iii) or any other information available to them reveal the existence of a serious animal health or public health hazard; and
  - (b) to be checked by the competent authority in accordance with Article 26.
3. Approval shall be suspended immediately if the conditions under which it was granted are no longer fulfilled.

*Article 19***Placing on the market and export of processed animal protein and other processed products that could be used as feed material**

Member States shall ensure that processed animal protein and other processed products that could be used as feed material are placed on the market or exported only if they:

- (a) have been prepared in a Category 3 processing plant approved and supervised in accordance with Article 17;
- (b) have been prepared exclusively with Category 3 material, as specified in Annex VII;
- (c) have been handled, processed, stored and transported in accordance with Annex VII and in such a manner as to ensure compliance with Article 22; and
- (d) meet the specific requirements laid down in Annex VII.

*Article 20***Placing on the market and export of petfood, dogchews and technical products**

1. Member States shall ensure that petfood, dogchews, technical products, other than those referred to in paragraphs 2 and 3, and those animal by-products referred to in Annex VIII are placed on the market or exported only if they:

- (a) meet either:
  - (i) the specific requirements laid down in Annex VIII, or
  - (ii) when a product could be used both as a technical product and as feed material, and Annex VIII contains no specific requirements, the specific requirements laid down by the relevant Chapter of Annex VII; and
- (b) come from plants approved and supervised in accordance with Article 18 or, in the case of animal by-products referred to in Annex VIII, from other plants approved in accordance with Community veterinary legislation.

2. Member States shall ensure that organic fertilizers and soil improvers produced from processed products, other than those produced from manure and digestive tract content, are placed on the market or exported only if they meet requirements, if any, laid down in accordance with the procedure referred to in Article 33(2), after consultation of the appropriate scientific committee.

3. Member States shall ensure that fat derivatives produced from Category 2 material are placed on the market or exported only if they:

- (a) have been prepared in a Category 2 oleochemical plant approved in accordance with Article 14 from rendered fats resulting from the processing of Category 2 material in a Category 2 processing plant approved in accordance with Article 13 following the application of any of processing methods 1 to 5;
- (b) have been handled, processed, stored and transported in accordance with Annex VI; and
- (c) meet any specific requirements laid down in Annex VIII.

▼B*Article 21***Safeguard measures**

Article 10 of Directive 90/425/EEC shall apply to the products covered by Annexes VII and VIII to this Regulation.

*Article 22***Restrictions on use**

1. The following uses of animal by-products and processed products are prohibited:
  - (a) the feeding of a species with processed animal protein derived from the bodies or parts of bodies of animals of the same species;
  - (b) the feeding of farmed animals other than fur animals with catering waste or feed material containing or derived from catering waste; and
  - (c) the application to pasture land of organic fertilizers and soil improvers, other than manure.
2. Rules for the implementation of this Article, including rules concerning control measures, shall be adopted in accordance with the procedure referred to in Article 33(2). Derogations from paragraph 1(a) may be granted in relation to fish and fur animals by the same procedure, after consultation of the appropriate scientific committee.

## CHAPTER V

**DEROGATIONS***Article 23***Derogations regarding the use of animal by-products**

1. Member States may authorise, under the supervision of the competent authorities:
  - (a) the use of animal by-products for diagnostic, educational and research purposes; and
  - (b) the use of animal by-products for taxidermy purposes in technical plants approved for this purpose in accordance with Article 18.
2. (a) Member States may also authorise the use of the animal by-products specified in subparagraph (b) for the feeding of the animals specified in subparagraph (c), under the supervision of the competent authorities and in accordance with the rules laid down in Annex IX.
  - (b) The animal by-products referred to in subparagraph (a) are:
    - (i) Category 2 material, provided that it comes from animals which were not killed or did not die as a result of the presence or suspected presence of a disease communicable to humans or animals, and
    - (ii) Category 3 material referred to in Article 6(1)(a) to (j) and, subject to Article 22, in Article 6(1)(l);
  - (c) The animals referred to in subparagraph (a) are:
    - (i) zoo animals,
    - (ii) circus animals,
    - (iii) reptiles and birds of prey other than zoo or circus animals,
    - (iv) fur animals,
    - (v) wild animals the meat of which is not destined for human consumption,
    - (vi) dogs from recognised kennels or packs of hounds, and
    - (vii) maggots for fishing bait.
  - (d) In addition, Member States may authorise the use, under the supervision of the competent authorities, of Category 1 material referred to in Article 4(1)(b)(ii) for the feeding of endangered or

▼B

protected species of necrophagous birds in accordance with rules laid down under the procedure referred to in Article 33(2) after consultation of the European Food Safety Authority.

3. Member States shall inform the Commission of:
  - (a) the use made of the derogations referred to in paragraph 2; and
  - (b) the verification arrangements introduced to ensure that the animal by-products concerned are used only for authorised purposes.
4. Each Member State shall draw up a list of users and collection centres authorised and registered pursuant to paragraph 2(c)(iv), (vi) and (vii) within its territory. Each user and collection centre shall be assigned an official number for inspection purposes and to be able to trace the origin of the products concerned.

The competent authority shall supervise the premises of users and collection centres referred to in the previous subparagraph and have free access at all times to all parts of such premises, to ensure compliance with the requirements referred to in paragraph 2.

If such inspections reveal that those requirements are not being complied with, the competent authority shall take appropriate action.

5. Detailed rules concerning verification measures may be adopted in accordance with the procedure referred to in Article 33(2).

*Article 24*

**Derogations regarding the disposal of animal by-products**

1. The competent authority may, where necessary, decide that:
  - (a) dead pet animals may be directly disposed of as waste by burial;
  - (b) the following animal by-products originating in remote areas may be disposed of as waste by burning or burial on site:
    - (i) Category 1 material referred to in Article 4(1)(b)(ii),
    - (ii) Category 2 material, and
    - (iii) Category 3 material; and
  - (c) animal by-products may be disposed of as waste by burning or burial on site in the event of an outbreak of a disease mentioned in List A of the International Office of Epizootic Diseases (OIE), if the competent authority rejects transport to the nearest incineration or processing plant because of the danger of propagation of health risks or because a widespread outbreak of an epizootic disease leads to a lack of capacity at such plants.
2. No derogation may be granted in respect of Category 1 material referred to in Article 4(1)(a)(i).
3. In the case of Category 1 material referred to in Article 4(1)(b)(ii), burning or burial may take place in accordance with paragraph 1(b) or (c) only if the competent authority authorises and supervises the method used and is satisfied that it precludes all risk of transmission of TSEs.
4. Member States shall inform the Commission of:
  - (a) the use they make of the possibilities provided for in paragraph 1(b) in respect of Category 1 and Category 2 material; and
  - (b) the areas that they categorise as remote areas for the purpose of applying paragraph 1(b) and the reasons for that categorisation.
5. The competent authority shall take the measures necessary:
  - (a) to ensure that the burning or burial of animal by-products does not endanger animal or human health; and
  - (b) to prevent the abandonment, dumping or uncontrolled disposal of animal by-products.
6. Detailed arrangements for implementing this Article may be laid down under the procedure referred to in Article 33(2).



## CHAPTER VI

**CONTROLS AND INSPECTIONS***Article 25***Plants' own-checks**

1. Operators and owners of intermediate and processing plants or their representatives shall adopt all measures necessary to comply with the requirements of this Regulation. They shall put in place, implement and maintain a permanent procedure developed in accordance with the principles of the system of hazard analysis and critical control points (HACCP). They shall in particular:

- (a) identify and control the critical control points in the plants;
- (b) establish and implement methods for monitoring and checking such critical control points;
- (c) in the case of processing plants, take representative samples to check compliance:
  - (i) of each processed batch with the standards for the products established by this Regulation, and
  - (ii) with the maximum permitted levels of physicochemical residues laid down in Community legislation;
- (d) record the results of the checks and tests referred to in points (b) and (c) and keep them for a period of at least two years for presentation to the competent authorities;
- (e) introduce a system ensuring the traceability of each batch dispatched.

2. Where the results of a test on samples taken pursuant to paragraph 1(c) do not comply with the provisions of this Regulation, the operator of the processing plant must:

- (a) notify the competent authority immediately of the full details of the nature of the sample and the batch from which it was derived;
- (b) establish the causes of failures of compliance;
- (c) reprocess or dispose of the contaminated batch under the supervision of the competent authority;
- (d) ensure that no material suspected or known to be contaminated is moved from the plant before being reprocessed under the supervision of the competent authority and re-sampled officially in order to comply with the standards laid down in this Regulation, unless destined for disposal;
- (e) increase the frequency of sampling and testing of production;
- (f) investigate animal by-products records appropriate to the finished sample; and
- (g) instigate appropriate decontamination and cleaning procedures within the plant.

3. Detailed arrangements for implementing this Article, including rules concerning the frequency of checks and reference methods for microbiological analyses, may be laid down under the procedure referred to in Article 33(2).

*Article 26***Official controls and lists of approved plants**

1. The competent authority shall at regular intervals carry out inspections and supervision at plants approved in accordance with this Regulation. Inspections and supervision of processing plants shall take place in accordance with Annex V, Chapter IV.

2. The frequency of inspections and supervision shall depend on the size of the plant, the type of products manufactured, risk assessment and guarantees offered in accordance with the principles of the system of hazard analysis and critical control points (HACCP).

**▼B**

3. If the inspection carried out by the competent authority reveals that one or more of the requirements of this Regulation are not being met, the competent authority shall take appropriate action.
4. Each Member State shall draw up a list of plants approved in accordance with this Regulation within its territory. It shall assign an official number to each plant, which identifies the plant with respect to the nature of its activities. Member States shall send copies of the list and updated versions to the Commission and other Member States.
5. Detailed arrangements for implementing this Article, including rules concerning the frequency of checks and reference methods for microbiological analyses, may be laid down under the procedure referred to in Article 33(2).

## CHAPTER VII

**COMMUNITY CONTROLS***Article 27***Community controls in Member States**

1. Experts from the Commission may make on-the-spot checks, in cooperation with the competent authorities of Member States, in so far as is necessary for the uniform application of this Regulation. The Member State on whose territory checks are made shall provide the experts with all the assistance necessary for carrying out their duties. The Commission shall inform the competent authority of the results of the checks made.
2. Rules for the implementation of this Article, in particular those governing the procedure for cooperation with national competent authorities, shall be laid down under the procedure referred to in Article 33(2).

## CHAPTER VIII

**PROVISIONS APPLICABLE TO THE IMPORTATION AND TRANSIT OF CERTAIN ANIMAL BY-PRODUCTS AND PRODUCTS DERIVED THEREFROM***Article 28***General provisions**

The provisions applicable to the importation of products referred to in Annexes VII and VIII from non-member countries shall be no more favourable or less favourable than those applicable to the production and marketing of those products in the Community.

However, the importation from third countries of petfood and raw material for petfood production, derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC, shall be permitted provided that such raw material is permanently marked and under specific conditions laid down under the procedure referred to in Article 33(2).

*Article 29***Prohibitions and compliance with Community rules**

1. The importation and transit of animal by-products and processed products shall be prohibited, except in accordance with this Regulation.
2. The importation into, and the transit through, the Community of the products referred to in Annexes VII and VIII may take place only if such products satisfy the requirements set out in paragraphs 3 to 6.
3. Products referred to in Annexes VII and VIII shall, save as otherwise specified in those Annexes, come from a third country or parts of third countries on a list to be drawn up and updated in accordance with the procedure referred to in Article 33(2).

**▼B**

The list may be combined with other lists drawn up for public and animal health purposes.

When the list is drawn up, particular account shall be taken of:

- (a) the legislation of the third country;
- (b) the organisation of the competent authority and its inspection services in the third country, the powers of those services, the supervision to which they are subject, and their authority to monitor effectively the application of their legislation;
- (c) the actual health conditions applied to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community;
- (d) the assurances the third country can give regarding compliance with the relevant health conditions;
- (e) experience of marketing the product from the third country and the results of import checks carried out;
- (f) the result of any Community inspections in the third country;
- (g) the health status of the livestock, other domestic animals and wild-life in the third country, having particular regard to exotic animal diseases and any aspects of the general health situation in the country which might pose a risk to public or animal health in the Community;
- (h) the regularity and speed with which the third country supplies information about the existence of infectious or contagious animal diseases in its territory, in particular the diseases mentioned in Lists A and B of the OIE or, in the case of diseases of aquaculture animals, the notifiable diseases as listed in the Aquatic Animal Health Code of the OIE;
- (i) the regulations on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on imports from other countries.

4. Products referred to in Annexes VII and VIII, except for technical products, must come from plants on a Community list drawn up under the procedure referred to in Article 33(2) on the basis of a communication from the competent authorities of the third country to the Commission declaring that the plant complies with the Community requirements and is subject to supervision by an official inspection service in the third country.

Approved lists shall be amended as follows:

- (a) the Commission shall inform the Member States of the modifications proposed by the third country concerned to the lists of plants within five working days of the receipt of the proposed modifications;
- (b) the Member States shall have seven working days, from receipt of the modifications to the lists of plants referred to in (a), to send any written comments to the Commission;
- (c) when at least one Member State makes written comments, the Commission shall inform the Member States within five working days and include the point on the agenda of the next meeting of the Standing Committee on the Food Chain and Animal Health for decision under the procedure referred to in Article 33(2);
- (d) when the Commission receives no comments from the Member States within the time limit referred to in subparagraph (b), Member States shall be considered to have accepted the modifications to the list. The Commission shall inform the Member States within five working days, and imports shall be authorised from such plants five working days after receipt of this information by the Member States.

5. Technical products referred to in Annex VIII must come from plants that the competent authorities of the third countries have approved and registered.

**▼B**

6. Save as otherwise specified in Annexes VII and VIII, a health certificate corresponding to the model laid down in Annex X, certifying that the products meet the conditions referred to in those Annexes and come from plants offering such conditions, must accompany consignments of products referred to in those Annexes.

7. Pending the compilation of the list provided for in paragraph 4 and the adoption of model certificates as referred to in paragraph 6, Member States may maintain the controls provided for in Directive 97/78/EC and certificates provided for under existing national rules.

*Article 30***Equivalence**

1. In accordance with the procedure referred to in Article 33(2), a decision may be taken recognising that the health measures applied by a third country, a group of third countries or a region of a third country to the production, manufacture, handling, storage and transport of one or more categories of products referred to in Annexes VII and VIII offer guarantees equivalent to those applied in the Community, if the third country supplies objective proof in this respect.

The decision shall set out the conditions governing the importation and/or transit of animal by-products from that region, country or group of countries.

2. The conditions referred to in paragraph 1 shall include:

- (a) the nature and content of the health certificate that must accompany the product;
- (b) specific health requirements applicable to importation into, and/or transit through, the Community; and
- (c) where necessary, procedures for drawing up and amending lists of regions or plants from which imports and/or transit are permitted.

3. Detailed rules for the application of this Article shall be laid down under the procedure referred to in Article 33(2).

*Article 31***Community inspections and audits**

1. Experts from the Commission, where appropriate accompanied by experts from the Member States, may carry out on-the-spot checks with a view to:

- (a) drawing up the list of third countries or parts thereof and determining conditions for importation and/or transit;
- (b) verifying compliance with:
  - (i) the conditions for inclusion in a Community list of third countries,
  - (ii) import and/or transit conditions,
  - (iii) the conditions for recognising equivalence of measures,
  - (iv) any emergency measures applied under Community legislation.

The Commission shall appoint experts from the Member States responsible for these checks.

2. The checks referred to in paragraph 1 shall be carried out on behalf of the Community, which shall meet the costs incurred.

3. The frequency of and the procedure for the checks referred to in paragraph 1 may be specified in accordance with the procedure referred to in Article 33(2).

4. If a check referred to in paragraph 1 reveals a serious infringement of the health rules, the Commission shall immediately ask the third country to take appropriate measures or shall suspend consignments of products and immediately inform the Member States.





