

**Proposal for a Regulation of the European Parliament and of the Council laying down the health rules concerning animal by-products not intended for human consumption**

(2001/C 96 E/02)

(Text with EEA relevance)

COM(2000) 574 final — 2000/0259(COD)

*(Submitted by the Commission on 19 October 2000)*

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,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Council Directive 90/667/EC 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 feedstuffs of animal or fish origin and amending Directive 90/425/EEC <sup>(1)</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. The main conclusion of those scientific opinions 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 on the basis of the nature of animal by-products used. The possibility of using certain animal materials should be limited. Alternative methods to the production of feed material should be laid down for the use or disposal of animal by-products.

(4) In the light of the experience gained in recent years, it is appropriate to clarify the relationship between Directive 90/667/EEC and Council Directive 75/442/EEC of 15 July 1975 on waste <sup>(2)</sup>, in order to avoid confusion and conflict of interest among the competent authorities of the Member States. In particular, when an animal by-product is consigned to a disposal or recovery operation, it should be treated as waste in order to ensure that it is disposed of or recovered in such a way that the objectives of Article 4 of Directive 75/442/EEC are achieved and the human health and environment are protected.

(5) The International Scientific Conference on Meat-and-Bone Meal organised by the Commission and the European Parliament, held in Brussels on 1—2 July 1997, has initiated a debate concerning 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, in order 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 in order to bring it in line with the new scientific information.

(6) From October 1996, the Food and Veterinary Office of the Commission (FVO) carried out a number of rounds of inspections to 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.

(7) In order to avoid any risk of dispersal of pathogens and/or residues, animal by-products should be processed and stored in an approved and supervised plant designated by the Member State concerned or else be disposed of in another 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.

<sup>(1)</sup> OJ L 363, 27.12.1990, p. 51. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

<sup>(2)</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).

- (8) Specific rules should be laid down on controls for processing plants, with particular reference to detailed procedures for the validation of processing methods and self-supervision of production.
- (9) In order to take into account certain practices, it should be possible to derogate from the processing laid down for controlled uses.
- (10) Community inspections should be carried out in the Member States in order to ensure uniform implementation of the health requirements. Such inspections should also include audit procedures.
- (11) 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.
- (12) A wide variety of approaches exist in Member States as regards the financial support for processing and disposal of animal by-products. In order 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.
- (13) In the light of the above, a fundamental revision of the Community rules applicable to animal by-products appears to be necessary.
- (14) 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. In order 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.
- (15) In order to ensure that products imported from third 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 third 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/EEC<sup>(3)</sup>. In order to ensure that such petfood and raw material are only used for their intended purpose, it is necessary to lay down appropriate control measures on importation of material covered by such derogations.
- (16) 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.
- (17) The abovementioned objectives are pursued by 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>(4)</sup>.
- (18) Several Decisions implementing Directives 90/667/EEC and 92/118/EEC have been adopted by the Council and by the Commission. Furthermore, Directive 92/118/EEC has been substantially amended and further amendments are to be made. Consequently, at present the sector of products of animal origin not destined for human consumption is regulated by a great number of different Community legislative acts. Therefore, there is a need for a simplification of the Community legislation dealing with these products.
- (19) Such a simplification will also 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, where required to ensure public and animal health protection, tighten the detailed health rules for products of animal origin not destined for human consumption.
- (20) The products concerned should be subject to the rules for veterinary checks 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>(5)</sup>.

<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 (amendment proposed by COM(2000) 320).

<sup>(4)</sup> OJ L 62, 15.3.1993, p. 49. Directive as last amended by Commission Decision 1999/724/EC (OJ L 290, 12.11.1999, p. 32).

<sup>(5)</sup> OJ L 224, 18.8.1990, p. 29. Directive as last amended by Directive 92/118/EEC.

- (21) 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 third countries <sup>(1)</sup>.
- (22) 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 feedstuffs for certain animal categories <sup>(2)</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>(3)</sup> should therefore be repealed.
- (23) In order 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 Veterinary Committee set up by Council Decision 68/361/EEC <sup>(4)</sup>.
- (24) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(5)</sup>, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS REGULATION:

#### CHAPTER I

#### GENERAL PROVISIONS

##### Article 1

##### Scope

1. This Regulation lays down:
- (a) the animal health and public health rules for the collection, transport, storing, handling, processing and use or disposal of animal by-products in order to prevent these products from presenting a risk to animal or public health;
- (b) the animal and public health rules for the placing on the market, trade and importation of animal by-products and products derived therefrom, intended for purposes other than human consumption.

2. Without prejudice to the relevant animal and public health rules, 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) carcasses or parts of wild animals not suspected of being infected with diseases communicable to man or animals;
- (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.

3. This Regulation shall not affect national veterinary legislation applicable to the eradication and control of certain diseases and to the use of catering waste.

##### Article 2

##### Definitions

For the purpose of this Regulation, the following definitions and the definitions laid down in Annex I shall apply:

- (1) *Animal by-products*: carcasses or parts of animal or products of animal origin referred to in Articles 4, 5 and 6 not intended for human consumption, with the exception of ova, embryos, semen and catering waste;
- (2) *Category 1 material*: animal by-products referred to in Article 4;
- (3) *Category 2 material*: animal by-products referred to in Article 5;
- (4) *Category 3 material*: animal by-products referred to in Article 6;
- (5) *Animals*: any vertebrate or invertebrate animal (including fish, reptiles or amphibians);
- (6) *Farmed animals*: any animal which is kept, fattened or bred for the production of food (meat, milk, eggs) wool, fur, feathers, skins, or any other product of animal origin;
- (7) *Wild animals*: animals not kept by man, excluding fish;

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

<sup>(2)</sup> OJ L 202, 26.8.1995, p. 8.

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

<sup>(4)</sup> OJ L 255, 18.10.1968, p. 23.

<sup>(5)</sup> OJ L 184, 17.7.1999, p. 23.

- (8) *Pet animals*: animals belonging to species normally nourished and kept, but not consumed, by man for purposes other than farming;
- (9) *Competent authority*: the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which it has delegated that competence;
- (10) *Placing on the market*: any operation the purpose of which is to supply animal by-products, or products derived therefrom covered by this Regulation, to a third party for sale, or any other form of transfer against payment or free of charge to a third party and storage with a view to supply to a third party, regardless of whether the operation takes place within a Member State, between Member States or between a Member State and a third country or vice versa;
- (11) *Trade*: trade between Member States in goods within the meaning of Article 23(2) of the Treaty;
- (12) *Producer*: any person whose activity produces animal by-products;
- (13) *Processing plant*: an animal by-products processing plant;
- (14) *Category 1 processing plant*: a plant in which Category 1 material is processed before its final disposal or further transformation;
- (15) *Category 2 processing plant*: a plant in which Category 2 material is processed before its final disposal or further transformation;
- (16) *Category 3 processing plant*: a plant in which Category 3 materials are processed into feed material;
- (17) *Processing methods*: methods listed in Annex III, Chapter III;
- (18) *Oleochemical plant*: a plant processing rendered fats derived from Category 2 material or Category 3 material under conditions set out in Annex IV, Chapter III;
- (19) *Incineration*: the disposal of animal by-products or products derived therefrom in an incineration plant;
- (20) *Co-incineration*: the disposal of animal by-products or products derived therefrom in a co-incineration plant;
- (21) *Incineration plant*: disposal site as defined in Article 3(4) of Directive 2000/. . ./EC of the European Parliament and of the Council [on the incineration of waste] <sup>(1)</sup>;
- (22) *Co-incineration plant*: disposal site as defined in Article 3(5) of Directive 2000/. . ./EC;
- (23) *Landfill*: disposal site as defined by Council Directive 1999/31/EC <sup>(2)</sup>;
- (24) *Biogas plant*: a plant in which biological degradation of organic material is undertaken under anaerobic conditions for the production and collection of biogas;
- (25) *Composting plant*: a plant in which biological degradation of organic material is undertaken under aerobic conditions;
- (26) *Technical products*: products 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 part of feathers, apiculture products, serum of equidae, blood products, pharmaceuticals, bone products for china, gelatine and glue, processed manure;
- (27) *Technical plant*: a plant producing technical products;
- (28) *Category 1 or Category 2 intermediate plant*: 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; it may be used for certain preliminary processing activities, such as removal of ruminant hides and skins, performing of *post-mortem* examination;
- (29) *Category 3 intermediate plant*: 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;
- (30) *Collection centres*: premises collecting and treating certain animal by-products intended to be used as feed for categories of animals referred to in Article 21(1)(c);
- (31) *Storage plant*: a plant, other than establishments and intermediaries covered by Council Directive 95/69/EC <sup>(3)</sup>, in which processed animal by-products are temporarily stored before their final use or disposal;

<sup>(1)</sup> COM(1998) 558 final.

<sup>(2)</sup> OJ L 182, 16.7.1999, p. 1.

<sup>(3)</sup> OJ L 332, 30.12.1995, p. 15.

- (32) *Unprocessed animal by-products*: animal by-products which have only undergone refrigeration or other treatment not resulting in sufficiently safe destruction of pathogenic agents;
- (33) *Processed animal protein*: animal proteins derived entirely from Category 3 material, which have been treated so as to render them suitable for direct use as feed material or organic fertilisers or soil improvers or in a feedingstuff for animals or in petfood; it includes fishmeal, meatmeal, bonemeal, meat-and-bone meal, bloodmeal, dry greaves, feathermeal, hoofmeal, hornmeal and other similar products, including mixtures or products containing these products;
- (34) *Feed material*: feed of animal origin for farmed animals, including processed animal proteins, rendered fats, fish oil, gelatine and hydrolysed proteins, dicalcium phosphate, milk and milk products;
- (35) *Organic fertilisers and soil improvers*: materials of animal origin that are 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 compost or digestion residues from biogas production;
- (36) *Batch*: a quantity of a product produced, manufactured or packaged under practically the same conditions;
- (37) *Rendered fats*: fats derived from processing of Category 2 material or Category 3 material;
- (38) *Greaves*: the protein-containing residue of rendering, after partial separation of fat and water;
- (39) *Petfood*: food for pet animals containing Category 3 material;
- (40) *Dogchews*: untanned edible products for pet animals produced from hides and skins of ungulates or other animal material;
- (41) *Petfood plant*: a plant producing petfood or petfood ingredients or dogchews and in which certain animal by-products are used in the preparation of such petfood or petfood ingredients or dogchews;
- (42) *Manure*: any excrement and/or urine of cloven-hoofed animals, equidae and/or poultry, with or without litter, and guano;

(43) TSEs: all transmissible spongiform encephalopathies with the exception of those occurring in humans;

(44) *Specified Risk material*: Material referred to in Annex II, Chapter B, to Regulation (EC) No .../... of the European Parliament and of the Council (laying down rules for the prevention and control of certain transmissible spongiform encephalopathies).

### Article 3

#### General obligations

Animal by-products, and products derived therefrom, shall be collected, transported, stored, handled, processed, disposed of, placed on the market, imported from third countries and used in accordance with this Regulation.

### CHAPTER II

#### CATEGORISATION, COLLECTION, TRANSPORTATION 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 parts of the body, including hides and skins, of the following animals:

(i) animals suspected of being infected by a TSE or in which the presence of a TSE has been officially confirmed, including animals which were killed in the context of TSE eradication measures,

(ii) animals other than farmed animals and wild animals, including in particular pet animals, zoo animals and circus animals,

(iii) experimental animals as defined by Article 2 of Council Directive 86/609/EEC <sup>(1)</sup>,

(iv) wild animals not kept by man when suspected of being infected with diseases communicable to man or animals;

(b) specified risk material, including dead ruminant animals containing such material;

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

(c) products derived from animals to which have been administered substances prohibited under Directive 96/22/EC 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<sup>(1)</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 slaughterhouses in which specified risk material is removed, including screenings, materials from desanding, grease and oil mixture, and sludge, and materials removed from drains from those premises;

(e) mixtures of Category 1 material with either Category 2 material or Category 3 material or both.

2. Category 1 material shall be collected and transported without undue delay in accordance with Article 7, and shall be:

(a) directly disposed of as waste by incineration in an incineration plant approved under Directive .../.../EC (on the incineration of waste);

(b) processed in a processing plant approved under Article 10 and the resulting material shall be finally disposed of as waste by incineration or by co-incineration in an incineration or co-incineration plant approved under Directive .../.../EC (on the incineration of waste);

(c) with the exclusion of material listed in paragraph 1(a)(i), processed in a processing plant approved in accordance with Article 10 following processing method 1, and the resulting material shall be finally disposed of as waste in a landfill approved under Directive 1999/31/EC;

(d) 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.

3. Intermediate handling or storage of Category 1 material shall take place only in intermediate plants approved in accordance with Article 9.

4. By way of derogation from paragraph 2, dead pet animals may be directly disposed of as waste by burial in accordance with Article 4 of Directive 75/442/EEC.

#### 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 from all animal species and the digestive tract content from mammalian species;

(b) all animal materials collected when treating waste water from slaughterhouses other than slaughterhouses referred to in Article 4(1)(d) or from Category 2 processing plants, including screenings, materials from desanding, grease and oil mixture, and sludge, and materials removed from drains from these 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) mixtures of Category 2 material with Category 3 material;

(e) animal by-products other than Category 1 material or Category 3 material.

2. Category 2 material shall be collected and transported without undue delay in accordance with Article 7, and shall be:

(a) disposed of as waste by incineration or by co-incineration in an incineration or co-incineration plant approved under Directive .../.../EC (on the incineration of waste);

(b) processed in a processing plant approved in accordance with Article 10 and:

(i) the resulting material shall be disposed of as waste either by incineration or by co-incineration in an incineration or co-incineration plant approved under Directive .../.../EC (on the incineration of waste) or in a landfill approved under Directive 1999/31/EC, or

(ii) the rendered fats shall be further processed into fat derivatives for use in organic fertilisers or soil improvers or other technical use in an oleochemical plant approved in accordance with Article 11;

<sup>(1)</sup> OJ L 125, 23.5.1996, p. 10.

- (c) processed in a processing plant approved in accordance with Article 10 following processing method 1 and:
- (i) the resulting proteinaceous material shall be used as organic fertiliser or soil improver, or
  - (ii) the resulting material shall be treated in a biogas plant or in a composting plant approved by the Member State in accordance with Article 12;
- (d) in case of material of fish origin, ensiled in compliance with rules to be adopted in accordance with the procedure referred to in Article 33(2);
- (e) in the case of manure and digestive tract content and material collected from slaughterhouses referred to in paragraph 1(b):
- (i) used without processing as raw material in a biogas plant or in a composting plant or treated in a technical plant approved for this purpose,
  - (ii) if not suspected of being capable of spreading serious transmissible diseases, spread on land in accordance with this Regulation;
- (f) 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.
3. Intermediate handling or storage of Category 2 material shall take place only in intermediate plants approved in accordance with Article 9.
4. By way of derogation from paragraph 2, the competent authority may, where necessary, decide that Category 2 material may be disposed of as waste by burial on site where:
- (i) a widespread epizootic disease leads to a lack of capacity at the processing plant or incineration plant, or
  - (ii) the animal by-products concerned originate from a place with difficult access and, therefore, the quantity and the distance to be covered does not justify collecting the animal by-products.
- Burial shall be carried out in accordance with Article 4 of Directive 75/442/EEC.

#### 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) all parts of slaughtered animals which are declared fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reason;
- (b) all slaughtered animal parts which have been rejected as unfit for human consumption but are not affected by any signs of diseases communicable to man or animals and have been derived from carcasses passed fit for human consumption in accordance with Community legislation;
- (c) hides and skins, hooves and horns, pig bristles and feathers originating from animals which have been slaughtered in a slaughterhouse, have undergone an *ante-mortem* inspection and been passed fit, as a result of such inspection, for slaughter in accordance with Community legislation;
- (d) blood obtained from animals which have been slaughtered in a slaughterhouse, have undergone an *ante-mortem* inspection and been passed fit, as a result of that 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) foodstuffs of animal origin, or foodstuffs containing products of animal origin, which were originally intended for human consumption but are destined for animal 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, which are destined for farmed animals and have not been processed in accordance with animal health legislation for the production of swill;
- (g) raw milk originating from animals which do not show clinical signs of any disease communicable through that product to man or animals;
- (h) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;
- (i) fresh fish offal 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 man or animals;

(k) blood, hides and skins, hooves, feathers, wool, horns, hair and fur originating from animals which did not show clinical signs of any disease communicable through that product to man or animals.

2. Animal by-products shall be collected and transported without undue delay in accordance with Article 7, and shall be:

(a) disposed of as waste by incineration or by co-incineration in an incineration or co-incineration plant approved under Directive . . ./EC (on the incineration of waste);

(b) processed in a processing plant approved in accordance with Article 15;

(c) transformed in a technical plant approved in accordance with Article 16;

(d) used as raw material in a petfood plant approved in accordance with Article 16;

(e) processed in a processing plant approved in accordance with Article 10 or in a processing plant approved in accordance with Article 15 and the resulting material is finally disposed of as waste either by incineration or by co-incineration in an incineration or co-incineration plant approved under Directive . . ./EC (on the incineration of waste) or in landfill approved under Directive 1999/31/EC; or

(f) transformed in a biogas plant or in a composting plant approved in accordance with Article 12.