## CHAPTER IX

**FINAL PROVISIONS***Article 32***Amendments to Annexes and transitional measures**

1. After consultation of the appropriate scientific committee on any question that could have an impact on animal or public health, the Annexes may be amended or supplemented and any appropriate transitional measures may be adopted in accordance with the procedure referred to in Article 33(2).
2. With regard to the ban on the feeding of catering waste referred to in Article 22, where appropriate control systems are in place in Member States prior to the application of this Regulation, transitional measures shall be adopted, in accordance with paragraph 1, to permit the continued use in feed of certain types of catering waste under strictly controlled circumstances for a period of not more than four years as from 1 November 2002. These measures shall ensure that there is no undue risk to animal or public health during the transitional period.

*Article 33***Regulatory procedure**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, hereinafter referred to as 'the Committee'.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.  
  
The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.
3. The Committee shall adopt its rules of procedure.

*Article 34***Consultation of scientific committees**

The appropriate scientific committees shall be consulted on any matter within the scope of this Regulation that could have an effect on animal or public health.

*Article 35***National provisions**

1. Member States shall communicate to the Commission the text of the provisions of any national law that they adopt in the field covered by this Regulation.
2. In particular, Member States shall inform the Commission of the measures taken to ensure compliance with this Regulation within one year of its entry into force. On the basis of the information received, the Commission shall submit a report to the European Parliament and the Council accompanied, if appropriate, by legislative proposals.
3. Member States may adopt or maintain national rules restricting the use of organic fertilizers and soil improvers further than envisaged in this Regulation pending the adoption of Community rules for their use in accordance with Article 20(2). Member States may adopt or maintain national rules restricting the use of fat derivatives produced from Category 2 material further than envisaged in this Regulation pending the addition to Annex VIII of Community rules for their use in accordance with Article 32.

*Article 36***Financial arrangements**

The Commission shall prepare a report on the financial arrangements in Member States for the processing, collection, storage and disposal of animal by-products accompanied by appropriate proposals.

*Article 37***Repeal**

Directive 90/667/EEC and Decisions 95/348/EC and 1999/534/EC shall be repealed with effect from six months after the entry into force of this Regulation.

References to Directive 90/667/EEC shall be construed from that date as references to this Regulation.

*Article 38***Entry into force**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

This Regulation shall apply six months after the date of its entry into force. However, Article 12(2) shall apply as specified in Article 20 of Directive 2000/76/EC and Articles 22(1)(b) and 32 shall apply from 1 November 2002.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

**▼B***ANNEX I***SPECIFIC DEFINITIONS**

For the purpose of this Regulation:

1. 'apiculture products' means honey, beeswax, royal jelly, propolis or pollen used in bee-keeping;
2. 'batch' means a unit of production produced in a single plant using uniform production parameters — or a number of such units, when stored together — and that can be identified for the purposes of recall and re-treatment or disposal should tests show that to be necessary;
3. 'biogas plant' means a plant in which biological degradation of products of animal origin is undertaken under anaerobic conditions for the production and collection of biogas;
4. 'blood products' means products derived from blood or fractions of blood, excluding blood meal; they include dried/frozen/liquid plasma, dried whole blood, dried/frozen/liquid red cells or fractions thereof and mixtures;
5. 'blood' means fresh whole blood;
6. 'bloodmeal' means products derived from the heat-treatment of blood in accordance with Annex VII, Chapter II, and intended for animal consumption or organic fertilizers;
7. 'canned petfood' means heat-processed petfood contained within a hermetically sealed container;
8. 'Category 1 or Category 2 intermediate plant' means a plant in which unprocessed Category 1 or Category 2 material is handled and/or temporarily stored for the purpose of further transportation to its final destination and where certain preliminary activities, such as removal of hides and skins and performing post-mortem examinations, may take place;
9. 'Category 1 processing plant' means a plant in which Category 1 material is processed before its final disposal;
10. 'Category 2 oleochemical plant' means a plant processing rendered fats derived from Category 2 material under conditions set out in Annex VI, Chapter III;
11. 'Category 2 processing plant' means a plant in which Category 2 material is processed before its final disposal, further transformation or use;
12. 'Category 3 intermediate plant' means a plant in which unprocessed Category 3 material is sorted and/or cut and/or chilled or deep-frozen into blocks and/or temporarily stored for the purpose of further transporting to its final destination;
13. 'Category 3 oleochemical plant' means a plant processing rendered fats derived from Category 3 material;
14. 'Category 3 processing plant' means a plant in which Category 3 material is processed into processed animal protein and other processed products that could be used as feed material;

**▼M1**

15. 'catering waste' means all waste food including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens;

**▼B**

16. 'co-incineration plant' means a disposal site as defined in Article 3(5) of Directive 2000/76/EC;
17. 'co-incineration' means the disposal of animal by-products or products derived therefrom in a co-incineration plant;
18. 'collection centres' means premises collecting and treating certain animal by-products intended to be used for the feeding of the animals specified in Article 23(2)(c);
19. 'composting plant' means a plant in which biological degradation of products of animal origin is undertaken under aerobic conditions;
20. 'digestion residues' means residues resulting from the transformation of animal by-products in a biogas plant;

**▼B**

21. 'digestive tract content' means the content of the digestive tract of mammals and raptines, whether or not separated from the digestive tract;
22. 'dogchews' means untanned products for pet animals to chew, produced from hides and skins of ungulates or other animal material;
23. 'feed material' means those feed materials, as defined in Directive 96/25/EC<sup>(1)</sup>, that are of animal origin including processed animal proteins, blood products, rendered fats, fish oil, fat derivatives, gelatin and hydrolysed proteins, dicalcium phosphate, milk, milk-based products and colostrum;
24. 'fishmeal' means processed animal protein derived from sea animals, except sea mammals;
25. 'fur animals' means animals kept or reared for the production of fur and not used for human consumption;
26. 'gelatin' means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry);
27. 'greaves' means the protein-containing residue of rendering, after partial separation of fat and water;
28. 'hermetically sealed container' means a container that is designed and intended to be secure against the entry of micro-organisms;
29. 'hides and skins' means all cutaneous and subcutaneous tissues;
30. 'high-capacity incineration plant' means an incineration plant other than a low-capacity incineration plant;
31. 'hydrolysed proteins' means polypeptides, peptides and aminoacids, and mixtures thereof, obtained by the hydrolysis of animal by-products;
32. 'incineration plant' means a disposal site as defined in Article 3(4) of Directive 2000/76/EC;
33. 'incineration' means the disposal of animal by-products or products derived therefrom in an incineration plant;
34. 'laboratory reagent' means a packaged product, ready for use by the end user, containing a blood product, and intended for laboratory use as reagent or reagent product, whether used alone or in combination;
35. 'landfill' means a disposal site as defined by Directive 1999/31/EC;
36. 'low-capacity incineration plant' means an incineration plant with a throughput of less than 50 kg of animal by-products per hour;

**▼M1**

37. 'manure' means any excrement and/or urine of farmed animals, with or without litter, or guano, that may be either unprocessed or processed in accordance with Chapter III of Annex VIII or otherwise transformed in biogas or composting plants;

**▼B**

38. 'organic fertilizers' and 'soil improvers' mean materials of animal origin used to maintain or improve plant nutrition and the physical and chemical properties and biological activity of soils, either separately or together; they may include manure, digestive tract content, compost and digestion residues;
39. 'pasture land' means land covered with grass or other herbage and grazed by farmed animals;
40. 'petfood plant' means a plant producing petfood or dogchews and in which certain animal by-products are used in the preparation of such petfood or dogchews;
41. 'petfood' means food for pet animals containing Category 3 material;

**▼M1**

42. 'processed animal protein' means animal proteins derived entirely from Category 3 material, which have been treated in accordance with Chapter II of Annex V so as to render them suitable for direct use as feed material or other use in feedingstuffs, including petfood, or use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, colostrum, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, tricalcium phosphate and collagen;

<sup>(1)</sup> Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC (OJ L 125, 23.5.1996, p. 35). Directive as last amended by Directive 2001/46/EC (OJ L 234, 1.9.2001, p. 55).

**▼B**

43. 'processed petfood' means petfood, other than raw petfood, that has undergone treatment in accordance with the requirements of Annex VIII;
44. 'processed products' means animal by-products that have undergone one of the processing methods or another treatment required by Annex VII or VIII;
45. 'processing methods' means the methods listed in Annex V, Chapter III;
46. 'processing plant' means an animal by-products processing plant;
47. 'product used for *in vitro* diagnosis' means a packaged product, ready for use by the end user, containing a blood product, and used as a reagent, reagent product, calibrator, kit or any other system, whether used alone or in combination, intended to be used *in vitro* for the examination of samples of human or animal origin, with the exception of donated organs or blood, solely or principally with a view to the diagnosis of a physiological state, state of health, disease or genetic abnormality or to determine safety and compatibility with reagents;
48. 'raw petfood' means petfood which has not undergone any preserving process other than chilling, freezing or quick freezing to ensure preservation;
49. 'remote areas' means areas where the animal population is so small, and where facilities are so far away, that the arrangements necessary for collection and transport would be unacceptably onerous compared to local disposal;
50. 'rendered fats' means fats derived from processing of Category 2 material or Category 3 material;
51. 'storage plant' means a plant, other than establishments and intermediaries covered by Directive 95/69/EC<sup>(1)</sup>, in which processed products are temporarily stored before their final use or disposal;
52. 'tanning' means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents;
53. 'technical plant' means a plant in which animal by-products are used to produce technical products;
54. 'technical products' means products directly derived from certain animal by-products, intended for purposes other than human or animal consumption, including tanned and treated hides and skins, game trophies, processed wool, hair, bristles, feathers and parts of feathers, serum of equidae, blood products, pharmaceuticals, medical devices, cosmetics, bone products for china, gelatin and glue, organic fertilizers, soil improvers, rendered fats, fat derivatives, processed manure and milk and milk-based products;

**▼M1**

55. 'unprocessed feathers and parts of feathers' means feathers and parts of feathers that have not been treated with a steam current or by some other method that ensures that no pathogens remain;
56. 'unprocessed wool' means sheep's wool that has not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;
57. 'unprocessed hair' means ruminant hair that has not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;
58. 'unprocessed pig bristles' means pig bristles that have not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;
59. 'collagen' means protein-based products derived from hides, skins and tendons of animals, including bones in the case of pigs, poultry and fish;
60. 'screenings' means visible solid animal materials retained in the waste water screen where a pre-treatment process as referred to in Annex II, Chapter IX, is required;
61. 'grease and oil mixture' means floating animal materials collected at the surface of waste water grease remover systems where a pre-treatment process as referred to in Annex II, Chapter IX, is required;

<sup>(1)</sup> Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC (OJ L 332, 30.12.1995, p. 15). Directive as last amended by Directive 1999/29/EC (OJ L 115, 4.5.1999, p. 32).

▼ M1

62. 'sludge' means visible solid animal materials or sediments retained in the waste water drains where a pre-treatment process as referred to in Annex II, Chapter IX, is required;
63. 'material from desanding' means visible solid animal materials or sediments retained in desanding systems where these constitute a pre-treatment process referred to in Annex II, Chapter IX.

**▼B***ANNEX II***HYGIENE REQUIREMENTS FOR THE COLLECTION AND TRANSPORT OF ANIMAL BY-PRODUCTS AND PROCESSED PRODUCTS****CHAPTER I****Identification**

1. All necessary measures must be taken to ensure that:
  - (a) Category 1, Category 2 and Category 3 materials are identifiable and kept separate and identifiable during collection and transportation; and
  - (b) processed products are identifiable and kept separate and identifiable during transportation.
2. During transport, a label attached to the vehicle, container, carton or other packaging material must clearly indicate:
  - (a) the category of the animal by-products or, in the case of processed products, the category of animal by-products from which the processed products were derived; and

**▼M1**

- (b)
  - (i) in the case of Category 3 material, the words 'not for human consumption';
  - (ii) in the case of Category 2 material (other than manure and digestive tract content) and processed products derived therefrom, the words 'not for animal consumption'; however, when Category 2 material is intended for the feeding of animals referred to in point (c) of Article 23(2) under the conditions provided for in that Article, the label shall instead indicate 'for feeding to ...' completed with the name of the specific species of those animal(s) for the feeding of which the material is intended;
  - (iii) in the case of Category 1 material and processed products derived therefrom, the words 'for disposal only';
  - (iv) in the case of manure and digestive tract content, the word 'manure'.

**▼B****CHAPTER II****Vehicles and containers**

1. Animal by-products and processed products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles.
2. Vehicles and reusable containers, and all reusable items of equipment or appliances that come into contact with animal by-products or processed products, must be:
  - (a) cleaned, washed and disinfected after each use;
  - (b) maintained in a clean condition; and
  - (c) clean and dry before use.
3. Reusable containers must be dedicated to the carriage of a particular product to the extent necessary to avoid cross-contamination.

**▼M1**

4. Packaging material must be incinerated or disposed of by some other means in accordance with instructions from the competent authority.

**▼B****CHAPTER III****Commercial documents and health certificates****▼M1**

1. During transportation, a commercial document or, when required by this Regulation, a health certificate must accompany animal by-products and processed products except in the case of processed products originating from Category 3 material which are supplied within the same Member State by retailers to final users other than business operators.

**▼B**

2. Commercial documents must specify:
  - (a) the date on which the material was taken from the premises;

**▼B**

- (b) the description of the material, including the information referred to in Chapter I, the animal species for Category 3 material and processed products derived therefrom destined for use as feed material and, if applicable, the ear-tag number;
  - (c) the quantity of the material;
  - (d) the place of origin of the material;
  - (e) the name and the address of the carrier;
  - (f) the name and the address of the receiver and, if applicable, its approval number; and
  - (g) if appropriate:
    - (i) the approval number of the plant of origin, and
    - (ii) the nature and the methods of the treatment.
3. The commercial document must be produced at least in triplicate (one original and two copies). The original must accompany the consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the carrier the other.
  4. A model for the commercial document may be laid down under the procedure referred to in Article 33(2).
  5. Health certificates must be issued and signed by the competent authority.

**CHAPTER IV****Records**

The records referred to in Article 9 must contain the information referred to in Chapter III, paragraph 2, as follows. They must contain:

- (a) the information referred to in subparagraphs (b) and (c); and
- (b) in the case of records kept by any person consigning animal by-products, the information referred to in subparagraphs (a), (e) and, if known, (f); or
- (c) in the case of records kept by any person transporting animal by-products, the information referred to in subparagraphs (a), (d) and (f); or
- (d) in the case of records kept by any person receiving animal by-products, the date of reception and the information referred to in subparagraphs (d) and (e).

**CHAPTER V****Retention of documents**

The commercial document and the health certificate referred to in Chapter III, and the records referred to in Chapter IV, must be kept for a period of at least two years for presentation to the competent authority.

**CHAPTER VI****Temperature conditions**

1. The transport of animal by-products must take place at an appropriate temperature, to avoid any risk to animal or public health.
2. Unprocessed Category 3 material destined for the production of feed material or pet food must be transported chilled or frozen, unless processed within 24 hours of departure.
3. The design of vehicles used for refrigerated transport must ensure the maintenance of an appropriate temperature throughout transport.

**CHAPTER VII****Specific rules for transit**

The carriage of animal by-products and processed products in transit must meet the requirements of Chapters I, II, III and VI.

**CHAPTER VIII****Control measures**

The competent authority must take the necessary measures to control the collection, transport, use and disposal of animal by-products and processed products, including by checking the keeping of required records and documents and, when this Regulation requires it or the competent authority considers it necessary, by sealing.



**▼B**

When the competent authority applies a seal to a consignment of animal by-products or processed products, it must inform the competent authority of the place of destination.