3. Intermediate handling and/or storage of Category 3 material shall take place only in intermediate plants approved in accordance with Article 9.

#### Article 7

##### Collection and transportation

Unprocessed and processed animal by-products shall be collected, transported and identified in accordance with Annex II.

#### Article 8

##### Records

1. Producers consigning animal by-products from any premises shall keep a record of each consignment showing:

(a) the date on which the material was taken from the premises;

(b) the quantity and description of the material;

(c) the destination to which it was consigned; and

(d) the name of the haulier transporting it.

2. Any person transporting animal by-products shall, at the time of collection, record:

(a) the address of the premises from which the material was collected;

(b) the date on which the material was collected;

(c) the quantity and description of the material;

(d) the destination to which it is to be taken.

3. Any person receiving animal by-products shall keep a record of incoming consignments showing:

(a) the date on which the material arrived;

(b) the address of the premises from which the material was consigned;

(c) the quantity and description of the material;

(d) the name and address of the haulier who transported it.

4. The records referred to in paragraphs 1, 2 and 3 shall be kept for a period of at least two years for presentation to the competent authorities.

#### Article 9

##### Intermediate plants and storage plants

1. Animal by-products intermediate plants and storage plants shall be subject to approval by the competent authority.

2. In order to be approved, the Category 1 or Category 2 intermediate plant must:

(a) meet the requirements of Annex VIII, Chapter I;

(b) handle and store Category 1 or Category 2 material in accordance with Annex VIII, Chapter II, Part B;

(c) have undergone the establishment's own checks provided for in Article 22;

(d) be checked by the competent authority in accordance with Article 23.

3. In order to be approved, the Category 3 intermediate plant must:

(a) meet the requirements of Annex VIII, Chapter I;

(b) handle and store Category 3 material in accordance with Annex VIII, Chapter II, Part A;

(c) have undergone the establishment's own checks provided for in Article 22;

(d) be checked by the competent authority in accordance with Article 23.

4. In order to be approved, storage plants must:

- (a) meet the requirements of Annex VIII, Chapter III;
- (b) store processed animal by-products in accordance with Annex VIII, Chapter III, point 3;
- (c) be supervised by the competent authority.

#### CHAPTER III

#### APPROVAL OF CATEGORY 1 AND 2 PROCESSING PLANTS, BIOGAS PLANTS, COMPOSTING PLANTS AND OLEOCHEMICAL PLANTS

##### Article 10

#### Approval of Category 1 and Category 2 processing plants

1. Member States shall approve for all or part of their territory one or more Category 1 and Category 2 processing plants for the collection and processing of Category 1 or Category 2 material. A Member State may decide to designate a Category 1 or Category 2 processing plant in another Member State after agreement with that State.

2. In order to be approved by the competent authority, Category 1 and Category 2 processing plants must:

- (a) meet the requirements of Annex III, Chapter I;
- (b) handle, process and store the Category 1 or Category 2 material in accordance with Annex III, Chapter II and Annex IV, Chapter I;
- (c) be validated by the competent authority in accordance with Annex III, Chapter V;
- (d) have undergone the establishment's own checks provided for in Article 22;
- (e) be checked by the competent authority in accordance with Article 23;
- (f) establish and implement methods of monitoring and checking the critical control points on the basis of the process used;
- (g) ensure that the products after processing satisfy the requirements of Annex IV, Chapter I.

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

##### Article 11

#### Approval of oleochemical plants

1. Oleochemical plants shall be subject to approval by the competent authority.

2. In order to be approved, an oleochemical plant must:

- (a) process the rendered fats in accordance with the standards laid down in Annex IV, 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;
- (d) be under the supervision of the competent authority to ensure that the operator or manager of the establishment complies with the requirements of this Regulation.

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

##### Article 12

#### Approval of biogas plants and composting plants

1. Biogas plants and composting plants which transform animal by-products shall be subject to approval by the competent authority.

2. In order to be approved, a biogas plant and composting plant must:

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

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

#### Article 13

##### **Dispatch of processed animal by-products to incineration or co-incineration plants or to landfill**

1. Processed animal by-products may be sent for disposal by incineration or co-incineration or landfill only subject to the following conditions:

- (a) processed animal by-products must be:
  - (i) transported in sealed covered containers or vehicles which bear the clear indication 'not for animal consumption — for incineration/co-incineration/landfill only', as appropriate,
  - (ii) consigned only to incineration or co-incineration plants approved under Directive .../.../EC (on the incineration of waste) or to landfill approved under Directive 1999/31/EC;
- (b) the competent authority of the place of origin must inform the competent authority of the place of destination of the dispatch of each consignment;
- (c) the competent authority of the place of destination must inform the competent authority of the place of origin of the arrival of each consignment;
- (d) the competent authority of the place of destination must ensure that the designated plant or landfill uses the consignment only for the authorised purposes and keeps full records demonstrating compliance with this Regulation.

2. Processed animal by-products may be sent for disposal by incineration or co-incineration to other Member States only subject to the following conditions:

- (a) the Member State of destination must have authorised the receipt of the material;
- (b) the processed animal by-products must:
  - (i) be accompanied by an official certificate as laid down in Annex VII,
  - (ii) be transported in sealed covered containers or vehicles which bear the clear indication 'not for animal consumption — for incineration or co-incineration

only', if appropriate in the language of the Member States of origin, destination and transit,

(iii) be conveyed directly to the incineration or co-incineration plant;

- (c) Member States which send processed animal by-products to other Member States must inform the competent authority of the place of destination of each consignment by means of the ANIMO system and the words 'Not for animal consumption — For incineration or co-incineration only' must be contained in the ANIMO message;
- (d) Member States of destination must inform the competent authority of the place of origin of the arrival of each consignment by means of the ANIMO system;
- (e) Member States of destination must ensure that the designated plants on their territory use the consignment only for the authorised purposes and keep full records demonstrating compliance with this Regulation.

#### CHAPTER IV

##### **PLACING ON THE MARKET OF PROCESSED ANIMAL PROTEINS AND OTHER FEED MATERIAL, PETFOOD, DOGCHEW AND TECHNICAL PRODUCTS**

#### Article 14

##### **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 Annex V and Annex VI, 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 plants 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 which:

- (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/EC<sup>(1)</sup>;

<sup>(1)</sup> OJ L 62, 15.3.1993, p. 69.

(b) were not slaughtered in an establishment 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 marketing of unprocessed animal by-products which come from a territory or part of a territory subject to animal health restriction 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 an establishment approved for that purpose by the Member State where the animal health problem occurred;

(c) are properly identified;

(d) comply with the special conditions laid down in Annexes V and VI, or with detailed rules to be adopted 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 15

##### Approval of Category 3 processing plants

1. Category 3 processing plants shall be subject to approval by the competent authority.

2. In order to be approved, Category 3 processing plants must:

(a) meet the requirements of Annex III, Chapter I and II and Annex V;

(b) handle, process and store Category 3 material in accordance with Annex V;

(c) have been validated by the competent authority in accordance with Annex III, Chapter V;

(d) have undergone the establishment's own checks provided for in Article 22 and be supervised by the competent authority in accordance with Article 23;

(e) ensure that after processing the products satisfy the requirements of Annex V, Chapter I.

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

#### Article 16

##### Approval of petfood plants and technical plants

1. Petfood plants and technical plants shall be subject to approval by the competent authority.

2. In order to be approved, the petfood plant or the technical plant must:

(a) undertake, in the light of the specific requirements laid down in Annex VI for the products the plant produces, to:

(i) comply with the specific production requirements set out in this Regulation,

(ii) establish and implement methods of monitoring and checking the critical control points on the basis of the process used,

(iii) depending on the products, 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) keep a record of the information obtained pursuant to (ii) and (iii) for presentation to the competent authority. The results of the checks and tests shall be kept for at least two years,

(v) should the result of the laboratory examination referred to in (iii) or any other information available to them reveal the existence of a serious animal health or public health hazard, inform the competent authority;

(vi) consign only products accompanied by a commercial document indicating the nature of the product, the name and the veterinary approval number of the establishment of production;

- (b) be under the supervision of the competent authority to ensure that the operator or manager of the establishment complies with the requirements of this Regulation.

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

#### Article 17

#### **Placing on the market of processed animal protein and other feed material**

Member States shall ensure that processed animal proteins and other feed material are placed on the market only if they:

- (a) have been prepared in a Category 3 processing plant approved and supervised in accordance with Article 15;
- (b) have been prepared exclusively with Category 3 material listed in points (a) to (j) of Article 6(1);
- (c) have been handled, processed, stored and transported in accordance with Annex V;
- (d) comply with the standards laid down in Annex V.

#### Article 18

#### **Placing on the market of petfood, dogchews and technical products**

Member States shall ensure that petfood, dogchew and technical products are placed on the market only if they:

- (a) meet the specific requirements laid down in Annex VI;
- (b) come from establishments approved and supervised in accordance with Article 16.

#### Article 19

#### **Safeguard measures**

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

#### Article 20

#### **Organic fertilisers and soil improvers**

The spreading on pasture land of organic fertilisers and soil improvers, other than manure, is prohibited.

#### CHAPTER V

#### **DEROGATIONS**

#### Article 21

#### **Derogations**

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;
- (b) the use of animal by-products for taxidermy purposes in technical plants approved for this purpose in accordance with Article 16;
- (c) in accordance with the rules laid down in Annex IX, the use of 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 man or animals, and Category 3 material referred to in Article 6(1)(a) to (j), for the feeding of:
  - (i) zoo animals,
  - (ii) circus animals,
  - (iii) reptiles other than zoo or circus animals,
  - (iv) fur animals,
  - (v) wild animals of endangered species,
  - (vi) wild animals of any species where this is necessary because of severe nutritional conditions or for preparing documentary reports,
  - (vii) recognised kennels or packs of hounds,
  - (viii) maggots for fishing bait.

2. Member States shall inform the Commission where they make use of the derogations referred to in paragraph 1 and shall notify it of the verification arrangements they introduce to prevent the animal by-products concerned from being used for unauthorised purposes.

3. Each Member State shall draw up a list of users and collection centres authorised and registered pursuant to paragraph 1(c) within its own territory. Each user and collection centre shall be assigned an official number for inspection purposes and in order to be able to trace the origin of the products concerned.

The premises of users and collection centres shall be supervised by the competent authority, which shall at all times have free access to all parts of the premises, in order to ensure compliance with the requirements referred to in paragraph 1(c).

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

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

#### CHAPTER VI

### CONTROLS AND INSPECTIONS TO BE CARRIED OUT ON INTERMEDIATE AND PROCESSING PLANTS

#### Article 22

##### Plants' own checks

1. Operators and owners of intermediate plants and processing plants or their representatives shall adopt all measures necessary to comply with the requirements of this Regulation and shall in particular:

- (a) identify and control the critical points in the plants;
- (b) establish and implement methods for monitoring and checking such critical points;
- (c) in the case of processing plants, take representative samples from each processed batch in order to check compliance with the standards for the products established by this Regulation and the maximum permitted levels of physico-chemical residues laid down in Community legislation;
- (d) record the results of the checks and tests referred to in (b) and (c) and keep them for a period of at least two years for presentation to the competent authorities;
- (e) introduce a system that makes it possible to link each batch dispatched and the time when it was produced.

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;

(b) establish the causes of failures of compliance;

(c) ensure that no material suspected or known to be contaminated is moved from the plant before being reprocessed under the direct supervision of the competent authority and re-sampled officially in order to comply with the standards laid down in this Regulation.

3. Detailed arrangements for implementing this Article may be adopted in accordance with the procedure referred to in Article 33(2).

#### Article 23

##### Official controls

1. The competent authorities shall at regular intervals carry out inspections and supervision at the intermediate plants and processing plants in accordance with Annex III, 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 Hazard Analysis Critical Control Points implementation.

3. If the inspection carried out by the competent authority reveals that not all of the requirements of this Regulation are being met, the competent authority must take appropriate action. In the case of non-compliance with the provisions of this Article in relation to microbiological standards, and the types of microbiological controls, the manufacturer shall:

- (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) process and reprocess the contaminated batch under the supervision of the competent authority;
- (c) increase the intensity of sampling and testing of production;
- (d) investigate unprocessed animal by-products records appropriate to the finished sample;
- (e) instigate appropriate decontamination and cleaning procedures within the plant.

4. Detailed arrangements for implementing this Article may be adopted in accordance with the procedure referred to in Article 33(2).

*Article 24***Frequency of checks and microbiological analyses**

1. The detailed arrangements for and frequency of the checks provided for in Articles 22 and 23 shall be established in accordance with the procedure referred to in Article 33(2).
2. The reference methods for the microbiological analyses shall be established in accordance with the procedure referred to in Article 33(2).

*Article 25***List of approved plants**

Each Member State shall draw up a list of plants approved pursuant to Articles 9 to 12 and Articles 15 and 16 within its own territory. Each plant shall be assigned an official number which identifies the plant with respect to the nature of its activities.

The Member States shall forward the list and its updates to the other Member States and to the Commission.

## CHAPTER VII

**COMMUNITY CONTROLS***Article 26***Community controls**

1. The Commission shall, in cooperation with the competent authorities of the Member States, carry out on-the-spot inspections and audits of all levels of production and placing on the market and disposal of animal by-products, and products derived therefrom and of the organisation and functioning of the competent authorities in the Member States, in order to ensure that the provisions of this Regulation, rules adopted pursuant thereto and any safeguard measures are applied uniformly.
2. Rules for the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 33(2).

## CHAPTER VIII

**PROVISIONS APPLICABLE TO THE IMPORTATION OF CERTAIN ANIMAL BY-PRODUCTS AND PRODUCTS DERIVED THEREFROM INTO THE COMMUNITY***Article 27***General provisions**

The provisions applicable to the importation of feed material referred to in Annex V and petfood, dogchews and technical

products referred to in Annex VI from third 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 under specific conditions to be laid down in accordance with the procedure referred to in Article 33(2).

*Article 28***Prohibitions**

Import of animal by-products and derived products into the Community shall be prohibited, except in accordance with this Regulation.

*Article 29***Compliance with Community rules**

1. Products referred to in Annexes V and VI may be imported into the Community only if they satisfy the requirements set out in paragraphs 2 to 5.
2. Products referred to in Annexes V and VI must, 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).

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 these 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 on the third country;
- (g) the health status of the livestock, other domestic animals and wildlife 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 International Office of Epizootic Diseases (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.

3. Products referred to in Annex V must come from establishments on a Community list to be drawn up in accordance with 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 establishments 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 establishments referred to in (a), to send any written comments to the Commission;
- (c) where written comments are made by at least one Member State, the Commission shall inform the Member States within five working days and include the point on the next meeting of the Standing Veterinary Committee for decision in accordance with the procedure referred to in Article 33(2);
- (d) where no comments are received from the Member States within the time limit referred to in (b), the modifications to the list shall be considered to have been accepted by the Member States. The Commission shall inform the Member States within five working days, and imports shall be authorised from such establishments five working days after receipt of this information by the Member States.

4. Products referred to in Annex VI must come from establishments that have been approved and registered by the competent authority of the third countries.

5. Consignments of products referred to in Annexes V and VI, must, save as otherwise specified in those Annexes, be accompanied by a health certificate corresponding to the specimen laid down in Annex X, certifying that the products meet the conditions referred to in those annexes and come from establishments offering such conditions.

#### 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 V and VI 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 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 which must accompany the product;
- (b) specific health requirements applicable to importation into the Community;
- (c) where necessary, procedures for drawing up and amending lists of regions or establishments from which imports are permitted.

3. The detailed rules for the application of this Article shall be adopted in accordance with 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;

(b) verifying compliance with:

- (i) the conditions for inclusion in a Community list of third countries,
- (ii) import conditions,
- (iii) the conditions for recognising equivalence of measures,
- (iv) any emergency measures applied under Community legislation.

The experts from the Member States responsible for these checks shall be appointed by the Commission.

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 request 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

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).

##### Article 33

#### Regulatory procedure

1. The Commission shall be assisted by the Standing Veterinary Committee instituted by Article 1 of Decision 68/361/EEC.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be 15 days.

##### Article 34

#### Consultation of scientific committees

The appropriate Scientific Committees may be consulted on any matter falling within the scope of this Regulation which is likely to have an effect on animal or public health.

##### Article 35

#### Communication of national provisions

The Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Regulation.

##### Article 36

#### Financing rules

The Commission shall prepare a report on the financial support in Member States for the processing and disposal of the animal by-products, with particular reference to Category 1 and Category 2 material, accompanied by appropriate proposals.

##### Article 37

#### Repeal

Directive 90/667/EEC and Decisions 95/348/EC and 1999/534/EC are repealed.

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

##### Article 38

#### Entry into force

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

It shall apply from 1 February 2003 <sup>(1)</sup>.

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

<sup>(1)</sup> This date has been indicated to provide a period of 18 months for the implementation of the new provisions.