**▼M1**

## CHAPTER IX

**Collection of animal material when treating waste water**

1. Category 1 processing plants and other premises where specified risk material is removed, slaughterhouses and Category 2 processing plants shall have a pre-treatment process for the retention and collection of animal material as an initial step in the treatment of waste water. The equipment used in the pre-treatment process shall consist of drain traps or screen with apertures or a mesh size of no more than 6 mm in the downstream end of the process or equivalent systems that ensures that the solid particles in the waste water passing through them are no more than 6 mm.
2. Waste water from the premises as referred to in paragraph 1 must enter a pre-treatment process which shall ensure that all waste water has been filtered through the process before being drained off the premises. No grinding or maceration shall take place which could facilitate the passage of animal material through the pre-treatment process.
3. All animal material retained in the pre-treatment process in premises as referred to in paragraph 1 shall be collected and transported as Category 1 or Category 2 material, as appropriate, and disposed of in accordance with this Regulation.
4. Waste water having passed the pre-treatment process in premises referred to in paragraph 1 and waste water from premises only receiving Category 3 material shall be treated in accordance with other relevant Community legislation.

**▼B***ANNEX III***HYGIENE REQUIREMENTS FOR INTERMEDIATE AND STORAGE PLANTS**

## CHAPTER I

**Requirements for the approval of intermediate plants**

1. Premises and facilities must meet at least the following requirements.
  - (a) The premises must be adequately separated from the public highway and other premises such as slaughterhouses. The layout of plants must ensure the total separation of Category 1 and Category 2 material from Category 3 material from reception until dispatch.
  - (b) The plant must have a covered space to receive animal by-products.
  - (c) The plant must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids.
  - (d) The plant must have adequate lavatories, changing rooms and washbasins for staff.
  - (e) The plant must have appropriate arrangements for protection against pests, such as insects, rodents and birds.
  - (f) The plant must have a waste-water disposal system which meets hygiene requirements.
  - (g) Where it is necessary for the purpose of achieving the objectives of this Regulation, plants must have suitable temperature-controlled storage facilities of sufficient capacity for maintaining animal by-products at appropriate temperatures and designed to allow the monitoring and recording of those temperatures.
2. The plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the vehicles, other than ships, in which they are transported. Adequate facilities must be provided for the disinfecting of vehicle wheels.

## CHAPTER II

**General hygiene requirements***A. Category 3 intermediate plants*

1. The plant must not engage in activities other than the importation, collection, sorting, cutting, chilling, freezing into blocks, temporary storage and dispatching of Category 3 material.
2. The sorting of Category 3 material must be carried out in such a way as to avoid any risk of the propagation of animal diseases.
3. All the time during sorting or storage, Category 3 material must be handled and stored separately from goods other than other Category 3 material and in such a way as to prevent any propagation of pathogens and to ensure compliance with Article 22.
4. Category 3 material must be stored properly, and, where appropriate, chilled or frozen, until re-dispatched.

**▼M1****▼B***B. Category 1 or Category 2 intermediate plants*

6. The plant must not engage in activities other than the collection, handling, temporary storage and dispatching of Category 1 or Category 2 material.
7. The sorting of the Category 1 or Category 2 material must be carried out in such a way as to avoid any risk of the propagation of animal diseases.
8. All the time during storage, the Category 1 or Category 2 material must be handled and stored separately from other goods and in such a way as to prevent any propagation of pathogens.
9. Category 1 or Category 2 material must be stored properly, including under appropriate temperature conditions, until re-dispatched.

**▼M1**

---

**▼B**

11. Waste water must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from Category 1 and Category 2 intermediate plants may be laid down in accordance with the procedure referred to in Article 33(2).

## CHAPTER III

**Requirements for the approval of storage plants**

Premises and facilities must meet at least the following requirements.

1. Premises storing processed products derived from Category 3 material must not be at the same site as premises storing processed products derived from Category 1 or Category 2 material, unless in a completely separate building.
2. The plant must:
  - (a) have a covered space to receive the products;
  - (b) be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids;
  - (c) have adequate lavatories, changing rooms and washbasins for staff; and
  - (d) have appropriate arrangements for protection against pests, such as insects, rodents and birds.
3. The plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which the products are received and the vehicles, other than ships, in which they are transported. Adequate facilities must be provided for the disinfecting of vehicle wheels.
4. Products must be stored properly until re-dispatched.

**▼B***ANNEX IV***REQUIREMENTS FOR INCINERATION AND CO-INCINERATION PLANTS TO WHICH DIRECTIVE 2000/76/EC DOES NOT APPLY**

## CHAPTER I

**General conditions****▼M1**

1. Incineration or co-incineration plants must be designed, equipped and operated in such a manner as to fulfil the requirements of this Regulation. The following hygiene conditions must be met:
  - (a) Animal by-products must be disposed of as soon as possible after arrival. They must be stored properly until disposal.
  - (b) Containers, receptacles and vehicles used for transporting unprocessed material must be cleaned in a designated area, thereby ensuring that waste water is treated during the storage referred to in Chapter III.
  - (c) Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest control programme must be used for that purpose.
  - (d) Cleaning procedures must be established and documented for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
  - (e) Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and maintained for at least two years.

**▼B**

2. The operator of an incineration or co-incineration plant must take all necessary precautions concerning the reception of animal by-products to prevent, or limit as far as practicable, direct risks to human or animal health.

## CHAPTER II

**Operating conditions**

3. Incineration or co-incineration plants must be designed, equipped, built and operated in such a way that the gas resulting from the process is raised in a controlled and homogeneous fashion, even under the most unfavourable conditions, to a temperature of 850 °C, as measured near the inner wall or at another representative point of the combustion chamber as authorised by the competent authority, for two seconds.
4. Each line of high-capacity incineration plants must be equipped with at least one auxiliary burner. This burner must be switched on automatically when the temperature of the combustion gases after the last injection of combustion air falls below 850 °C. It must also be used during plant start-up and shut-down operations to ensure that the temperature of 850 °C is maintained at all times during these operations and as long as unburned material is in the combustion chamber.
5. High-capacity incineration or co-incineration plants must have and operate an automatic system to prevent feed with animal by-products:
  - (a) at start-up, until the temperature of 850 °C has been reached; and
  - (b) whenever the temperature of 850 °C is not maintained.
6. Animal by-products should, where practicable, be placed straight in the furnace without direct handling.

## CHAPTER III

**Water discharges**

7. Incineration or co-incineration plant sites, including associated storage areas for animal by-products, must be designed in such a way as to prevent unauthorised and accidental release of any polluting substances into soil, surface water and groundwater in accordance with the provisions provided for in relevant Community legislation. Moreover, storage capacity must be provided for contaminated rainwater run-off from the incineration plant site or for contaminated water arising from spillage or fire-fighting operations.
8. The storage capacity must be adequate to ensure that such waters can be tested and treated before discharge where necessary.

**▼B**

## CHAPTER IV

**Residues**

9. For the purposes of this Chapter, 'residues' means any liquid or solid material generated by the incineration or co-incineration process, the waste-water treatment or other processes within the incineration or co-incineration plant. They include bottom ash and slag, fly ash and boiler dust.
10. Residues resulting from the operation of the incineration or co-incineration plant must be minimised in their amount and harmfulness. Residues must be recycled, where appropriate, directly in the plant or outside in accordance with relevant Community legislation.
11. Transport and intermediate storage of dry residues in the form of dust must take place in such a way as to prevent dispersal in the environment (e.g., in closed containers).

## CHAPTER V

**Temperature measurement**

12. Techniques must be used to monitor the parameters and conditions relevant to the incineration or co-incineration process. High-capacity incineration and co-incineration plants must have and use temperature measurement equipment.
13. The approval issued by the competent authority, or conditions attached to it, must lay down temperature measurement requirements.
14. The appropriate installation and the functioning of any automated monitoring equipment must be subject to control and to an annual surveillance test. Calibration must be carried out by means of parallel measurements with the reference methods at least every three years.
15. Temperature measurement results must be recorded and presented in an appropriate fashion to enable the competent authority to verify compliance with the permitted operating conditions laid down in this Regulation in accordance with procedures to be decided upon by that authority.

## CHAPTER VI

**Abnormal operating**

16. In the case of a breakdown, or abnormal operating conditions, the operator must reduce or close down operations as soon as practicable until normal operations can be resumed.

**▼M1**

## CHAPTER VII

**Incineration of Category 1 material referred to in Article 4(1)(b)**

1. The low-capacity incineration plant must be located on a well-drained hard standing.
2. Livestock must not have access to the low-capacity incineration plant, animal by-products that are awaiting incineration or ash resulting from the incineration of animal by-products. If the low-capacity incineration plant is located on a livestock holding:
  - (a) there must be total physical separation between the incinerator and the livestock and their feed and bedding, with fencing where necessary;
  - (b) equipment must be dedicated entirely to the operation of the incinerator and not used elsewhere on the farm;
  - (c) the operators must change their outer clothing and footwear before handling livestock or livestock feed.
3. The storage of animal by-products and of ashes must be covered, labelled and leak proof.
4. The operator must check that animal by-products are incinerated in such a way that they are completely reduced to ash. Ash must be disposed of to a landfill approved under Directive 1999/31/EC.
5. Incompletely incinerated animal by-products must not be disposed of to a landfill, but must be re-incinerated or otherwise disposed of in accordance with this Regulation.
6. The low-capacity incineration plant must be equipped with an afterburner.

▼ M1

7. The operator must keep records of the quantities, category and species of animal by-products incinerated and the date of incineration.
8. The competent authority must inspect the low-capacity incineration plant before approval, and at least once a year to monitor compliance with this Regulation.

**▼B***ANNEX V***GENERAL HYGIENE REQUIREMENTS FOR THE PROCESSING OF  
CATEGORY 1, 2 AND 3 MATERIAL****CHAPTER I****General requirements for the approval of Category 1, 2 and 3 processing  
plants**

1. Premises and facilities must meet at least the following requirements:

**▼M1**

- (a) premises for the processing of animal by-products must not be at the same site as slaughterhouses, unless located in a completely separate building. However, a conveyer system may link an individual processing plant to a slaughterhouse on the same site provided the following conditions are met:
- (i) there are separate entrances, reception bays, equipment, exits and personnel for the processing plant and the slaughterhouse; and
  - (ii) the animal by-products to be processed originate on the same premises.

Unauthorised persons and animals must not have access to the processing plant;

**▼B**

- (b) the processing plant must have a clean and unclean sector, adequately separated. The unclean sector must have a covered place to receive animal by-products and must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid in such a way as to facilitate the draining of liquids. The processing plant must have adequate lavatories, changing rooms and washbasins for staff;
  - (c) the processing plant must have sufficient production capacity for hot water and steam for the processing of animal by-products;
  - (d) the unclean sector must, if appropriate, contain equipment to reduce the size of animal by-products and equipment for loading the crushed animal by-products into the processing unit;
  - (e) all installations in which animal by-products are processed must operate in accordance with the requirements of Chapter II. Where heat treatment is required, all installations must be equipped with:
    - (i) measuring equipment to monitor temperature against time and, if necessary, pressure at critical points;
    - (ii) recording devices to record continuously the results of these measurements; and
    - (iii) an adequate safety system to prevent insufficient heating;
  - (f) to prevent recontamination of the finished product by incoming animal by-products, there must be a clear separation between the area of the plant where incoming material for processing is unloaded and the areas set aside for the processing of that product and the storage of the processed product.
2. The processing plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the vehicles, other than ships, in which they are transported.
3. Adequate facilities must be provided for the disinfecting of vehicle wheels, on leaving the unclean sector of the processing plant.
4. All processing plants must have a waste-water disposal system meeting the competent authority's requirements.
5. The processing plant must have its own laboratory or make use of the services of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority.

**CHAPTER II****General hygiene requirements**

1. Animal by-products must be processed as soon as possible after arrival. They must be stored properly until processed.
2. Containers, receptacles and vehicles used for transporting unprocessed material must be cleaned in a designated area. That area must be situated or designed to prevent the risk of contamination of processed products.

**▼B**

3. Persons working in the unclean sector must not enter the clean sector without changing their working clothes and footwear or without disinfecting the latter. Equipment and utensils must not be taken from the unclean sector into the clean sector, unless first cleaned and disinfected. Personnel movement procedures must be established to control the movement of personnel between areas and to prescribe the proper use of foot baths and wheel baths.
4. Waste water originating in the unclean sector must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from processing plants may be laid down under the procedure referred to in Article 33(2).
5. Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest control programme must be used for that purpose.
6. Cleaning procedures must be established and documented for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
7. Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and maintained for at least two years.
8. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.
9. Processed products must be handled and stored at the processing plant in such a way as to preclude recontamination.

## CHAPTER III

**Processing methods***Method 1*

## Reduction

1. If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 50 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process must be stopped and repairs made before the process is resumed.

## Time, temperature and pressure

2. After reduction the animal by-products must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars produced by saturated steam <sup>(1)</sup>; the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.
3. The processing may be carried out in batch or continuous systems.

*Method 2*

## Reduction

1. If the particle size of the animal by-products to be processed is more than 150 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 150 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 150 millimetres, the process must be stopped and repairs made before the process is resumed.

## Time, temperature and pressure

2. After reduction the animal by-products must be heated to a core temperature greater than 100 °C for at least 125 minutes, a core temperature greater than 110 °C for at least 120 minutes and a core temperature greater than 120 °C for at least 50 minutes.

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



**▼B**

3. The processing must be carried out in a batch system.

**▼M1**

4. The animal by-products may be cooked in such a manner that the time-temperature requirements are achieved at the same time.

**▼B***Method 3*

## Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

## Time, temperature and pressure

2. After reduction the animal by-products must be heated to a core temperature greater than 100 °C for at least 95 minutes, a core temperature greater than 110 °C for at least 55 minutes and a core temperature greater than 120 °C for at least 13 minutes.
3. The processing may be carried out in batch or continuous systems.
4. The animal by-products may be cooked in such a manner that the time-temperature requirements are achieved at the same time.

*Method 4*

## Reduction

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 30 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process must be stopped and repairs made before the process is resumed.

## Time, temperature and pressure

2. After reduction the animal by-products must be placed in a vessel with added fat and heated to a core temperature greater than 100 °C for at least 16 minutes, a core temperature greater than 110 °C for at least 13 minutes, a core temperature greater than 120 °C for at least eight minutes and a core temperature greater than 130 °C for at least three minutes.
3. The processing may be carried out in batch or continuous systems.
4. The animal by-products may be cooked in such a manner that the time-temperature requirements are achieved at the same time.

*Method 5*

## Reduction

1. If the particle size of the animal by-products to be processed is more than 20 millimetres, the animal by-products must be reduced in size using appropriate equipment, set so that the particle size after reduction is no greater than 20 millimetres. The effectiveness of the equipment must be checked daily and its condition recorded. If checks disclose the existence of particles larger than 20 millimetres, the process must be stopped and repairs made before the process is resumed.

## Time, temperature and pressure

2. After reduction the animal by-products must be heated until they coagulate and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material must then be heated to a core temperature greater than 80 °C for at least 120 minutes and a core temperature greater than 100 °C for at least 60 minutes.
3. The processing may be carried out in batch or continuous systems.

**▼B**

4. The animal by-products may be cooked in such a manner that the time-temperature requirements are achieved at the same time.

*Method 6*

(for animal by-products of fish origin only)

## Reduction

1. The animal by-products must be reduced to ... millimetres. They must then be mixed with formic acid to reduce the pH to .... The mixture must be stored for ... hours pending further treatment.
2. The mixture must then be introduced into a heat converter and be heated to a core temperature of ... °C for at least ... minutes. The progression of the product through the heat converter must be controlled by means of mechanical commands limiting its displacement in such a way that at the end of the heat treatment operation the product has undergone a cycle which is sufficient in both time and temperature.
3. After heat treatment, the product must be separated into liquid, fat and greaves by mechanical means. To obtain processed animal protein concentrate, the liquid phase must be pumped into two heat exchangers which are steam-heated and equipped with vacuum chambers in order for its humidity to be removed therein in the form of water vapour. The greaves must be reincorporated into the protein concentrate before storage.