## ANNEX I

## DEFINITIONS

*Gelatine*: 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);

*Hydrolysed proteins*: mixtures of polypeptides, peptides and aminoacids obtained by the hydrolysis of collagen;

*Hides and skins*: all cutaneous and subcutaneous tissues;

*Tanning*: 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;

*Processed petfood*: petfood, other than raw petfood, which has undergone a treatment which ensures its stability;

*Canned petfood*: heat-processed petfood contained within a hermetically sealed container;

*Hermetically sealed container*: container that is designed and intended to be secure against the entry of micro-organisms;

*Raw petfood*: petfood which has not undergone any preserving process other than chilling, freezing or quick freezing, or equivalent processes to ensure preservation;

*Fishmeal*: processed animal protein derived from sea animals, except sea mammals;

*Blood*: fresh whole blood;

*Blood products*: 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;

*Bloodmeal*: blood products derived from the heat-treatment of blood in accordance with Annex V, Chapter II and intended for animal consumption or fertilisers;

*Blood products for technical and pharmaceutical use*: blood products intended for technical or pharmaceutical purposes;

*Products used for in vitro diagnosis*: a packaged product, ready for use by the end user, containing a blood product, and used as 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;

*Laboratory reagents*: a packaged product, ready for use by the end user, containing a blood product, and intended for laboratory use as a reagent or reagent product, whether used alone or in combination;

*Unprocessed wool, hair and bristles*: sheep's wool, ruminant hair and pig bristles which have not undergone factory washing or been obtained from tanning;

*Unprocessed feathers and parts of feathers*: feathers and parts of feathers which have not been treated with a steam current or by some other method ensuring that no pathogens are transmitted;

*Apiculture products*: honey, beeswax, royal jelly, propolis or pollen, not intended for human consumption or industrial use.

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## ANNEX II

**HYGIENE REQUIREMENTS FOR THE COLLECTION AND TRANSPORT OF ANIMAL BY-PRODUCTS**

1. All the necessary measures shall be taken to assure that Category 1, Category 2 and Category 3 materials are identifiable and kept identifiable during collection and transportation.
2. Animal by-products must be collected and transported in suitable containers or vehicles in such a way as to prevent leakage. The containers or vehicles must be adequately covered. Vehicles for refrigerated transport must have been designed in such a way that the temperature required can be maintained throughout the period of transport.
3. Vehicles, tarpaulin covers and reusable containers must be cleaned and disinfected after each use and must be maintained in a clean condition.
4. Where animal by-products are not transported directly in bulk, the information on the origin, name and nature of the animal by-products and the words 'Animal by-products — Not for human consumption' must also be indicated on a label attached to the container, cartons or other packaging material in letters at least 2 cm high.
5. During transportation, unprocessed and processed animal by-products, and products derived therefrom, must be accompanied either
  - (i) by a commercial document, specifying:
    - the date on which the material was taken from the premises
    - the description of the material, including its classification in accordance with this Regulation
    - the quantity of the material
    - the place of origin of the material
    - the name and the address of the carrier
    - the name and the address of the receiver and the registration number
    - if appropriate,
      - the approval or registration number of the plant of origin
      - the nature and the methods of the treatment.

The commercial document must be produced in triplicate (one original and two copies). The original shall accompany the consignment to its final destination and shall be retained by the receiver, one copy shall be retained by the producer, another shall be retained by the carrier;

or

- (ii) when specifically requested by this Regulation, by a health certificate issued and signed by the competent authority.

The commercial document and the health certificate referred to in (i) and (ii) shall be kept for a period of at least two years for presentation to the competent authorities.

A model for the commercial document referred to in (i) or for the health certificate referred to in (ii) may be laid down in accordance with the procedure referred to in Article 33(2).

6. The competent authority shall take the necessary measures to control the movements of unprocessed and processed animal by-products and products derived therefrom by checking the keeping of required records and documents, which shall accompany those products during their transport to the place of destination, and, if necessary, by sealing.

## ANNEX III

**GENERAL HYGIENE REQUIREMENTS FOR ANIMAL BY-PRODUCTS PROCESSING PLANTS**

## CHAPTER I

**General conditions for the approval of animal by-products processing plants**

1. Premises and facilities must meet at least the following requirements:
  - (a) The premises of the processing plant must be adequately separated from the public highway and other premises such as slaughterhouses. Premises for the processing of animal by-products must not be at the same site as slaughterhouses, unless in a completely separate part of a building. Unauthorised persons and animals shall have no access to the plant.
  - (b) The processing plant must have a clean and unclean section, adequately separated. The unclean section must have a covered place to receive the 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 capacity and hot water and steam production for the processing of animal by-products.
  - (d) The unclean section 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:
    - measuring equipment to monitor temperature against time and, if necessary, pressure at critical points;
    - recording devices to record continuously the results of these measurements;
    - an adequate safety system to prevent insufficient heating.
  - (f) To prevent recontamination of the finished product by incoming unprocessed animal by-product, 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 process of that product and the storage of the processed product.
2. The processing plant must have adequate facilities for cleaning and disinfecting the vehicles or containers and recipients in which animal by-products are received — other than ships — or in which they are transported.
3. Adequate facilities must be provided for the disinfecting of vehicle wheels, upon leaving the unclean section of the processing plant.
4. A waste-water disposal system meeting the competent authority's requirements is required for all processing plants.
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 make the essential analysis and must be approved by the competent authority.

## CHAPTER II

**General conditions of hygiene**

1. Animal by-products must be processed as soon as possible after arrival. They must be stored properly until processed.
2. Containers, recipients and vehicles used for the transport of animal by-products must be cleaned, washed and disinfected after each use. Containers, recipients and vehicles used for transporting unprocessed material shall be cleaned in a designated area. This area shall be situated or designed to prevent the risk of contamination of processed products.

3. Persons working in the unclean section must not enter the clean section without changing their working clothes and footwear or without disinfecting the latter. Equipment and utensils shall not be taken from the unclean section into the clean section. Personnel movement procedures shall 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 section must be treated to ensure that no pathogens remain.

The Commission shall lay down requirements for the treatment of waste water from processing plants in accordance with 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 program shall be used for that purpose.
6. Cleaning procedures shall be documented and established for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
7. Hygiene control should include regular inspections of the environment and equipment. Inspection schedules and results shall be documented.
8. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.
9. The processed animal by-products must be handled and stored at the processing plant in such a way as to preclude recontamination.

### CHAPTER III

#### **Processing methods**

##### Method 1

#### ***Continuous or batch pressure***

##### *Reduction*

1. If the particle size of the animal by-products to be processed is more than 50 millimetres, the animal by-products shall 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 shall be checked daily and its condition recorded. If checks disclose the existence of particles larger than 50 millimetres, the process shall be stopped and repairs made before the process is resumed.

##### *Time, temperature and pressure*

2. After reduction, the animal by-products shall 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

#### ***Natural fat batch***

##### *Reduction*

1. If the particle size of the animal by-products to be processed is more than 150 millimetres, the animal by-products shall 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 shall be checked daily and its condition recorded. If checks disclose the existence of particles larger than 150 millimetres, the process shall be stopped and repairs made before the process is resumed.

##### *Time, temperature and pressure*

2. After reduction, the animal by-products shall 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.

3. The processing shall be carried out in a batch system.
4. The animal by-products may be cooked such that the time-temperature requirements are achieved at the same time.

#### Method 3

##### **Natural fat batch — Continuous or batch**

###### *Reduction*

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products shall 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 shall be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process shall be stopped and repairs made before the process is resumed.

###### *Time, temperature and pressure*

2. After reduction, the animal by-products shall 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 such that the time-temperature requirements are achieved at the same time.

#### Method 4

##### **Added fat — Continuous or batch**

###### *Reduction*

1. If the particle size of the animal by-products to be processed is more than 30 millimetres, the animal by-products shall 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 shall be checked daily and its condition recorded. If checks disclose the existence of particles larger than 30 millimetres, the process shall be stopped and repairs made before the process is resumed.

###### *Time, temperature and pressure*

2. After reduction, the animal by-products shall 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 and a core temperature greater than 120 °C for at least 8 minutes and a core temperature greater than 130 °C for at least 3 minutes.
3. The processing may be carried out in batch or continuous systems.
4. The animal by-products may be cooked such that the time-temperature requirements are achieved at the same time.

#### Method 5

##### **Defatted — Continuous or batch**

###### *Reduction*

1. If the particle size of the animal by-products to be processed is more than 20 millimetres, the animal by-products shall 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 shall be checked daily and its condition recorded. If checks disclose the existence of particles larger than 20 millimetres, the process shall be stopped and repairs made before the process is resumed.

###### *Time, temperature and pressure*

2. After reduction, the animal by-products shall be heated until they coagulate and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material shall be then 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.
4. The animal by-products may be cooked such that the time-temperature requirements are achieved at the same time.

#### Method 6

##### **(For animal by-products of fish origin only) Combined acidification and heat treatment**

1. The animal by-products shall be reduced to . . . millimetres. They shall then be mixed with formic acid to reduce the pH to . . . The mixture shall be stored for . . . hours pending new treatment.
2. The mixture shall then be introduced into a heat converter and shall be heated to a core temperature of . . . °C for at least . . . minutes. The progression of the product through the heat converter is 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 shall be separated into liquid, fat and greaves by mechanical means. In order to obtain processed animal protein concentrate, the liquid phase is 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 are reincorporated in the protein concentrate before storage.

#### Method 7

Any processing method approved by the competent authority where it has been demonstrated to the competent 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:

1. Samples of material taken directly after heat treatment:
  - *Clostridium perfringens* absent in 1 g of the products
2. 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 = 3 X 10<sup>2</sup> in 1 g

Where

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

Details of the critical control points under which each processing plant satisfactorily complies with the microbiological standards shall be recorded and maintained so that the owner, operator or his representative and the competent authority can monitor the operation of the processing plant. The information to be recorded and monitored shall include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed-rate and fat recycling rate.

This information shall be made available to the Commission on request.

## CHAPTER IV

### **Supervision of production**

1. Processing plants shall be subject to supervision by the competent authority, which must ensure that the requirements of this Regulation are met and in particular:
  - (a) check:
    - (i) the general conditions of hygiene of the premises, equipment and staff;

- (ii) the efficacy of the own checks carried out by the plant, in accordance with Article 22, notably by examining the results and taking samples;
  - (iii) the standards of the products after processing. The analyses and tests shall be carried out in accordance with methods which are scientifically recognised, and in particular those laid down in Community provisions or, where none exist, in recognised international standards;
  - (iv) the storage and transport conditions;
- (b) take any samples required for laboratory tests;
- (c) make any other checks it considers necessary to ensure compliance with this Regulation.
2. The competent authority must have free access at all times to all parts of the processing plant and to the records and commercial documents or health certificate in order to ensure that this Regulation is being strictly complied with.

#### CHAPTER V

##### Validation procedures

The processing plant must be validated by the competent authority in accordance with the following procedures which shall take into account at least the following 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 system;
- (c) Compliance with the specific process requirements laid down by this Regulation;
- (d) Achievement of the following requirements:
  - Particle size for batch-pressure and continuous processes. The particle size is defined by the mincer hole or the anvil gap size
  - Temperature, pressure, processing time and material processing rate (for continuous system only):
    - I. batch pressure system:
      - the temperature must be monitored with a permanent thermocouple and it must be plotted against real time;
      - the pressure stage must be monitored with a permanent pressure gauge. Pressure must be plotted against real time;
      - the processing time must be shown by time/temperature and time/pressure diagrams.
    - At least once a year the thermocouple and the pressure gauge must be calibrated.
    - II. continuous pressure system:
      - the temperature and the pressure must be monitored with thermocouples, or an infrared temperature gun, and pressure gauges used at defined positions throughout the process system in such a way that temperature and pressure comply with the required conditions inside the whole continuous system or in a section of it. The temperature and pressure must be plotted against real time;
      - measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the required conditions, must be provided to the competent authorities, using insoluble markers (i.e. manganese dioxide) or a method which offers equivalent guarantees. Accurate measurement and control of the material process rate is essential and must be measured during the validation test in relation to a CCP that can be continuously monitored such as:
        - feed-screw revolutions per minute (rev/min), or

- electric power (amps at given voltage), or
- evaporation/condensation rate, or
- number of pump strokes per unit time.

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

The validation procedures shall be repeated periodically or when it is considered necessary by the competent authority and in any case each time any significant alterations are made to the process (i.e. modification of the machinery, change of raw materials etc.).

The Commission shall lay down validation procedures based on testing method in accordance with the procedure referred to in Article 33(2).

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#### ANNEX IV

### HYGIENE REQUIREMENTS FOR PROCESSING AND DISPOSAL OF ANIMAL BY-PRODUCTS DESTINED FOR BIOGAS OR COMPOSTING PLANT OR FOR AN OLEO-CHEMICAL PLANT

#### CHAPTER I

##### **Special conditions for the processing of Category 1 or Category 2 material**

##### **Requirement for the approval of Category 1 or Category 2 processing plants**

In addition to the general requirements laid down in Annex III,

1. Premises for the processing of Category 1 material must not be at the same site as premises processing Category 2 material, unless in a completely separate part of a building.
2. By way of derogation from the above paragraph, Member States may allow that the premises of a Category 2 processing plant are
  - (i) temporarily used for the processing of Category 1 material where a wide-spread epizootic disease leads to a lack of capacity at the Category 1 processing plant; or
  - (ii) permanently used for the processing of Category 1 material where the additional capacity necessary in order to authorise plant for specific purposes does not exist,

only under the following conditions:

    - the plant must be under permanent official supervision;
    - all unloading, processing, storage or other handling of Category 1 material must take place under official supervision;
    - Category 1 material must be stored in a completely separate room or separate reception area;
    - Category 1 material must be processed in separate rooms using separate installations and equipment, except where
      - (i) the processing takes place in completely enclosed installations or equipment used exclusively for this purpose; or
      - (ii) the batch of Category 2 material processed immediately following the processing of Category 1 material shall be deemed as Category 1 material;
    - the processed Category 1 material must be stored in a different room or separate tanks which are labelled appropriately. The room or the separate tanks must be kept locked under seal of the competent authority when the latter is not present;
    - Category 2 processing plants which have been temporarily or permanently processing Category 1 material must undergo a thorough regime of cleansing and disinfection as agreed by the competent authority before processing material of a higher health category.

*Processing standards*

3. Animal by-products, other than rendered fats derived from Category 2 material and destined for an oleo-chemical plant, must be processed in accordance with
  - Processing method 1, in case of Category 2 material, other than manure and digestive tract content from mammalian species, destined for biogas or composting plants or intended to be used as organic fertilisers or soil improvers, and Category 1 and Category 2 material destined for landfill
  - Any of the processing methods listed in Annex III, Chapter III, in case of Category 1 or Category 2 material destined for incineration or co-incineration.

*Requirements of the products after processing*

4. After processing, the products must be permanently coloured or marked using a system approved by the competent authority. The Commission shall establish detailed rules of the system referred to in the above paragraph in accordance with the procedure referred to in Article 33(2).
5. Samples of processed animal by-products destined for bio-gas or composting plant or for landfill or intended to be used as organic fertilisers or soil improvers, 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

**Special requirements for biogas and composting plant**A. *Requirements for approval of biogas and composting plant handling animal by-products*

1. Biogas plant must be equipped with:
  - (a) a pasteurization/hygienisation unit, which cannot be by-passed, in which the processed Category 2 material or the unprocessed Category 3 material are heat treated before entering the biogas reactor. This unit must have:
    - installations for monitoring temperature against time,
    - recording devices to record continuously the results of these measurements,
    - an adequate safety system to prevent insufficient heating,
  - (b) adequate facilities for cleaning and disinfecting of vehicles and containers upon leaving the biogas plant.
2. Composting plant must be equipped with:
  - (a) a closed composting reactor which must have:
    - installations for monitoring temperature against time,
    - recording devices to record continuously the results of these measurements,
    - an adequate safety system to prevent insufficient heating;
  - (b) adequate facilities for cleaning and disinfecting of vehicles and containers transporting untreated animal by-products.
3. Biogas plants and composting plants must have their own laboratory or make use of the services of a laboratory equipped to make the essential analyses.

B. *Special conditions of hygiene*

1. Only Category 2 material which has undergone processing method 1 in a Category 2 processing plant and Category 3 material may be transformed in a biogas plant or in a composting plant.
2. Animal by-products referred to in paragraph 1 must be transformed as soon as possible after arrival. They must be stored properly until treated.

3. Containers, recipients and vehicles used for the transport of animal by-products must be cleaned, washed and disinfected after each use. Containers, recipients and vehicles used for transporting untreated material shall be cleaned in a designated area. This area shall be situated or designed to prevent risk of contamination of treated products.
  4. Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest control program shall be used for that purpose.
  5. Cleaning procedures shall be documented and established for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
  6. Hygiene control should include regular inspections of the environment and equipment. Inspection schedules and results shall be documented.
  7. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.
  8. Digestion residues must be handled and stored at the plant in such a way as to preclude recontamination.
- C. *Heat-treatment conditions*
1. Animal by-products used as raw material in a biogas plant must be submitted to the following minimum requirements:
    - (a) maximum particle size before entering the pasteurization unit: 12 mm
    - (b) minimum temperature in all material in the pasteurization unit: 70 °C
    - (c) minimum time in the pasteurization unit without interruption: 60 minutes.
  2. Animal by-products 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
    - (c) minimum time in the reactor at 70 °C (all material): 60 minutes.