*Method 7*

1. Any processing method approved by the competent authority where it has been demonstrated to that authority that the final product has been sampled on a daily basis over a period of one month in compliance with the following microbiological standards:
  - (a) Samples of material taken directly after heat treatment:
 

*Clostridium perfringens* absent in 1 g of the products
  - (b) Samples of material taken during or upon withdrawal from storage at the processing plant:
 

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

*Enterobacteriaceae*: n = 5, c = 2, m = 10, M = 300 in 1 g

where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples 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 samples is M or more; and

c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.
2. Details of the critical control points under which each processing plant satisfactorily complies with the microbiological standards must be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the processing plant. The information to be recorded and monitored must include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed-rate and fat recycling rate.
3. This information must be made available to the Commission on request.

## CHAPTER IV

**Supervision of production**

1. The competent authority must supervise processing plants to ensure compliance with the requirements of this Regulation. It must in particular:
  - (a) check:
    - (i) the general conditions of hygiene of the premises, equipment and staff;

**▼B**

- (ii) the efficacy of the own checks carried out by the plant, in accordance with Article 25, particularly by examining the results and taking samples;
  - (iii) the standards of the products after processing. The analyses and tests must be carried out in accordance with scientifically-recognised methods (in particular, those laid down in Community legislation or, where none exist, recognised international standards or, in their absence, national standards); and
  - (iv) the storage conditions;
- (b) take any samples required for laboratory tests; and
- (c) make any other checks it considers necessary to ensure compliance with this Regulation.
2. To allow it to carry out its responsibilities under paragraph 1, the competent authority must have free access at all times to all parts of the processing plant and to records, commercial documents and health certificates.

## CHAPTER V

**Validation procedures**

1. The competent authority must validate the processing plant in accordance with the following procedures and indicators:
- (a) description of the process (by a process flow diagram);
  - (b) identification of critical control points (CCPs) including the material process rate for continuous systems;
  - (c) compliance with the specific process requirements laid down by this Regulation; and
  - (d) achievement of the following requirements:
    - (i) particle size for batch-pressure and continuous processes — defined by the mincer hole or the anvil gap size, and
    - (ii) temperature, pressure, processing time and material processing rate (for continuous system only) as specified in paragraphs 2 and 3.
2. In the case of a batch pressure system:
- (a) the temperature must be monitored with a permanent thermocouple and it must be plotted against real time;
  - (b) the pressure stage must be monitored with a permanent pressure gauge. Pressure must be plotted against real time;
  - (c) 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.
3. In the case of a continuous pressure system:
- (a) 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 required conditions inside the whole continuous system or in a section of it. The temperature and pressure must be plotted against real time;
  - (b) measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the required conditions, must be provided to the competent authorities, using insoluble markers (for example, 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:
    - (i) feed screw revolutions per minute (rev./min.),
    - (ii) electric power (amps at given voltage),
    - (iii) evaporation/condensation rate, or
    - (iv) number of pump strokes per unit time.

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

4. The competent authority must repeat the validation procedures periodically, when it considers it necessary, and in any case each time any significant alterations are made to the process (for example, modification of the machinery or a change of raw materials).

**▼B**

5. Validation procedures based on testing methods may be laid down under the procedure referred to in Article 33(2).

**▼B***ANNEX VI***SPECIFIC REQUIREMENTS FOR THE PROCESSING OF CATEGORY 1 AND 2 MATERIAL AND FOR BIOGAS AND COMPOSTING PLANTS**

## CHAPTER I

**Specific requirements for the processing of Category 1 and Category 2 material**

The following requirements apply in addition to the general requirements laid down in Annex V.

*A. Premises*

1. The layout of Category 1 and Category 2 processing plants must ensure the total separation of Category 1 material from Category 2 material from reception of the raw material until dispatch of the resulting processed product.
2. However, the competent authority may authorise the temporary use of a Category 2 processing plant for the processing of Category 1 material when a widespread outbreak of an epizootic disease or other extraordinary and unforeseeable circumstances leads to a lack of capacity at a Category 1 processing plant.

The competent authority must re-approve the Category 2 processing plant in accordance with Article 13 before it processes Category 2 material again.

*B. Processing standards*

3. The critical control points that determine the extent of the heat treatments applied in processing must be identified for each processing method as specified in Annex V, Chapter III. The critical control points may include:
  - (a) raw material particle size;
  - (b) temperature achieved in the heat treatment process;
  - (c) pressure applied to the raw material; and
  - (d) duration of the heat treatment process or feed rate to a continuous system.

Minimum process standards must be specified for each applicable critical control point.
4. Records must be maintained for at least two years to show that the minimum process values for each critical control point are applied.
5. Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept to show the date of calibration of gauges/recorders.
6. Material that may not have received the specified heat treatment (e.g. material discharged at start up, or leakage from cookers) must be recirculated through the heat treatment or collected and reprocessed.
7. Animal by-products must be processed in accordance with the following processing standards.
  - (a) Processing method 1 must be applied to:

**▼M1**

- (i) Category 2 material (other than manure, digestive tract content separated from the digestive tract, milk and colostrum), destined for biogas or composting plants or intended to be used as organic fertilisers or soil improvers, and

**▼B**

- (ii) Category 1 and Category 2 material destined for landfill.
- (b) Any of processing methods 1 to 5 must be applied to:
  - (i) Category 2 material from which the resulting protein is destined for incineration or co-incineration,
  - (ii) Category 2 material from which the rendered fat is destined for a Category 2 oleochemical plant, and
  - (iii) Category 1 or Category 2 material destined for incineration or co-incineration.

▼ M1▼ BC. *Processed products*

8. Processed products derived from Category 1 or 2 materials, with the exception of liquid products destined for biogas or composting plants, must be permanently marked, where technically possible with smell, using a system approved by the competent authority. Detailed rules for such marking may be laid down under the procedure referred to in Article 33(2).
9. Samples of processed products destined for biogas or composting plants or landfill, taken directly after heat treatment, must be free from heat-resistant pathogenic bacteria spores (*Clostridium perfringens* absent in 1 g of the products).

## CHAPTER II

**Specific requirements for the approval of biogas and composting plants**A. *Premises*▼ M1

1. If the biogas plant is located on premises where farmed animals are kept, the plant shall be located at an adequate distance to the area where animals are kept and there must be in any case total physical separation between that plant and the animals and their feed and bedding, with fencing where necessary. The biogas plant must be equipped with:

- (a) a pasteurisation/hygienisation unit, which cannot be by-passed, with:
  - (i) installations for monitoring temperature against time;
  - (ii) recording devices to record continuously the results of those measurements; and
  - (iii) an adequate safety system to prevent insufficient heating; and
- (b) adequate facilities for the cleaning and disinfecting vehicles and containers upon leaving the biogas plant.

However, a pasteurisation/hygienisation unit is not mandatory for biogas plants that transform only animal by-products that have undergone processing Method 1.

In addition, a pasteurisation/hygienisation unit is not mandatory for biogas plants that transform only Category 3 material that has undergone pasteurisation/hygienisation elsewhere.

2. If the composting plant is located on premises where farmed animals are kept, the plant shall be located at an adequate distance to the area where animals are kept and there must be in any case total physical separation between that plant and the animals and their feed and bedding, with fencing where necessary. The composting plant must be equipped with:

- (a) a closed composting reactor, which cannot be by-passed, with:
  - (i) installations for monitoring temperature against time;
  - (ii) recording devices to record, where appropriate continuously, the results of those measurements; and
  - (iii) an adequate safety system to prevent insufficient heating; and
- (b) adequate facilities for cleaning and disinfecting vehicles and containers transporting untreated animal by-products.

However, other types of composting systems may be allowed provided they:

- (i) ensure that there is no access by vermin;
- (ii) are managed in such a way that all the material in the system achieves the required time and temperature parameters, including, where appropriate, continuous monitoring of the parameters;
- (iii) comply with all other requirements of this Regulation.

▼ B

3. Each biogas plant and composting plant must have its own laboratory or make use of an external laboratory. The laboratory must be equipped to carry out the necessary analyses and approved by the competent authority.

**▼B***B. Hygiene requirements*

4. Only the following animal by-products may be transformed in a biogas or composting plant:
  - (a) Category 2 material, when using processing method 1 in a Category 2 processing plant;

**▼M1**

- (b) manure and digestive tract content separated from the digestive tract, milk and colostrum, and

**▼B**

- (c) Category 3 material.
5. Animal by-products referred to in paragraph 4 must be transformed as soon as possible after arrival. They must be stored properly until treated.
6. Containers, receptacles and vehicles used for transporting untreated material must be cleaned in a designated area. This area must be situated or designed to prevent risk of contamination of treated products.
7. Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest-control programme must be used for that purpose.
8. Cleaning procedures must be documented and established for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
9. Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented.
10. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.
11. Digestion residues must be handled and stored at the plant in such a way as to preclude recontamination.

*C. Processing standards*

12. Category 3 material used as raw material in a biogas plant equipped with a pasteurisation/hygenisation unit must be submitted to the following minimum requirements:
  - (a) maximum particle size before entering the unit: 12 mm;
  - (b) minimum temperature in all material in the unit: 70 °C; and
  - (c) minimum time in the unit without interruption: 60 minutes.
13. Category 3 material used as raw material in a composting plant must be submitted to the following minimum requirements:
  - (a) maximum particle size before entering the composting reactor: 12 mm,
  - (b) minimum temperature in all material in the reactor: 70 °C; and
  - (c) minimum time in the reactor at 70 °C (all material): 60 minutes.

**▼M1**

14. However, pending the adoption of rules in accordance with Article 6(2)(g), the competent authority may, when catering waste is the only animal by-product used as raw material in a biogas or composting plant, authorise the use of specific requirements other than those laid down in this Chapter provided that they guarantee an equivalent effect regarding the reduction of pathogens. Those specific requirements may also apply to catering waste when it is mixed with manure, digestive tract content separated from the digestive tract, milk and colostrum provided that the resulting material is considered as if it were from catering waste.

Where manure, digestive tract content separated from the digestive tract, milk and colostrum are the only material of animal origin being treated in a biogas or composting plant, the competent authority may authorise the use of specific requirements other than those specified in this Chapter provided that it:

- (a) does not consider that those material present a risk of spreading any serious transmissible disease;
- (b) considers that the residues or compost are untreated material.

**▼B***D. Digestion residues and compost*

15. Samples of the digestion residues or compost taken during or on withdrawal from storage at the biogas or composting plant must comply with the following standards:

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

*Enterobacteriaceae*:  $n = 5$ ,  $c = 2$ ,  $m = 10$ ,  $M = 300$  in 1 g

where:

- $n$  = number of samples to be tested;
- $m$  = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples 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 samples is  $M$  or more; and
- $c$  = number of samples the bacterial count of which may be between  $m$  and  $M$ , the sample still being considered acceptable if the bacterial count of the other samples is  $m$  or less.

## CHAPTER III

**Treatment standards for the further processing of rendered fats**

The following processes may be used to produce fat derivatives from rendered fats derived from Category 2 material:

1. transesterification or hydrolysis at least 200 °C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); or
2. saponification with NaOH 12M (glycerol and soap):
  - (a) in a batch process at 95 °C for three hours; or
  - (b) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes, or under equivalent conditions laid down in accordance with the procedure referred to in Article 33(2).



**▼B***ANNEX VII***SPECIFIC HYGIENE REQUIREMENTS FOR THE PROCESSING AND PLACING ON THE MARKET OF PROCESSED ANIMAL PROTEIN AND OTHER PROCESSED PRODUCTS THAT COULD BE USED AS FEED MATERIAL**

## CHAPTER I

**Specific requirements for the approval of Category 3 processing plants**

The following requirements apply in addition to the general requirements laid down in Annex V.

*A. Premises*

1. Premises for the processing of Category 3 material must not be at the same site as premises processing Category 1 or Category 2 material, unless in a completely separate building.
2. However, the competent authority may authorise the temporary use of a Category 3 processing plant for the processing of Category 1 or Category 2 material when a widespread outbreak of an epizootic disease or other extraordinary and unforeseeable circumstances lead to a lack of capacity at a Category 1 or Category 2 processing plant.

The competent authority must re-approve the Category 3 processing plant in accordance with Article 17 before it processes Category 3 material again.

3. Category 3 processing plants must have:
  - (a) an installation to check the presence of extraneous matter, such as packaging material, metallic pieces, etc. in the animal by-products; and
  - (b) if the volume of products treated requires regular or permanent presence of the competent authority, an adequately equipped lockable room for the exclusive use of the inspection service.

*B. Raw material***▼M1**

4. Only Category 3 material listed in points (a) to (j) of Article 6(1) that has been handled, stored and transported in accordance with Articles 7, 8 and 9 may be used for the production of processed animal proteins and other feed material.

**▼B**

5. Before processing, animal by-products must be checked for the presence of extraneous matter. When present, it must be removed immediately.

*C. Processing standards*

6. The critical control points that determine the extent of the heat treatments applied in processing must be identified for each processing method as specified in Annex V, Chapter III. The critical control points must at least include:
  - raw material particle size,
  - temperature achieved in the heat treatment process,
  - pressure applied to the raw material, if applicable, and
  - duration of the heat treatment process or feed rate to a continuous system.
 Minimum process standards must be specified for each applicable critical control point.
7. Records must be maintained for at least two years to show that the minimum process values for each critical control point are applied.
8. Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept for at least two years to show the date of calibration of gauges/recorders.
9. Material that may not have received the specified heat treatment (for example, material discharged at start up, or leakage from cookers) must be recirculated through the heat treatment or collected and reprocessed.

**▼B***D. Processed products*

10. Samples of the final products taken during or on withdrawal from storage at the processing plant must comply with the following standards:

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

*Enterobacteriaceae*:  $n = 5$ ,  $c = 2$ ,  $m = 10$ ,  $M = 300$  in 1 g

where:

- $n$  = number of samples to be tested;
- $m$  = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples 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 samples is  $M$  or more; and
- $c$  = number of samples the bacterial count of which may be between  $m$  and  $M$ , the sample still being considered acceptable if the bacterial count of the other samples is  $m$  or less.

**▼M1**

11. Unused or surplus processed products may after they have been permanently marked:
- be disposed of as waste by incineration or co-incineration in an incineration or co-incineration plant approved in accordance with Article 12;
  - be disposed of in a landfill approved under Directive 1999/31/EC; or
  - be transformed in a biogas plant or in a composting plant approved in accordance with Article 15.

**▼B**

## CHAPTER II

**Specific requirements for processed animal protein**

The following conditions apply in addition to the general conditions laid down in Chapter I.

*A. Processing standards***▼M1**

1. Mammalian processed animal protein must have been submitted to processing Method 1.

However, while the feed ban provided for in Council Decision 2000/766/EC remains in force, mammalian processed animal protein may have been submitted to any of the processing Methods 1 to 5 or Method 7, and shall be permanently marked with a stain or otherwise immediately after that processing, before its disposal as waste in accordance with applicable Community legislation.

In addition, while the feed ban provided for in Council Decision 2000/766/EC remains in force, processed animal protein of mammalian origin exclusively destined for use in petfood, which is transported in dedicated containers that are not used for the transport of animal by-products or feedingstuffs for farmed animals, and which is consigned directly from Category 3 processing plant to the petfood plants, may have been submitted to any of the processing Methods 1 to 5 or 7.

**▼B**

- Non-mammalian processed animal protein, with the exclusion of fishmeal, must have been submitted to any of processing methods 1 to 5 or 7.
- Fishmeal must have been submitted:
  - to any of the processing methods; or
  - to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I, paragraph 10.

*B. Storage*

- Processed animal protein must be packed and stored in new or sterilised bags or stored in properly constructed bulk bins.
- Sufficient measures must be taken to minimise condensation inside bins, conveyors or elevators.

▼B

6. Products in conveyors, elevators and bins must be protected from casual contamination.
7. Processed animal protein handling equipment must be maintained in a clean and dry condition and should have adequate inspection points so that equipment can be examined for cleanliness. All storage facilities must be emptied and cleaned regularly, as production requirements require.
8. Processed animal protein must be kept dry. Leakages and condensation in the storage area must be prevented.

C. *Importation*

9. Member States must authorise the importation of processed animal protein:
  - (a) if it comes from third countries that appear on the list in Part II of Annex XI or, in the case of fishmeal, that appear on the list in Part III of Annex XI;
  - (b) if it comes from a processing plant that appears on the list referred to in Article 29(4);
  - (c) if it has been produced in accordance with this Regulation; and
  - (d) if it is accompanied by a health certificate as provided for in Article 29(6).
10. Before consignments are released for free circulation within the Community, the competent authority must sample imports of processed animal protein at the border inspection post to ensure compliance with the requirements of Chapter I, paragraph 10. The competent authority must:
  - (a) sample each consignment of products carried in bulk; and
  - (b) carry out random sampling of consignments of products packaged in the manufacturing plant of origin.
11. However, when six consecutive tests on bulk consignments originating in a given third country prove negative, the competent authority may carry out random sampling of subsequent bulk consignments from that third country. If one of these random samples proves positive, the competent authority carrying out the sampling must inform the competent authority of the country of origin so that it can take appropriate measures to remedy the situation. The competent authority of the country of origin must bring these measures to the attention of the competent authority carrying out the sampling. In the event of a further positive result from the same source, the competent authority must sample each consignment from the same source until six consecutive tests again prove negative.
12. Competent authorities must keep a record for at least two years of the results of sampling carried out on all consignments that have undergone sampling.
13. Where a consignment proves to be positive for *salmonella*, it must either:
  - (a) be dealt with in accordance with the procedure laid down by Article 17(2)(a) of Directive 97/78/EC <sup>(1)</sup>; or
  - (b) reprocessed in a processing plant approved pursuant to this Regulation or decontaminated by a treatment authorised by the competent authority. A list of permitted treatments may be established in accordance with the procedure referred to in Article 33(2). The consignment must not be released until it has been treated, tested for *salmonella* by the competent authority in accordance with Chapter I, paragraph 10, and a negative result obtained.

## CHAPTER III

**Specific requirements for blood products**

The following conditions apply in addition to the general conditions laid down in Chapter I.

A. *Raw material*

1. Only blood coming under paragraph 1(a) and (b) of Article 6 may be used for the production of blood products.

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

**▼B***B. Processing standards*

2. Blood products must have been submitted:
  - (a) to any of processing methods 1 to 5 or 7; or
  - (b) to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I, paragraph 10.

*C. Importation*

3. Member States must authorise the importation of blood products if they:
  - (a) come from third countries that appear on the list in Part V of Annex XI;
  - (b) come from a processing plant that appears on the list referred to in Article 29(4);
  - (c) have been produced in accordance with this Regulation; and
  - (d) are accompanied by a health certificate as provided for in Article 29(6).

## CHAPTER IV

**Specific requirements for rendered fats and fish oil**

The following conditions apply in addition to the general conditions laid down in Chapter I.

*A. Processing standards***▼M1**

1. Unless the rendered fats have been produced in accordance with Chapter II of Annex C to Council Directive 77/99/EEC <sup>(1)</sup>, or Chapter 9 of Annex I to Council Directive 92/118/EEC <sup>(2)</sup>, rendered fats must be produced using Methods 1 to 5 or Method 7, and fish oils may be produced using Method 6, as referred to in Annex V, Chapter III.

Rendered fats derived from ruminant animals must be purified in such a way that the maximum levels of remaining total insoluble impurities does not exceed 0,15 % in weight.

**▼B***B. Importation of rendered fats*

2. Member States must authorise the importation of rendered fats if they:
  - (a) come from third countries appearing on the list in Part IV of Annex XI;
  - (b) come from a processing plant that appears on the list referred to in Article 29(4);
  - (c) have been produced in accordance with this Regulation;
  - (d) either:
    - (i) are entirely or partly derived from swine raw material and come from a country or a part of the territory of a country free from foot-and-mouth disease for the previous 24 months and free from classical swine fever and African swine fever for the previous 12 months,
    - (ii) are entirely or partly derived from poultry raw material and come from a country or a part of the territory of a country free from Newcastle disease and avian influenza for the previous six months,
    - (iii) are entirely or partly derived from ruminant raw material and come from a country or a part of the territory of a country free from foot-and-mouth disease for the previous 24 months and free from Rinderpest for the previous 12 months, or
    - (iv) where there has been an outbreak of one of the abovementioned diseases during the relevant period mentioned above, have been subjected to one of the following heat treatment processes:
      - at least 70 °C for at least 30 minutes, or
      - at least 90 °C for at least 15 minutes,
 and details of the critical control points are recorded and maintained so that the owner, operator or their representative and, as necessary, the competent authority can monitor the operation of the plant. The information must include the particle size, critical temperature and,

<sup>(1)</sup> OJ L 26, 31.1.1977, p. 85.

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

▼B

as appropriate, the absolute time, pressure profile, raw material feed-rate and fat recycling rate; and

- (e) are accompanied by a health certificate as provided for in Article 29(6).

*C. Importation of fish oil*

3. Member States must authorise the importation of fish oil if it:

- (a) comes from third countries appearing on the list in Part III of Annex XI;
- (b) comes from a processing plant that appears on the list referred to in Article 29(4);
- (c) has been produced in accordance with this Regulation; and
- (d) is accompanied by a health certificate as provided for in Article 29(6).

*D. Hygiene requirements*

4. Where rendered fat or fish oil is packaged, it must be packaged in new containers or in containers that have been cleaned, and all precautions must be taken to prevent its recontamination. Where bulk transport of the products is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the products from the manufacturing plant either directly on to the ship or into shore tanks or direct to plants must have been inspected and found to be clean before use.

## CHAPTER V

### **Specific requirements for milk, milk-based products and colostrum**

The following conditions apply in addition to the general conditions laid down in Chapter I.

*A. Processing standards*

1. Raw milk and colostrum must be produced under conditions offering adequate guarantees as regards animal health. Such conditions may be established in accordance with the procedure referred to in Article 33(2).
2. Milk or treated or processed milk products must be subjected to a heat treatment of at least 2 °C for at least 15 seconds or any combination of temperature and time having at least an equivalent heat effect and producing a negative reaction to the phosphatase test, followed by:
  - (a) in the case of dried milk or dried milk products, a drying process; or
  - (b) in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6.
3. In addition to the requirements laid down in paragraph 2, dried milk or dried-milk products must meet the following requirements:
  - (a) after completion of the drying process, every precaution must be taken to prevent contamination of the products; and
  - (b) the final product must be:
    - (i) packed in new containers, or
    - (ii) in the case of bulk transport, transported in vehicles or containers that have been disinfected using a product approved by the competent authority before loading with the milk, milk-based product or colostrum.

*B. Importation*

4. Member States must authorise imports of milk and milk-based products if:

- (a) they come from third countries appearing on the list in Part I of Annex XI;
- (b) in the case of milk and milk-based products from third countries or parts of third countries listed in column B of the Annex to Decision 95/340/EC <sup>(1)</sup>, they have undergone a pasteurisation treatment sufficient to

<sup>(1)</sup> Commission Decision 95/340/EC of 27 July 1995 drawing up a provisional list of third countries from which Member States authorise imports of milk and milk-based products and revoking Decision 94/70/EC (OJ L 200, 24.8.1995, p. 38). Decision as last amended by Decision 96/584/EC (OJ L 255, 9.10.1996, p. 20).

▼B

- produce a negative phosphatase test and a health certificate conforming to the model laid down in Chapter 2(A) of Annex X accompanies them;
- (c) in the case of milk-based products with a pH reduced to less than 6 from third countries or parts of third countries listed in column C of the Annex to Decision 95/340/EC, they have first undergone a pasteurisation treatment sufficient to produce a negative phosphatase test and a health certificate conforming to the model laid down in Chapter 2(B) of Annex X accompanies them;
  - (d) in the case of milk and milk-based products from third countries or parts of third countries listed in column C of the Annex to Decision 95/340/EC, they have first undergone a sterilisation process or a double heat treatment where each treatment was sufficient to produce a negative phosphatase test on its own and a health certificate conforming to the model laid down in Chapter 2(C) of Annex X accompanies them; and
  - (e) they come from a processing plant which appears on the list referred to in Article 29(4).
5. Milk and milk-based products from third countries or parts of third countries listed in column C of the Annex to Decision 95/340/EC where there has been an outbreak of foot-and-mouth disease in the last 12 months or where vaccination against foot-and-mouth disease has been carried out in the last 12 months must, before introduction on to Community territory, have undergone either:
- (a) a sterilisation process whereby an Fc value equal to or greater than 3 is achieved; or
  - (b) an initial heat treatment with a heating effect at least equal to that achieved by a pasteurisation process of at least 72 °C for at least 15 seconds and sufficient to produce a negative reaction to a phosphatase test, followed by:
    - (i) a second heat treatment with a heating effect at least equal to that achieved by the initial heat treatment, and which would be sufficient to produce a negative reaction to a phosphatase test, followed, in the case of dried milk, or dried milk-based products, by a drying process, or
    - (ii) an acidification process such that the pH has been maintained at less than 6 for at least one hour.
6. Where a risk of introduction of an exotic disease or any other risk to animal health is identified, additional conditions for the protection of animal health may be established in accordance with the procedure referred to in Article 33(2).

## CHAPTER VI

**Specific requirements for gelatin and hydrolysed protein**

The following conditions apply in addition to the general conditions laid down in Chapter I.

*A. Processing standards for gelatin*

1. (a) Gelatin must be produced by a process that ensures that unprocessed Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatin must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.
  - (b) After having been subjected to the processes referred to in subparagraph (a), gelatin may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
  - (c) The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.
2. Gelatin must be wrapped, packaged, stored and transported under satisfactory hygiene conditions. In particular:
- (a) a room must be provided for storing materials for wrapping and packaging;
  - (b) wrapping and packaging must take place in a room or in a place intended for that purpose;
  - and
  - (c) wrappings and packages containing gelatin must carry the words 'gelatin suitable for animal consumption'.

**▼B***B. Processing standards for hydrolysed protein***▼M1**

3. Hydrolysed protein must be produced using a production process involving appropriate measures to minimise contamination of raw Category 3 material. Hydrolysed protein shall have a molecular weight below 10 000 Dalton.

In addition, hydrolysed proteins entirely or partly derived from ruminants hides and skins shall be produced in a processing plant dedicated only to hydrolysed protein production, using a process involving the preparation of raw Category 3 material by brining, liming and intensive washing followed by:

- (a) exposure of the material to a pH of more than 11 for more than three hours at a temperature of more than 80 °C and subsequently by heat treatment at more than 140 °C for 30 minutes at more than 3,6 bar;
- (b) exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140 °C for 30 minutes at 3 bar; or
- (c) an equivalent production process approved in accordance with the procedure referred to in Article 33(2).

**▼B***C. Importation***▼M1**

4. Member States must authorise the importation of gelatine and hydrolysed proteins if they:
- (a) come from third countries that appear on the list in Part XI of Annex XI;
  - (b) come from a processing plant that appears on the list referred to in Article 29(4);
  - (c) have been produced in accordance with this Regulation; and
  - (d) are accompanied by a health certificate as provided for in Article 29(6).

## CHAPTER VII

**Specific requirements for dicalcium phosphate**

The following conditions apply in addition to the general conditions laid down in Chapter I.

*A. Processing standards*

1. Dicalcium phosphate must be produced by a process that:
- (a) ensures that all Category 3 bone-material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;
  - (b) following the procedure at (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and
  - (c) finally, air dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C, or

by an equivalent process approved in accordance with the procedure referred to in Article 33(2).

2. Where dicalcium phosphate is derived from defatted bones it shall be derived from bones fit for human consumption following ante and post-mortem inspection.

*B. Importation*

3. Member States must authorise the importation of dicalcium phosphate if it:
- (a) comes from third countries that appear on the list in Part XI of Annex XI;
  - (b) comes from a processing plant that appears on the list referred to in Article 29(4);
  - (c) has been produced in accordance with this Regulation; and
  - (d) is accompanied by a health certificate as provided for in Article 29(6).

▼ **M1**

## CHAPTER VIII

**Specific requirements for tricalcium phosphate**

The following conditions apply in addition to the general conditions laid down in Chapter I.

*A. Processing standards*

1. Tricalcium phosphate must be produced by a process that ensures:

- (a) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);
- (b) grinding of the chips below 1 mm before cooking and continuous cooking with steam at 145 °C during 30 minutes at 4 bars;
- (c) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation; and
- (d) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200 °C; or

by an equivalent production process approved in accordance with the procedure referred to in Article 33(2).

*B. Importation*

2. Member States must authorise the importation of tricalcium phosphate if it:

- (a) comes from third countries that appear on the list in Part XI of Annex XI;
- (b) comes from a processing plant that appears on the list referred to in Article 29(4);
- (c) has been produced in accordance with this Regulation; and
- (d) is accompanied by a health certificate as provided for in Article 29(6).



▼**B**

## ANNEX VIII

**REQUIREMENTS FOR THE PLACING ON THE MARKET OF  
PETFOOD, DOGCHEWS AND TECHNICAL PRODUCTS**

## CHAPTER I

**Requirements for the approval of petfood and technical plants**

Plants producing petfood, dogchews and technical products, other than organic fertilizers, soil improvers and fat derivatives derived from Category 2 material, must fulfil the following requirements:

1. they must have adequate facilities for storing and treating incoming material in complete safety; and
2. they must have adequate facilities for disposing of unused animal by-products remaining after the production of the products in accordance with this Regulation, or this material must be sent to a processing plant or to an incineration or co-incineration plant in accordance with this Regulation.

## CHAPTER II

**Requirements for petfood and dogchews**A. *Raw material*

1. The only animal by-products that may be used to produce petfood and dogchews are those referred to in Article 6(1)(a) to (j). However, raw petfood may be manufactured only from animal by-products referred to in Article 6(1)(a).

B. *Processing standards*

2. Canned petfood must be subjected to heat treatment to a minimum Fc value of 3.
3. Processed petfood other than canned petfood must be subjected to a heat treatment of at least 90 °C throughout its substance. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination. The product must be packed in new packaging.
4. Dogchews must be subjected to a heat treatment during processing sufficient to destroy pathogenic organisms (including *salmonella*). After treatment, every precaution must be taken to ensure that the product is not exposed to contamination. The product must be packed in new packaging.
5. Raw petfood must be packed in new packaging preventing any leakage. Effective steps must be taken to ensure that the product is not exposed to contamination throughout the production chain and up to the point of sale. The wording 'petfood only' must be visibly and legibly displayed on the packaging.

▼**M1**

6. Random samples must be taken during production and/or during storage (before dispatch) to verify compliance with the following standards:

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

*Enterobacteriaceae*: n = 5, c = 2, m = 10, M = 300 in 1 g

Where:

- n = number of samples to be tested;
- m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples 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 samples is M or more; and
- c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

**▼M1**

However, for canned petfood that has undergone the heat treatment referred to in paragraph 2, sampling and testing for *Salmonella* and *Enterobacteriaceae* may not be necessary.

**▼B***C. Importation*

7. Member States must authorise importation of petfood and dogchews if they:

- (a) come from third countries that appear on the list in Part X of Annex XI;
- (b) come from petfood plants approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;
- (c) have been produced in accordance with this Regulation;
- (d) are accompanied:
  - (i) in the case of canned petfood, by a certificate that conforms to the model laid down in Chapter 3(A) of Annex X,
  - (ii) in the case of processed petfood other than canned petfood, by a certificate that conforms to the model laid down in Chapter 3(B) of Annex X,
  - (iii) in the case of dogchews, by a certificate that conforms to the model laid down in Chapter 3(C) of Annex X, or
  - (iv) in the case of raw petfood, by a certificate that conforms to the model laid down in Chapter 3(D) of Annex X.