D. *Requirements concerning the digestion residues and compost*

Samples of the digestion residues or compost taken during or upon 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 = 3 X 10<sup>2</sup> in 1 g

Where

n = number of units comprising the sample

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

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

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

Chapter III

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

1. Transesterification or hydrolysis at at least: 200 °C, under corresponding appropriate pressure for 20 minutes (glycerol, fatty acids and esters).
2. Saponification with NaOH 12M (glycerol and soap):
  - in a batch process: at 95 °C for three hours;
  - or
  - in a continuous process: at 140 °C, 2 bars (2 000 hPa) for eight minutes or equivalent conditions.

## ANNEX V

**SPECIFIC CONDITIONS FOR PLACING ON THE MARKET AND IMPORTATION OF PROCESSED ANIMAL PROTEIN AND OTHER FEED MATERIAL**

## CHAPTER I

**General requirements***Requirements for approval of processing plants*

In addition to the general requirements laid down in Annex III:

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 part of a building.
2. By way of derogation from the above paragraph, Member States may allow that the premises of a Category 3 processing plant are
  - (i) temporarily used for the processing of Category 1 or Category 2 material where a wide-spread epizootic disease leads to a lack of capacity at the Category 1 or Category 2 processing plant; or
  - (ii) permanently used for the processing of Category 1 or Category 2 material where the additional capacity necessary in order to authorise plant for specific purposes does not exist.

Only under the following conditions:

- the plant must be under permanent official supervision;
  - all unloading, processing, storage or other handling of Category 1 or Category 2 material must take place under official supervision;
  - Category 1 or Category 2 material must be stored in a completely separate room or separate reception area;
  - Category 1 or Category 2 material must be processed in separate rooms using separate installations and equipment, except where the processing takes place in completely enclosed installations or equipment used exclusively for this purpose;
  - the processed Category 1 or Category 2 material must be stored in a different room or separate tanks which are labelled appropriately and must not go for animal consumption. The room or the separate tanks must be kept locked under seal of the competent authority when the latter is not present;
  - Category 3 processing plants which have been temporarily or permanently processing Category 1 or Category 2 material must undergo a thorough regime of cleansing and disinfection as agreed by the competent authority before processing material of a higher health category.
3. Category 3 processing plants shall have:
    - (a) an installation to check the presence of extraneous matter, such as packaging material, metallic pieces, etc., in the unprocessed animal by-products;
    - (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.

*Special conditions of hygiene for processing plants***Raw material reception**

4. Only Category 3 material listed in points (a) to (l) of Article 6 can be used for the production of processed animal proteins and other feed material;
5. Before processing, animal by-products shall be checked for the presence of extraneous matter. When present these must be removed.

#### Heat-treatment 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 III Chapter III. The critical control points may include:
  - Raw material particle size
  - Temperature achieved in the heat-treatment process
  - Pressure applied to the raw material
  - Duration of the heat-treatment process or feed rate to a continuous system
  - Minimum process values shall be specified for each applicable critical control point.
7. Records shall be maintained to show that the minimum process values for each critical control point are applied.
8. Accurately calibrated temperature gauges/recorders shall be used to monitor continuously the processing conditions. Records shall be kept to show the date of calibration of temperature gauges/recorders.
9. Material that may not have received the specified heat treatment (i.e. material discharged at start up, or leakage from cookers), shall be re-circulated through the heat treatment or shall be collected and reprocessed.

#### Requirements concerning the products after processing

10. Samples of the final products taken during or upon 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*:  $n = 5$ ,  $c = 2$ ,  $m = 10$ ,  $M = 3 \times 10^2$  in 1 g

Where

$n$  = number of units comprising the sample

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

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

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

## CHAPTER II

### Special conditions for processed animal protein

In addition to the conditions of Chapter I, the following conditions apply:

#### Processing standards

1. Mammalian processed animal protein, with the exclusion of blood meal, must have been submitted to the processing method 1.
2. Blood meal and non mammalian processed animal protein, with the exclusion of fishmeal, must have been submitted to any of the processing methods listed in Annex III, Chapter III.
3. Fishmeal must have been submitted to
  - (i) any of the processing methods listed in Annex III, Chapter III; or
  - (ii) a method and parameters which ensure that the processed products comply with the microbiological standards set in Chapter I(10) of this Annex.

*Storage and dispatch of processed animal proteins*

4. Processed animal protein shall be packed and stored in new or sterilised bags or shall be stored in properly constructed bulk bins.
5. Adequate measures shall be taken to minimise condensation inside bins, conveyors or elevators.
6. Products in conveyors, elevators and bins shall be protected from casual contamination.
7. Processed animal protein handling equipment shall 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 shall be emptied and cleaned regularly, as production requirements require.
8. Processed animal protein must be kept dry. Leakages and condensation in the storage area shall be prevented.
9. Processed animal protein shall be dispatched in sealed new bags or in covered bulk containers or vehicles.
10. Every vehicle must be checked and must be clean and dry before it is loaded.

*Importation of processed animal protein*

11. Member States shall authorise the importation of processed animal protein only if:
  - It comes from third countries which appear on the list in Part II of Annex XI or, in the case of fishmeal, which appear on the list in Part III of Annex XI;
  - It comes from a processing plant which appears on the list referred to in Article 29(3);
  - It has been produced in accordance with this Regulation;
  - It is accompanied by a health certificate as laid down in Chapter 1 of Annex X.
12. For release for free circulation in Community territory of consignments of processed animal protein, imports of processed animal protein are subject to sampling by the competent authority at the border inspection post of
  - (i) each consignment of products submitted in bulk;
  - (ii) random consignments of products packaged in the manufacturing plant of origin.
13. Member States may carry out random sampling of bulk consignments origination from a third countries from which the last six consecutive tests have proved negative. Where during one of these checks a result has proved positive, the competent authority of the country of origin must be informed so that it can take appropriate measures to remedy the situation. These measures must be brought to the attention of the competent authority for the import checks. In the event of a further positive result from the same source, further tests must be carried out on all consignments from the same source until the requirements laid down in the first sentence are again satisfied.
14. Member States must keep a record of the results of sampling carried out on all consignments which have undergone sampling.
15. Where a consignment proves to be positive for salmonella, it is either:
  - (a) re-exported from the Community;
  - (b) reprocessed in a processing plant approved pursuant to this Regulation or decontaminated by treatments permitted under Community legislation. The consignment shall not be released until it has been treated, tested for salmonella by the competent authority in accordance with Chapter I(10) of this Annex and a negative result has been obtained.

## CHAPTER III

**Special conditions for blood products**

In addition to the conditions of Chapter I, the following conditions apply:

1. Only blood referred to in points (a) and (b) of Article 6 can be used for the production of blood products;
2. Blood products must have been submitted to
  - (i) any of the processing methods listed in Annex III, Chapter III; or
  - (ii) a method and parameters which ensure that the processed product comply with the microbiological standards set in Chapter I(10) of this Annex.

*Importation of processed blood products*

3. Member States shall authorise the importation of blood products only if:
  - they come from third countries which appear on the list of Part V of Annex X;
  - they come from a processing plant which appears on the list referred to in Article 29(3);
  - they have been produced in accordance with this Regulation;
  - they are accompanied by an health certificate as provided for in Article 29(5).

## CHAPTER IV

**Special conditions for rendered fats and fish oil**

In addition to the conditions of Chapter I, the following conditions apply:

1. 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.

*Importation of rendered fats*

2. Member States shall authorise the importation into the Community of rendered fats only if:
    - they come from third countries appearing on the list of Part IV of Annex XI;
    - they come from a processing plant which appears on the list referred to in Article 29(3);
    - they have been produced in accordance with this Regulation, and:
      - (a) where it is entirely or partly derived from swine raw material, comes from a country or a part of the territory of a country free of foot-and-mouth disease from the previous twenty-four months and free of classical swine fever, African swine fever for the previous twelve months,
      - (b) where it is entirely or partly derived from poultry raw material comes from a country or a part of the territory of a country free of Newcastle disease and avian influenza for the previous 6 months,
      - (c) where it is entirely or partly derived from ruminant raw material, Comes from a country or a part of the territory of a country free of foot-and-mouth disease from the previous twenty-four months and free of Rinderpest for the previous twelve months,
- or
- (d) where there has been an outbreak of one of the above mentioned diseases during the relevant period mentioned above, has been subjected to one of the following heat treatment processes:
    - (i) at least 70 °C for at least 30 minutes, or

(ii) 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 his representative and, as necessary, the competent authority can monitor the operation of the plant. The information shall include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed-rate and fat recycling rate;

— they are accompanied by an health certificate as as provided for in Article 29(5).

#### *Importation of fish oil*

3. Member States shall authorise the importation into the Community of fish oil only if:

— it comes from third countries appearing on the list of Part III of Annex XI;

— it comes from a processing plant which appears on the list referred to in Article 29(3);

— it has been produced in accordance with this Regulation;

— it is accompanied by a health certificate as provided for in Article 29(5).