## CHAPTER III

**Requirements for manure, processed manure and processed manure products***I. Unprocessed manure**A. Trade*

1. (a) Trade in unprocessed manure of species other than poultry or equidae is prohibited, except for manure:
  - (i) from an area which is not subject to restrictions by virtue of a serious transmissible disease, and
  - (ii) intended for application, under the supervision of the competent authorities, to land forming part of a single holding located on both sides of the border of two Member States.
- (b) However, the competent authority may grant specific approval for the introduction on to its territory of:
  - (i) manure intended for processing in a technical plant or a biogas plant or in a composting plant approved by the competent authority in accordance with this Regulation with a view to the manufacture of the products referred to under Section II below. The competent authority must take account of the origin of the manure when approving such plants; or
  - (ii) manure intended for applying to land on a holding. Such trade can only occur with the consent of the competent authorities of both the Member States of origin and destination. When considering giving consent, the competent authorities must have particular regard to the origin of the manure, its destination and animal health and safety considerations.

A health certificate conforming to a model laid down under the procedure referred to in Article 33(2) must accompany the manure in such cases.

2. Trade in unprocessed poultry manure is subject to the following conditions:

- (a) the manure must originate in an area which is not subject to restrictions by virtue of Newcastle disease or avian influenza;
- (b) in addition, unprocessed manure from poultry flocks vaccinated against Newcastle disease must not be dispatched to a region which has obtained

▼B

Newcastle disease non-vaccinating status pursuant to Article 15(2) of Directive 90/539/EEC <sup>(1)</sup>; and

- (c) a health certificate conforming to a model laid down under the procedure referred to in Article 33(2) must accompany the manure.
3. Trade in unprocessed manure of equidae is not subject to any animal health conditions.

## B. Importation

4. Member States must authorise the importation of unprocessed manure if it:
- (a) comes from third countries that appear on the list in Part IX of Annex XI;
  - (b) satisfies, according to the species concerned, the requirements of paragraph 1(a);
  - (c) is accompanied by a health certificate as provided for in Article 29(6).

II. *Processed manure and processed manure products*

## A. Placing on the market

5. The placing on the market of processed manure and processed manure products is subject to the following conditions:
- (a) they must come from a technical plant, a biogas plant or a composting plant approved by the competent authority in accordance with this Regulation;
  - (b) they must have been subjected to a heat treatment process of at least 70 °C for at least 60 minutes or to an equivalent treatment in accordance with rules laid down under the procedure referred to in Article 33(2);
  - (c) they must:
    - (i) be free from *salmonella* (no *salmonella* in 25 g treated product),
    - (ii) be free from *enterobacteriaceae* (based on the aerobic bacteria count: < 1 000 cfu per gram of treated products), and
    - (iii) have been subjected to reduction in spore-forming bacteria and toxic formation; and
  - (d) they must be stored in such a way that, once processed, contamination or secondary infection and dampness is impossible. They must therefore be stored in:
    - (i) well-sealed and insulated silos, or
    - (ii) properly sealed packs (plastic bags or 'big bags').

## B. Importation

6. Member States must authorise importation of processed manure and processed manure products if they:
- (a) come from third countries that appear on the list in Part IX of Annex XI;
  - (b) come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;
  - (c) satisfy the requirements of paragraph 5 above; and
  - (d) are accompanied by a health certificate as provided for in Article 29(6).

III. *Guano*

7. The placing on the market of 'guano' is not subject to any animal health conditions.

<sup>(1)</sup> Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of poultry and hatching eggs (OJ L 303, 31.10.1990, p. 6). Directive as last amended by Commission Decision 2000/505/EC (OJ L 201, 9.8.2000, p. 8).

**▼B**

## CHAPTER IV

**Requirements for blood and blood products used for technical purposes, including pharmaceuticals, *in vitro* diagnosis and laboratory agents, but excluding serum of equidae**A. *Placing on the market*

1. The placing on the market of blood products covered by this Chapter is subject to the requirements laid down in Article 20.

B. *Importation*

2. Imports of blood are subject to the requirements laid down in Chapter XI.
  3. Member States must authorise importation of blood products if they:
    - (a) come from third countries that appear on the list in Part VI of Annex XI;
    - (b) come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation; and
    - (c) are accompanied by a health certificate as provided for in Article 29(6); and either
    - (d) originate in a third country in which no case of foot-and-mouth disease has been recorded within at least 24 months and no case of vesicular stomatitis, swine vesicular disease, rinderpest, *peste des petits ruminants*, Rift Valley Fever, blue tongue, African horse sickness, classical swine fever, African swine fever, Newcastle disease or avian influenza has been recorded for 12 months in the susceptible species and in which vaccination has not been carried out against those diseases for at least 12 months. The health certificate may be made out according to the species of animal from which the blood products are derived; or
    - (e) in the case of blood products derived from bovine animals:
      - (i) originate in an area of a third country fulfilling the requirements of subparagraph (d) from which imports of bovine animals, their fresh meat or their sperm are authorised pursuant to Community legislation. The blood from which such products are manufactured must be from bovine animals from that area of the third country and must have been collected:
        - in slaughterhouses approved in accordance with Community legislation,
        - or
        - in slaughterhouses approved and supervised by the competent authority of the third country. The Commission and Member States must be notified of the address and approval number of such slaughterhouse or the certificate must indicate them; or
      - (ii) have undergone one of the following treatments guaranteeing the absence of pathogens of the bovine diseases referred to in subparagraph (d):
        - heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,
        - irradiation at 2,5 megarads or by gamma rays, followed by an effectiveness check,
        - change in pH to pH 5 for two hours, followed by an effectiveness check,
        - heat treatment of at least 90 °C throughout their substance, followed by an effectiveness check, or
        - any other treatment provided for in accordance with the procedure referred to in Article 33(2); or
      - (iii) fulfil the requirements laid down in Chapter X. In this case, the packaging may not be opened during storage and the technical plant must carry out one of the treatments listed in point (i).
4. The specific conditions relating to imports of products for use in *in vitro* diagnosis and laboratory reagents may be laid down, where necessary, under the procedure referred to in Article 33(2).

**▼M1****▼B**



CHAPTER V

**Requirements for serum of equidae**

A. *Raw material*

1. Serum must:

- (a) come from equidae which show no signs of the serious transmissible diseases referred to in Directive 90/426/EEC <sup>(1)</sup> or of any other serious transmissible disease to which equidae are susceptible; and
- (b) have been obtained in bodies or centres not subject to health restrictions pursuant to that Directive.

B. *Importation*

2. Member States must authorise the import of serum of equidae if:

- (a) it comes from equidae born and raised in a third country from which the importation of horses for slaughter is authorised;
- (b) it was obtained, processed and dispatched in conformity with the following conditions:
  - (i) it comes from a country where the following diseases are compulsorily notifiable: African horse sickness, dourine, glanders, equine encephalomyelitis (all types including VEE), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;
  - (ii) it was obtained, under the supervision of a veterinarian, from equidae which, at the time of collection, were free from clinical signs of infectious disease;
  - (iii) it was obtained from equidae that have remained since birth in the territory or, in case of official regionalisation according to Community legislation, in parts of the territory of a third country in which:
    - Venezuelan equine encephalomyelitis had not occurred during the last two years,
    - dourine had not occurred during the last six months, and
    - glanders had not occurred during the last six months;
  - (iv) it was obtained from equidae that had never been present on a holding that had been subject to prohibition for animal health reasons or where:
    - in the case of equine encephalomyelitis, the date on which all the equidae suffering from the disease were slaughtered was at least six months before the date of collection,
    - in the case of infectious anaemia, all the infected animals had been slaughtered and the remaining animals showed a negative reaction to two Coggins tests carried out three months apart,
    - in the case of vesicular stomatitis, the prohibition was lifted at least six months before the date of collection,
    - in the case of rabies, the last recorded case was at least a month before the date of collection,
    - in the case of anthrax, the last recorded case was at least 15 days before the date of collection, or
    - all the animals of species susceptible to the disease located on the holding were slaughtered and the premises disinfected, at least 30 days before the date of collection (or, in the case of anthrax, at least 15 days before);
  - (v) it has undergone all precautions to avoid contamination with pathogenic agents during production, handling and packaging;
  - (vi) it was packed in sealed impermeable containers clearly labelled 'serum from equidae' and bearing the registration number of the establishment of collection;
- (c) it comes from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation; and
- (d) a certificate conforming to the model laid down in Chapter 4 of Annex X accompanies it.

<sup>(1)</sup> Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae (OJ L 224, 18.8.1990, p. 42). Directive as last amended by Commission Decision 2001/298/EC (OJ L 102, 12.4.2001, p. 63).



## CHAPTER VI

### Requirements for hides and skins of ungulates

#### A. *Scope*

1. The provisions of this Chapter do not apply:
  - (a) to hides and skins of ungulates fulfilling the requirements of Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat <sup>(1)</sup>;
  - (b) to hides and skins of ungulates having undergone the complete process of tanning;
  - (c) to 'wet blue';
  - (d) to 'pickled pelts'; and
  - (e) to limed hides (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).
2. Within the scope defined in paragraph 1, the provisions of this Chapter apply to fresh, chilled and treated hides and skins. For the purpose of this Chapter, 'treated hides and skins' means hides and skins that have been:
  - (a) dried;
  - (b) dry-salted or wet-salted for at least 14 days prior to dispatch;
  - (c) salted for seven days in sea salt with the addition of 2 % of sodium carbonate;
  - (d) dried for 42 days at a temperature of at least 20 °C; or
  - (e) preserved by a process other than tanning specified in accordance with the procedure referred to in Article 33(2).

#### B. *Trade*

3. Trade in fresh or chilled hides and skins is subject to the same health conditions as those applicable to fresh meat pursuant to Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat <sup>(2)</sup>.
4. Trade in treated hides and skins is authorised on condition that the commercial document provided for in Annex II accompanies each consignment and attests that:
  - (a) the hides and skins have been treated in accordance with paragraph 2; and
  - (b) the consignment has not been in contact with other animal products or live animals presenting a risk of spreading a serious transmissible disease.

#### C. *Importation*

5. Member States must authorise the import of fresh or chilled hides and skins if:
  - (a) they have been obtained from animals referred to in Article 6(1)(b) or (c);
  - (b) they originate from a third country or, in the case of regionalisation in accordance with Community legislation, from a part of a third country from which imports of all categories of fresh meat of the corresponding species are authorised and which:
    - (i) for at least 12 months before dispatch, has been free from the following diseases:
      - classical swine fever,
      - African swine fever, and
      - rinderpest, and
    - (ii) has been free for at least 24 months before dispatch from foot-and-mouth disease and where, for 12 months before dispatch, no vaccination has been carried out against foot-and-mouth disease;

<sup>(1)</sup> OJ L 121, 29.7.1964, p. 2012. Directive as last amended by Directive 95/23/EC (OJ L 243, 11.10.1995, p. 7).

<sup>(2)</sup> OJ L 302, 31.12.1972, p. 24. Directive last amended by the 1994 Act of Accession.

▼B

- (c) they have been obtained from:
    - (i) animals that have remained in the territory of the country of origin for at least three months before being slaughtered or since birth in the case of animals less than three months old,
    - (ii) in the case of hides and skins from bi-ungulates, animals that come from holdings in which there has been no outbreak of foot-and-mouth disease in the previous 30 days, and around which within a radius of 10 km there has been no case of foot-and-mouth disease for 30 days,
    - (iii) in the case of hides and skins from swine, animals that come from holdings in which there has been no outbreak of swine vesicular disease in the previous 30 days, or of classical or African swine fever in the previous 40 days, and around which within a radius of 10 km there has been no case of these diseases for 30 days, or
    - (iv) animals that have passed the ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter and have shown no evidence of foot-and-mouth disease, rinderpest, classical swine fever, African swine fever or swine vesicular disease;
  - (d) they have undergone all precautions to avoid recontamination with pathogenic agents; and
  - (e) a certificate conforming to the model laid down in Chapter 5(A) of Annex X accompanies them.
6. Member States must authorise the import of treated hides and skins if:
- (a) they have been obtained from animals referred to in Article 6(1)(b), (c) or (k);
  - (b) a certificate conforming to the model laid down in Chapter 5(B) of Annex X accompanies them;
  - (c) they come either:
    - (i) from animals originating in a region of a third country or in a third country not subject, pursuant to Community legislation, to restrictions as a result of an outbreak of a serious transmissible disease to which the animals of the species concerned are susceptible and they have been treated in accordance with paragraph 2, or
    - (ii) from animals originating from other regions of a third country or other third countries and they have been treated in accordance with paragraph 2(c) or (d), or
    - (iii) from ruminant animals and have been treated in accordance with paragraph 2 and have been kept separate for 21 days or have undergone transport for 21 uninterrupted days. In this case, the certificate referred to in subparagraph (b) is replaced by a declaration conforming to the model laid down in Chapter 5(C) of Annex X, to the effect that or proving that those requirements have been met;
  - (d) in the case of salted hides and skins transported by ship, the hides have been salted before importation for the duration stated in the certificate accompanying the consignment; and
  - (e) the consignment has not been in contact with other animal products or with live animals presenting a risk of spreading a serious transmissible disease.
7. Fresh, chilled or treated hides and skins of ungulates must be imported in containers, road vehicles, railway wagons or bales sealed by the competent authority of the third country of dispatch.

## CHAPTER VII

**Requirements for game trophies**A. *Raw material*

1. Without prejudice to the measures adopted pursuant to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein <sup>(1)</sup>, game trophies:
  - (a) of ungulates and birds having undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures; and
  - (b) of species other than ungulates and birds,

<sup>(1)</sup> OJ L 61, 3.3.1997, p. 1. Regulation as last amended by Commission Regulation No 1579/2001 (OJ L 209, 2.8.2001, p. 14).

▼**B**

are not subject to any ban or restriction for reasons of animal health.

2. Without prejudice to the measures adopted pursuant to Regulation (EC) No 338/97, game trophies of ungulates and birds not having undergone the treatment mentioned in paragraph 1(a) are subject to the following conditions. They must:
  - (a) come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible; or
  - (b) comply with the conditions laid down in paragraphs 3 or 4 if they come from animals originating in an area subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible.
3. In respect of game trophies consisting solely of bone, horns, hooves, claws, antlers or teeth, the trophies must:
  - (a) have been immersed in boiling water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;
  - (b) have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned;
  - (c) be packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
  - (d) be accompanied by a document or certificate certifying that the above conditions have been met.
4. In respect of game trophies consisting solely of hides or skin, the trophies must:
  - (a) have been either:
    - (i) dried, or
    - (ii) dry- or wet-salted for a minimum of 14 days before dispatch, or
    - (iii) preserved by a treatment other than tanning approved in accordance with the procedure referred to in Article 33(2);
  - (b) be packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
  - (c) be accompanied by a document or certificate certifying that the above conditions have been met.

#### B. *Importation*

5. Member States must authorise the importation of treated game trophies from birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, from third countries if:
  - (a) a certificate that conforms to the model laid down in Chapter 6(A) of Annex X accompanies them; and
  - (b) they comply with the requirements of paragraphs 3 and 4. However, in the case of dry-salted or wet-salted skins transported by ship, the skins need not be salted 14 days before dispatch, provided that they are salted for 14 days before importation.
6. Member States must, in accordance with the requirements of paragraph 7, authorise the importation of game trophies from birds and ungulates consisting of entire anatomical parts, not having been treated in any way, from third countries:
  - (a) that appear in one of the lists in the Annex to Commission Decision 94/86/EC of 16 February 1994 drawing up a provisional list of third countries from which Member States authorise imports of wild game meat <sup>(1)</sup>; and
  - (b) from which the importation of all categories of fresh meat of the corresponding species is authorised.

<sup>(1)</sup> OJ L 44, 17.2.1994, p. 33.



**▼B**

7. Member States must authorise importation of the game trophies referred to in paragraph 6 if:
- (a) they come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible;
  - (b) they were packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
  - (c) a certificate conforming to the model laid down in Chapter 6(B) of Annex X accompanies them.

## CHAPTER VIII

**Requirements for wool, hair, pig bristles, feathers and parts of feathers**A. *Raw material***▼M1**

1. (a) Unprocessed wool, unprocessed hair, unprocessed pig bristles and unprocessed feathers and parts of feathers must have been obtained from animals referred to in Article 6(1)(c) or (k). They must be securely enclosed in packaging and dry. However, in the case of unprocessed feather and part of feathers sent directly from the slaughterhouse to the processing plant, the competent authority may allow derogation from the dry requirement, provided that:
  - (i) all necessary measures are taken to avoid any possible spread of disease;
  - (ii) the transport takes place in leak-proof containers and/or vehicles which must be cleansed and disinfected immediately after each use; and
  - (iii) the Member State notifies the Commission when such derogation is given.
- (b) Movements of pig bristles from regions in which African swine fever is endemic are prohibited except for pig bristles that have:
  - (i) been boiled, dyed or bleached; or
  - (ii) undergone some other form of treatment which is certain to kill pathogenic agents, provided that evidence to this effect is submitted in the form of a certificate from the veterinarian responsible for the place of origin. Factory washing may not be regarded as a form of treatment for the purposes of this provision.

**▼B**

2. The provisions of paragraph 1 do not apply to decorative feathers or feathers:
  - (a) carried by travellers for their private use; or
  - (b) in the form of consignments sent to private individuals for non-industrial purposes.

B. *Importation*

3. Member States must authorise the importation of pig bristles from third countries or, in case of regionalisation according to Community legislation, regions thereof, if:
  - (a) the pig bristles were obtained from animals originating, and slaughtered in a slaughterhouse, in the country of origin; and
  - (b) either:
    - (i) where no case of African swine fever has occurred during the previous 12 months, a certificate conforming to the model laid down in Chapter 7(A) of Annex X accompanies the consignment; or
    - (ii) where one or more cases of African swine fever have occurred during the previous 12 months, a certificate conforming to the model laid down in Chapter 7(B) of Annex X accompanies the consignment.
4. Member States must authorise the importation of unprocessed wool, hair, feathers and parts of feathers if they are:
  - (a) securely enclosed in packaging and dry; and

**▼B**

- (b) sent directly to the technical plant or to an intermediate plant in conditions such that any spread of pathogenic agents is avoided.

## CHAPTER IX

**Requirements for apiculture products**A. *Raw material***▼M1**

1. Apiculture products intended exclusively for use in apiculture must:
  - (a) not come from an area which is subject of a prohibition order associated with an occurrence of:
    - (i) American foulbrood, except where the competent authority has assessed the risk to be negligible, issued a specific authorisation for use only in that Member State, and taken all other necessary measures to ensure no spread of that disease; or
    - (ii) acariosis, except where the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC <sup>(1)</sup>; and
  - (b) meet the requirements provided for in Article 8(a) of Directive 92/65/EEC.

**▼B**B. *Importation*

2. Member States must authorise the importation of apiculture products intended for use in apiculture if:
  - (a) the commercial document accompanying the consignment includes the following information:
    - (i) the country of origin,
    - (ii) the name of the establishment of production,
    - (iii) the registration number of the establishment of production,
    - (iv) the nature of the products, and
    - (v) the indication: 'Apiculture products intended exclusively for use in apiculture originating from a holding not subject to restrictions because of occurrence of bee diseases and collected in the centre of a region with a radius of 3 kilometres which is not subjected to restrictions because of American foulbrood, which is a notifiable disease, for at least 30 days.'; and
  - (b) the competent authority supervising the registered establishment of production has stamped the commercial document.

## CHAPTER X

**Requirements for bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for use other than as feed material, organic fertilizers or soil improvers**

1. Member States must authorise the importation of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) to produce technical products if:
  - (a) the products are dried before export and not chilled or frozen;
  - (b) the products are conveyed only by land and sea from their country of origin direct to a border inspection post in the Community and are not transhipped at any port or place outside the Community;
  - (c) following the document checks provided for in Directive 97/78/EC, the products are conveyed directly to the technical plant.

<sup>(1)</sup> Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54). Directive as last amended by Commission Decision 2001/298/EC (OJ L 102, 12.4.2001, p. 63).

**▼B**

2. Each consignment must be accompanied by:
- (a) a commercial document stamped by the competent authority supervising the establishment of origin, including the following information:
- (i) the country of origin,
  - (ii) the name of the establishment of production,
  - (iii) the nature of the product (dried bone/dried bone product/dried horns/dried horn products/dried hooves/dried hoof products), and
  - (iv) the fact that the product was:
    - derived from healthy animals slaughtered in a slaughterhouse, or
    - dried for 42 days at an average temperature of at least 20 °C, or
    - heated for one hour to at least 80 °C to the core before drying, or
    - ashed for one hour to at least 80 °C to the core before drying, or
    - underwent an acidification process such that the pH was maintained at less than 6 to the core for at least one hour before drying, and
- is not intended at any stage to be diverted for any use in food, feed material, organic fertilizers or soil improvers; and
- (b) the following declaration of the importer which must be in at least one official language of the Member State through which the consignment first enters the Community and in at least one official language of the Member State of destination:

**MODEL DECLARATION**

I, the undersigned, declare that the following products: bones and bone products (excluding bone meal), horns and horn products (excluding hornmeal) and hooves and hoof products (excluding hoof meal) are intended to be imported by me into the Community, and I declare that these products will not be diverted at any stage for any use in food, feed material, organic fertilizers or soil improvers and will be conveyed directly to the following processing establishment:

Name ..... Address .....

The importer

Name ..... Address .....

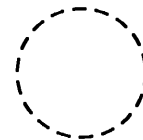
Done at .....  
(place) (date)

Signature .....

Reference number as indicated on the certificate provided for in Annex B to Commission Decision 93/13/EEC:

.....

Official stamp of the border inspection post of entry into the EC



Signature .....

(signature of the official veterinarian of the border inspection post)

.....

(name in capital letters)

3. On dispatch to the Community territory, the material must be enclosed in sealed containers or vehicles or carried in bulk in a ship. If transported in containers, the containers, and in all cases all the accompanying documents, must bear the name and the address of the technical plant.
4. Following the border check provided for in Directive 97/78/EC, and in accordance with the rules laid down in Article 9(4) of that Directive, the material must be transported direct to the technical plant.

**▼B**

5. Records must be kept of the quantity and nature of the material, during manufacture, in such a way as to ensure that the material has actually been used for the intended purposes.

## CHAPTER XI

**Animal by-products for the manufacture of petfood and pharmaceutical and other technical products**

Member States must authorise the importation of animal by-products intended for the manufacture of petfood, pharmaceutical products and other technical products if:

1. they come from third countries which appear on the list in Part VII of Annex XI;
2. they consist only of animal by-products referred to in Article 6(1)(a);
3. they have been deep frozen at the plant of origin;
4. they have undergone all precautions to avoid recontamination with pathogenic agents;
5. they were packed in new packaging preventing any leakage;
6. a certificate conforming to the model laid down in Chapter 8 of Annex X accompanies them; and
7. following the border check provided for in Directive 97/78/EC, and in accordance with the rules laid down in Article 9(4) of that Directive, they are transported either:
  - (a) directly to a petfood or technical plant, which has given the guarantee that the animal by-products will be used only for the permitted purpose and will not leave the plant untreated; or
  - (b) to an intermediate plant.

## CHAPTER XII

**Rendered fats for oleochemical purposes**

Member States must authorise the importation of rendered fat intended to be processed by a method that at least meets the standards of one of the processes described in Annex VI, Chapter III, if:

1. the product is conveyed only by land and sea from the country of origin direct to a border inspection post in the Community;
2. following the document checks provided for in Directive 97/78/EC, and in accordance with the rules laid down in Article 9(4) of that Directive, the products are conveyed to the oleochemical plant where they will be processed;
3. a declaration made by the importer accompanies each consignment. This declaration must state that products imported in accordance with this Chapter will not be diverted for any use other than further processing by a method which at least meets the standards of one of the processes described in Annex VI, Chapter III. This declaration must be presented to, and annotated by, the competent authority at the border inspection post at the first point of entry of the goods into the Community, and thereafter accompany the consignment up to the oleochemical plant.

**▼B***ANNEX IX***RULES APPLICABLE TO THE USE OF CERTAIN CATEGORY 2 AND CATEGORY 3 MATERIAL FOR THE FEEDING OF CERTAIN ANIMALS IN ACCORDANCE WITH ARTICLE 23(2)**

1. This Annex applies only to users and collection centres authorised and registered pursuant to Article 23(2)(c)(iv), (vi) and (vii). For the purposes of this Annex, 'relevant material' means the animal by-products specified in Article 23(2)(b) and products derived therefrom.
2. Relevant material must be transported to the users or to collection centres in accordance with Annex II.

**▼M1**

- 2a. Entire bodies of dead animals shall be handled as Category 2 material during collection and transportation, without prejudice to the requirement to remove the specific risk material for subsequent disposal before the rest of the body may be used for feeding as provided for in Article 23.

**▼B**

3. Collection centres must:
  - (a) comply at least with the following requirements of Annex V:
    - (i) Chapter I, paragraphs 1(a), (b), (c), (d) and (f), 2, 3 and 4, and
    - (ii) Chapter II, paragraphs 1, 2, 4, 5 and 9; and
  - (b) have adequate facilities for destroying unused unprocessed relevant material, or send it to a processing plant or to an incineration or co-incineration plant in accordance with this Regulation.

Member States may authorise the use of a Category 2 processing plant as a collection centre.

4. In addition to the records required in accordance with Annex II, the following records must be kept in relation to relevant material:
  - (a) in the case of final users, the quantity used and the date of use; and
  - (b) in the case of collection centres:
    - (i) the quantity treated in accordance with paragraph 5;
    - (ii) the name and address of each final user buying the material;
    - (iii) the premises to which the material is taken for use;
    - (iv) the quantity dispatched; and
    - (v) the date on which the material was dispatched.
5. Operators of collection centres supplying relevant material other than fish offal to final users, must ensure that:
  - (a) it undergoes one of the following treatments (either in the collection centre or in a slaughterhouse approved by the competent authority in accordance with Community legislation):
    - (i) denaturing with a solution of a colouring agent approved by the competent authority. The solution must be of such a strength that the colouring on the stained material is clearly visible, and the whole surface of all pieces of material have been covered with a solution as aforesaid either by immersing the material in, or spraying or otherwise applying the solution;
    - (ii) sterilisation, that is to say boiling or steaming under pressure until every piece of material is cooked throughout; or
    - (iii) any other treatment approved by the competent authority; and
  - (b) it is packaged after treatment and before distribution in packaging that is clearly and legibly marked with the name and the address of the collection centre and the indication 'not for human consumption'.



ANNEX X

**MODEL HEALTH CERTIFICATES FOR THE IMPORTATION FROM THIRD COUNTRIES OF CERTAIN ANIMAL BY-PRODUCTS AND PRODUCTS DERIVED THEREFROM**

CHAPTER 1

**Health certificate**

*For processed animal protein not intended for human consumption, including mixtures and products other than petfood containing such protein, intended for dispatch to the European Community*

*Note for the importer: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.*

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

I. Identification of the processed animal protein or product

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

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

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Batch production reference number: .....

II. Origin of the processed animal protein or product

Address and approval number of the approved establishment: .....  
.....

III. Destination of processed animal protein or product

The processed animal protein or product will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of signor: .....

Name and address of consignee: .....

**▼B**

## IV. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No .../... and certify that:

1. The processed animal protein or product described above contains exclusively or partially processed animal protein not intended for human consumption that:

(a) has been prepared and stored in a processing plant approved, validated and supervised by the competent authority in accordance with Article 17 of Regulation (EC) No .../...;

(b) has been prepared exclusively with the following animal by-products:

(i) parts of slaughtered animals, which were fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,

(ii) parts of slaughtered animals, which were rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that were fit for human consumption in accordance with Community legislation,

(iii) hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, underwent ante-mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with Community legislation,

(iv) blood obtained from animals other than ruminants that were slaughtered in a slaughterhouse, underwent ante-mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with Community legislation,

(v) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,

(vi) former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,

(vii) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,

(viii) fresh by-products from fish from plants manufacturing fish products for human consumption,

(ix) shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals; and

(c) has been subjected to the following processing standard:

— heating to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars produced by saturated steam, with a particle size prior to processing of not more than 50 millimetres <sup>(1)</sup>, or

— in the case of non-mammalian protein other than fishmeal, processing method ... as set out in Annex V, Chapter III, of Regulation (EC) .../... <sup>(1)</sup>, or

— in the case of fishmeal, according to processing method ... as set out in Annex V, Chapter III, of Regulation (EC) .../... <sup>(1)</sup> or to heating to at least 80 °C throughout its substance <sup>(1)</sup>.

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

**▼B**

2. The competent authority examined a random sample immediately prior to dispatch and found it to comply with the following standards <sup>(1)</sup>:

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

*Enterobacteriaceae*: n = 5, c = 2, m = 10, M = 300 in 1 g.

3. The end product:

— was packed in new or sterilised bags <sup>(2)</sup>, or

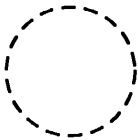
— transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use <sup>(2)</sup>.

4. The end product was stored in enclosed storage.

5. The product has undergone all precautions to avoid recontamination with pathogenic agents after treatment.

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

Stamp <sup>(3)</sup>



.....  
(signature of the official veterinarian) <sup>(3)</sup>

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

<sup>(1)</sup> Where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples 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 samples is M or more; and

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

<sup>(2)</sup> Delete as appropriate.

<sup>(3)</sup> The signature and the stamp must be in a different colour to that of the printing.



▼B

## CHAPTER 2(A)

**Health certificate**

*For milk and milk-based products, which have undergone a single heat treatment and are not intended for human consumption for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of milk/milk-based product

Milk of: .....  
(species)

Description of milk/milk-based product: .....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Lot/batch production reference number: .....

## II. Origin

Address and registration number of treatment or processing establishment <sup>(1)</sup>: .....  
.....

## III. Destination of milk/milk-based product

The milk/milk-based product will be sent:

From: .....  
(place of loading)

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

By the following means of transport <sup>(2)</sup>: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

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

<sup>(2)</sup> For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.





## CHAPTER 2(B)

**Health certificate**

*For heat-treated milk-based products with a pH reduced to less than 6 not intended for human consumption and for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of milk-based product

Milk of: .....  
(species)

Description of milk-based product: .....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Lot/batch production reference number: .....

## II. Origin

Address and registration number of treatment or processing establishment <sup>(1)</sup>: .....  
.....

## III. Destination of milk-based product

The milk-based product will be sent:

From: .....  
(place of loading)

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

By the following means of transport <sup>(2)</sup>: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

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

<sup>(2)</sup> For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

**▼B**

## IV. Health attestation

I, the undersigned official veterinarian, certify that:

1. The milk-based product referred to in this certificate:

(a) has been prepared from raw milk that comes from animals:

(i) not showing clinical signs of a disease that can be transmitted through the milk to humans or animals,  
and

(ii) belonging to holdings that are not under official restriction due to foot-and-mouth disease or rinderpest;  
and

(b) has undergone a process involving heating to ... (temperature) for ... (time), which ensured a negative reaction to the phosphatase test, followed by, in the case of dried milk or dried milk-based product, a drying process; and

(c) has undergone an acidification process whereby its pH has been maintained at less than 6 for at least one hour.

2. Every precaution was taken to avoid contamination of the milk-based product after processing.

3. The milk-based product was packed:

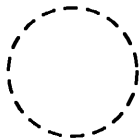
— in new containers <sup>(1)</sup>, or

— in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority <sup>(1)</sup>,

and the containers are marked so as to indicate the nature of the milk-based product.

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

Stamp <sup>(2)</sup>



.....  
(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.

▼B

## CHAPTER 2(C)

**Health certificate**

*For milk and milk-based products, which have undergone a sterilisation or a double heat treatment and are not intended for human consumption, for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country:.....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of milk/milk-based product

Milk of: .....  
(species)

Description of milk/milk-based product: .....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Lot/batch production reference number: .....

## II. Origin

Address and registration number of treatment or processing establishment <sup>(1)</sup>: .....  
.....

## III. Destination of milk/milk-based product

The milk/milk-based product will be sent:

From: .....  
(place of loading)

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

By the following means of transport <sup>(2)</sup>: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

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

<sup>(2)</sup> For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

**▼B**

## IV. Health attestation

I, the undersigned official veterinarian, certify that:

1. The milk/milk-based product referred to in this certificate:

(a) has been prepared from raw milk that comes from animals:

(i) not showing clinical signs of a diseases that can be transmitted through the milk to humans or animals,  
and

(ii) belonging to holdings that are not under official restriction due to foot-and-mouth disease or rinderpest;  
and

(b) has undergone either:

(i) a sterilisation process whereby an  $F_c$  value equal to or greater than 3 is achieved, or

(ii) an initial process involving heating to ... (temperature) for ... (time), which ensured a negative reaction to the phosphatase test, followed by a further process involving heating to ... (temperature) for ... (time), which ensured a negative reaction to the phosphatase test, followed, in the case of dried milk, or dried milk-based products, by a drying process.

2. Every precaution was taken to avoid contamination of the milk/milk-based product after processing.

3. The milk/milk-based product was packed:

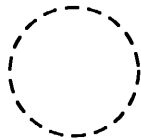
— in new containers <sup>(1)</sup>, or

— in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority <sup>(1)</sup>,

and the containers are marked so as to indicate the nature of the milk/milk-based product.

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

Stamp <sup>(2)</sup>



.....  
(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.



## CHAPTER 3(A)

**Health certificate***For canned petfood intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of petfood

The petfood was produced from raw material of the following species: .....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Lot/batch production reference number: .....

## II. Origin of petfood

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

.....

## III. Destination of petfood

The petfood will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

## IV. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No .../... and certify that the petfood described above:

1. has been prepared and stored in a processing plant approved and supervised by the competent authority in accordance with Article 18 of Regulation (EC) No .../...;





▼ **B**

## CHAPTER 3(B)

**Health certificate**

*For processed petfood, other than canned petfood, intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of petfood

The petfood was produced from raw material of the following species: .....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Lot/batch production reference number: .....

## II. Origin of petfood

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

.....

## III. Destination of petfood

The petfood will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

## IV. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No .../... and certify that the petfood described above:

1. has been prepared and stored in a processing plant approved and supervised by the competent authority in accordance with Article 18 of Regulation (EC) No .../...;

**▼B**

2. has been prepared exclusively with the following animal by-products:
- (a) parts of slaughtered animals, which were fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,
  - (b) parts of slaughtered animals, which were rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that were fit for human consumption in accordance with Community legislation,
  - (c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, underwent ante-mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with Community legislation,
  - (d) blood obtained from animals other than ruminants that were slaughtered in a slaughterhouse, underwent ante-mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with Community legislation,
  - (e) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,
  - (f) former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,
  - (g) raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals,
  - (h) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,
  - (i) fresh by-products from fish from plants manufacturing fish products for human consumption,
  - (j) shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals;
3. was subjected to a heat treatment of at least 90 °C throughout its substance;
4. was analysed by a random sampling of at least five samples from each processed batch taken during or after storage at the processing plant and complies with the following standards <sup>(1)</sup>:

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

*Enterobacteriaceae*: n = 5, c = 2, m = 10, M = 300 in 1 g.

<sup>(1)</sup> Where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples 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 samples is M or more; and

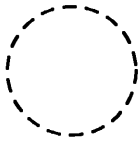
c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.

▼B

- 5. has undergone all precautions to avoid recontamination with pathogenic agents after treatment; and
- 6. was packed in new packaging.

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

Stamp <sup>(1)</sup>



.....  
(signature of the official veterinarian) <sup>(1)</sup>

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

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



## CHAPTER 3(C)

**Health certificate***For dogchews intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of dogchews

The dogchews were produced from raw material of the following species: .....  
.....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

## II. Origin of dogchews

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

## III. Destination of dogchews

The dogchews will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

## IV. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No .../... and certify that the dogchews described above:

1. have been prepared and stored in a processing plant approved and supervised by the competent authority in accordance with Article 18 of Regulation (EC) No .../...;





CHAPTER 3(D)

**Health certificate**

*For raw petfood intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

I. Identification of raw petfood

The raw petfood was produced from animal by-products derived from the following species: .....

.....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Lot/batch production reference number: .....

II. Origin of raw petfood

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

.....

III. Destination of raw petfood

The raw petfood will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....





CHAPTER 4

**Health certificate**

*For the import of serum from equidae from third countries or parts of third countries from which the import of live equidae for slaughter is allowed, intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....

(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

I. Identification of the serum

Serum of: .....

(species)

Nature of packaging: .....

Number of packages: .....

Net weight: .....

II. Origin of the serum

Address and veterinary control number of the registered establishment of collection: .....

.....

III. Destination of the serum

The serum will be sent:

From: .....

(place of loading)

To: .....

(country and place of destination)

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

IV. Health attestation

I, the undersigned official veterinarian, certify that the serum from equidae described above:

1. comes from a country where the following diseases are compulsorily notifiable: African horse sickness, dourine, glanders, equine encephalomyelitis (all types including VEE), equine infectious anemia, vesicular stomatitis, rabies, anthrax;





**▼B**

## CHAPTER 5(A)

**Health certificate**

*For fresh or chilled hides and skins of ungulates, intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of the hides and skins

Hides and skins of: .....  
(species)

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Number(s) of the seal(s) on the container(s), road vehicle(s), railway wagon(s) or bale(s): .....  
.....

## II. Origin of the hides and skins

Address and veterinary control number of the registered and supervised establishment: .....  
.....

## III. Destination of the hides and skins

The hides and skins will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Name and address of consignor: .....

Name and address of consignee: .....

## IV. Health attestation

I, the undersigned official veterinarian, certify that the hides and skins described above:





## CHAPTER 5(B)

**Health certificate**

*For treated hides and skins of ungulates intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this health certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of the hides and skins

Hides and skins of: .....  
(species)

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Number(s) of the seal(s) on the container(s), road vehicle(s), railway wagon(s) or bale(s): .....  
.....

## II. Origin of the hides and skins

Address and veterinary control number of the registered and supervised establishment: .....  
.....

## III. Destination of the hides and skins

The hides and skins will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Name and address of consignor: .....

Name and address of consignee: .....

## IV. Health attestation

I, the undersigned official veterinarian, certify that the hides and skins described above:





## CHAPTER 5(C)

**Official declaration**

*For treated hides and skins of ruminants that are intended for dispatch to the European Community and have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation*

*Note for the importer: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.*

Reference number of this official declaration: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of the hides and skins

Hides and skins of: .....  
(species)

Nature of packaging: .....

Number of packages: .....

Net weight: .....

Number(s) of the seal(s) on the container(s), road vehicle(s), railway wagon(s) or bale(s): .....  
.....

## II. Origin of the hides and skins

Address and veterinary control number of the establishment: .....  
.....

## III. Destination of the hides and skins

The hides and skins will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Name and address of consignor: .....

Name and address of consignee: .....

## IV. Health attestation

I, the undersigned official veterinarian, certify that the hides and skins described above:



▼**B**

## CHAPTER 6(A)

**Health certificate**

*For treated game trophies or birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of game trophies

Game trophies of: .....  
(species)

Nature of the game trophies:

(a) solely bones, horns, hooves, claws, antlers, teeth <sup>(1)</sup>: .....

(b) solely hides or skins <sup>(1)</sup>: .....

Nature of packaging: .....

Number of parts or packages: .....

Reference number of CITES certificate <sup>(1)</sup>: .....

## II. Destination of the game trophies

The game trophies will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

## III. Health attestation

I, the undersigned official veterinarian, certify that the game trophies described above:

1. have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and

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







## CHAPTER 6(B)

**Health certificate**

*For treated game trophies or birds and ungulates consisting of entire parts not having been treated, intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of game trophies

Game trophies of: .....  
(species)

Nature of packaging: .....

Number of parts or packages: .....

Reference number of CITES certificate <sup>(1)</sup>: .....

## II. Destination of the game trophies

The game trophies will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

## III. Health attestation

I, the undersigned official veterinarian, certify that the game trophies described above:

1. with respect to game trophies of cloven-hoofed animals, excluding swine <sup>(1)</sup>:

(a) ... (region) has been free from foot-and-mouth disease and rinderpest for the previous 12 months, and during the same period, no vaccination against any of those diseases has taken place; and

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



**▼B**

## CHAPTER 7(A)

**Health certificate**

*For pig bristles from third countries or regions thereof that are free from African swine fever, intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this certificate: .....

Country of destination: .....

(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of the pig bristles

Nature of packaging: .....

Number of parts or packages: .....

Net weight: .....

## II. Origin of the pig bristles

Address and veterinary control number of the registered establishment: .....

.....

## III. Destination of the pig bristles

The pig bristles will be sent:

From: .....

(place of loading)

To: .....

(country and place of destination)

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....

**▼B**

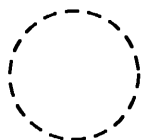
## IV. Health attestation

I, the undersigned official veterinarian, certify that:

1. The pig bristles described above have been obtained from pigs originating, and slaughtered in a slaughterhouse, in the country of origin.
2. The pigs from which the pig bristles have been obtained did not show during inspection, carried out at the time of slaughtering, signs of diseases communicable to humans or animals and were not killed to eradicate any epizootic disease.
3. The country of origin or, in case of regionalisation according to Community legislation, the region of origin, has been free from African swine fever for at least 12 months.
4. The pig bristles are dry and securely enclosed in packaging.

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

Stamp <sup>(1)</sup>



.....  
(signature of the official veterinarian) <sup>(1)</sup>

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

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



CHAPTER 7(B)

**Health certificate**

*For pig bristles from third countries or regions thereof that are not free from African swine fever, intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

I. Identification of the pig bristles

Nature of packaging: .....

Number of parts or packages: .....

Net weight: .....

II. Origin of the pig bristles

Address and veterinary control number of the registered establishment: .....

.....

III. Destination of the pig bristles

The pig bristles will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....





## CHAPTER 8

**Health certificate**

*For animal by-products for the manufacture of pet food or technical products, including pharmaceutical products, intended for dispatch to the European Community*

*Note for the importer:* this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Reference number of this certificate: .....

Country of destination: .....  
(name of the EC Member State)

Exporting country: .....

Responsible Ministry: .....

Certifying department: .....

## I. Identification of animal by-products

Nature of animal by-products and species: .....

Nature of packaging: .....

Number of parts or packages: .....

Net weight: .....

Lot/batch production reference number: .....

## II. Origin of animal by-products

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

.....

## III. Destination of animal by-products

The animal by-products will be sent:

From: .....  
(place of loading)

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

By the following means of transport: .....

Number of seal (if applicable): .....

Name and address of consignor: .....

Name and address of consignee: .....



**▼B**

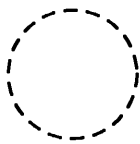
IV. Health attestation

I, the undersigned official veterinarian, certify that the animal by-products described above:

1. consist of animal by-products derived from species referred to under Section I and satisfy the relevant animal health requirements laid down in Commission Decision(s) . . ./. . ./. . . (1);
2. consist only of parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reason;
3. have been deep-frozen at the plant of origin;
4. have undergone all precautions to avoid recontamination with pathogenic agents;
5. were packed in new packaging preventing any leakage.

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

Stamp (2)



.....  
 (signature of the official veterinarian) (2)

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

(1) The number of the relevant and current Decisions for fresh meat of the corresponding susceptible domestic species must be included.  
 (2) The signature and the stamp must be in a different colour to that of the printing.



*ANNEX XI*

**LISTS OF THIRD COUNTRIES FROM WHICH MEMBER STATES  
MAY AUTHORISE IMPORTS OF ANIMAL BY-PRODUCTS NOT  
INTENDED FOR HUMAN CONSUMPTION**

The inclusion of a country on one of the following lists is a necessary, but not sufficient, condition for the importation of relevant products from that country. Imports must also fulfil the relevant animal health and public health requirements.

PART I

**List of third countries from which Member States may authorise imports of  
milk and milk-based products**

Third countries listed in column B or column C of the Annex to Decision 95/340/EC.

PART II

**List of third countries from which Member States may authorise imports of  
processed animal proteins (excluding fishmeal)**

Third countries listed in Part I of the Annex to Decision 79/542/EEC.

PART III

**List of third countries from which Member States may authorise imports of  
fishmeal and fishoil**

Third countries listed in the Annex to Decision 97/296/EC.

PART IV

**List of third countries from which Member States may authorise imports of  
rendered fats (excluding fishoil)**

Third countries listed in Part I of the Annex to Decision 79/542/EEC.

PART V

**List of third countries from which Member States may authorise imports of  
blood products for feed material**

A. Blood products from ungulates

Third countries or parts of countries listed in Part I of the Annex to Decision 79/542/EEC from which imports of all categories of fresh meat of the respective species are authorised.

B. Blood products from other species

Third countries listed in Part I of the Annex to Decision 79/542/EEC.

PART VI

**List of third countries from which Member States may authorise imports of  
blood products (with the exception of equidae) intended for technical and  
pharmaceutical uses**

A. Blood products from ungulates

Third countries or parts of countries listed in Part I of the Annex to Decision 79/542/EEC from which imports of all categories of fresh meat of the respective species are authorised.

B. Blood products from other species

Third countries listed in Part I of the Annex to Decision 79/542/EEC.

**▼B**

## PART VII

**List of third countries from which Member States may authorise imports of unprocessed material for the manufacture of petfood and technical products**

A. Unprocessed material from bovine, ovine, caprine, porcine and equine animals

Third countries or parts of countries listed in Part I of the Annex to Decision 79/542/EEC from which imports of all categories of fresh meat of the respective species are authorised.

B. Unprocessed material from poultry

Third countries from which Member States authorise imports of fresh poultry-meat.

C. Unprocessed material from other species

Third countries listed in Part I of the Annex to Decision 79/542/EEC.

## PART VIII

**List of third countries from which Member States may authorise imports of untreated pig bristles**

Third countries listed in Part I of the Annex to Decision 79/542/EEC.

## PART IX

**List of third countries from which Member States may authorise imports of manure for treatment of the soil**

A. Processed manure products

Third countries listed in Part I of the Annex to Decision 79/542/EEC.

B. Processed manure from equidae

Third countries listed in Part I of the Annex to Decision 79/542/EEC for live equidae.

C. Unprocessed manure from poultry

Third countries from which Member States authorise imports of fresh poultry-meat.

## PART X

**List of third countries from which Member States may authorise imports of petfood and dogchews**

Third countries listed in Part I of the Annex to Decision 79/542/EEC, and the following countries:

(LK) Sri Lanka <sup>(1)</sup>

(JP) Japan <sup>(2)</sup>

(TW) Taiwan <sup>(2)</sup>.

## PART XI

**List of third countries from which Member States may authorise imports of gelatin, hydrolysed protein and dicalcium phosphate**

Third countries listed in Part I of the Annex to Decision 79/542/EEC, and the following countries:

(KR) The Republic of Korea <sup>(3)</sup>

(MY) Malaysia <sup>(3)</sup>

(PK) Pakistan <sup>(3)</sup>

(TW) Taiwan <sup>(3)</sup>.

<sup>(1)</sup> Dogchews made from hides and skins of ungulates only.

<sup>(2)</sup> Processed petfood for ornamental fish only.

<sup>(3)</sup> Gelatin only.