4. Where the rendered fat or the fish oil are packaged, they have been packed in new containers or in containers that have been cleaned, and all precautions have been taken to prevent their 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 establishments have been inspected and found to be clean before use.

## CHAPTER V

### **Special conditions for milk, milk-based products and colostrum**

In addition to the conditions of Chapter I, the following conditions apply:

1. Raw milk and colostrum must be produced under conditions offering adequate guarantees as regard animal health. Such conditions must 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 72 °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:

(i) in case of dried milk or dried milk products, a drying process;

(ii) 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 6,0;

3. In addition to the requirements laid down in paragraph 2, dried milk or dried milk products must meet the following requirements:

(i) after completion of the drying process, every precaution must be taken to prevent contamination of the products;

(ii) the final product must be packed in new containers;

4. In the case of bulk containers, before the milk, milk product or colostrum is loaded into any vehicles or container for conveyance to its destination, the said vehicle or container must be disinfected using a product approved by the competent authority.

#### *Importation of milk and milk-based products*

5. Member States shall authorise the imports of milk and milk-based products only if:

— they come from third countries appearing on the list of Part I of Annex XI, and

- (a) 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 if they have undergone a pasteurisation treatment sufficient to produce a negative phosphatase test and are accompanied by a copy of the health certificate laid down in Chapter 2(A) of Annex X;
  - (b) 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 if they have first undergone a pasteurization treatment sufficient to produce a negative phosphatase test and are accompanied by a copy of the health certificate laid down in Chapter 2(B) of Annex X;
  - (c) 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 if 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 are accompanied by a copy of the health certificate laid down in Chapter 2(C) of Annex X;
- they come from a processing plant which appears on the list referred to in Article 29(3).
6. Milk and milk based products from third countries or parts of third countries listed in column C of the Annex to Decision 95/304/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 practised in the last 12 months must, before introduction onto Community territory, have undergone
- either:
- (i) a sterilisation process whereby a  $F_0$  value equal to or greater than 3 is achieved; or
  - (ii) 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:
    - 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
    - an acidification process such that the pH has been maintained at less than 6 for at least one hour.
7. 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

### Special conditions for gelatine and hydrolysed protein

In addition to the conditions of Chapter I, the following conditions apply:

#### A. *Gelatine*

1. Gelatine must be produced by a process which ensure 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. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.
  - After having been subjected to the processes referred to in paragraph 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
  - The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.

2. Gelatine must be wrapped, packaged, stored and transported under satisfactory hygiene conditions, in particular:

- a room must be provided for storing, wrapping and packaging materials,
- wrapping and packaging must take place in a room or in a place intended for that purpose,
- wrappings and packages containing gelatine must carry the words 'Gelatine for animal consumption'.

*B. Hydrolysed protein*

3. Hydrolysed protein must be produced by a production process which involves appropriate measures to minimise contamination of raw Category 3 material, preparation of the raw Category 3 material by brining, liming and intensive washing followed by

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

*Importation of gelatine and hydrolysed protein*

4. Member States shall authorise the importation of gelatine only if:

- it comes from third countries which appear on the list of Part XI of Annex X;
- it comes from a processing plant which appears on the list referred to in Article 29(3);
- it has been produced in accordance with this Regulation;
- it is accompanied by an health certificate as provided for in Article 29(5).

5. Member States shall authorise the importation of hydrolysed proteins only if:

- they come from third countries which appear on the list of Part XI of Annex X;
- they come from a processing plant which appears on the list referred to in Article 29(3);
- they have been produced in accordance with this Regulation;
- they are accompanied by an health certificate as provided for in Article 29(5).

## CHAPTER VII

### **Special conditions for dicalcium phosphate**

1. Dicalcium phosphate must be produced by a process which 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 pH < 1,5) over a period of at least two days followed by a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7, which is finally air dried for 15 minutes with inlet temperature of 270-325 °C and end temperature between 60-65 °C or by an equivalent process approved in accordance with the procedure referred to in Article 33(2).

*Importation of dicalcium phosphate*

2. Member States shall authorise the importation of dicalcium phosphate only if:

- it comes from third countries which appear on the list of Part XI of Annex X;
- it comes from a processing plant which appears on the list referred to in Article 29(3);
- it has been produced in accordance with this Regulation;
- it is accompanied by an health certificate as provided for in Article 29(5).

## ANNEX VI

**SPECIAL CONDITIONS FOR PLACING ON THE MARKET, TRADE AND IMPORTATION OF PETFOOD, DOGCHEW AND TECHNICAL PRODUCTS**

## CHAPTER I

**General conditions for approval of petfood and technical plants**

Establishments producing petfood, dogchews and technical products must fulfil the following requirements:

- (a) they must have adequate facilities for storing and treating incoming material in complete safety;
- (b) they must have adequate facilities for disposing of, in accordance with this Regulation, unused unprocessed animal by-products remaining after the production of the products, or must send it to a processing plant or to an incinerator or co-incineration plant in accordance with this Regulation.

## CHAPTER II

**Petfood and dogchews**

Petfood and dogchews must satisfy the following requirements:

- (a) the ingredients of animal origin from which the petfood is manufactured are animal by-products referred to in points (a) to (l) of Article 6 only;
- (b) canned petfood shall be subjected to heat treatment to a minimum  $F_c$  value of 3,0;
- (c) processed 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;
- (d) 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;
- (e) raw petfood
  - must be manufactured only from animal by-products listed in point (a) of Article 6 derived from animals slaughtered in an EC approved slaughterhouse;
  - the final product was packed in new packaging preventing any leakage;
  - effective steps must be taken to ensure that the product is not exposed to contamination through all the production chain up to the point of sale;
  - the wording 'petfood only' must be visibly and legibly displayed on the packaging;
- (f) must be examined by random samples taken along production and/or during storage (before dispatching) to verify its compliance with the following standards:

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

*Importation of petfood and dogchews*

Member States shall authorise importation of petfood and dogchew only if:

- they comes from third countries which appear on the list of Part X of Annex XI;
- they comes from petfood plants approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;
- they has been produced in accordance with this Regulation;

- they are accompanied
  - (a) in case of canned petfood, by the certificate that conforms to the model laid down in Chapter 3(A) of Annex X;
  - (b) in case of processed petfood, by the certificate that conforms to the model laid down in Chapter 3(B) of Annex X;
  - (c) in case of dogchews, by the certificate that conforms to the model laid down in Chapter 3(C) of Annex X;
  - (d) in case of raw petfood, by the certificate that conforms to the model laid down in Chapter 3(D) of Annex X.

### CHAPTER III

#### **Manure, processed manure and processed manure products**

##### *I. Unprocessed manure*

###### **Trade in unprocessed manure**

1. (a) The trade of unprocessed manure of species other than poultry or equidae is prohibited, except for manure:
  - from an area which is not subjected to restrictions by virtue of a serious transmissible disease, and
  - intended for spreading, under the supervision of the competent authorities, on land forming part of a single holding located on both sides of the frontier of two Member States.

- (b) However, in derogation to (a), Member States may grant specific approval for the introduction onto its territory of:

- manure intended for processing in a technical plant or a biogas plant or in a composting plant approved by the competent authorities in accordance with this Regulation with a view to manufacture of the products referred to under II below. When such plants are being approved, account is to be taken of the origin of the manure, or
- manure intended for spreading 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 giving consent, account is to be taken in particular of the origin of the manure, its destination and animal health and safety considerations.

In such cases the manure is to be accompanied by a health certificate that conforms to the model laid down in accordance with the procedure referred to in Article 33(2).

2. Trade of 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 Newcastle disease non-vaccinating status pursuant to Article 12(2) of Directive 90/539/EEC;
- (c) the manure is to be accompanied by a health certificate that conforms to the model laid down in accordance with the procedure referred to in Article 33(2).

3. Trade in unprocessed manure of equidae is not subject to any animal health conditions.

###### **Imports of unprocessed manure**

4. Member States shall authorise importation of unprocessed manure only if:

- it comes from third countries which appear on the list of Part IX of Annex XI;
- it satisfies, according to the species concerned, the requirements under (1)(a) above;
- it is accompanied by a health certificate as provided for in Article 29(c).

##### *II. Processed manure and processed manure products*

5. 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 or a biogas plant or a composting plant approved by the competent authorities in accordance with this Regulation;
- (b) they must have been subjected to a heat-treatment processes of at least 70 °C for at least 60 minutes;
- (c) they must:
  - be free from salmonella (no salmonella in 25 g treated product)

- be free from *enterobacteriaceae* (based on the aerobic bacteria count: < 1 000 cfu per gram of treated products),
  - have been subjected to reduction in spore-forming bacteria and toxic formation;
- (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:

- well-sealed and insulated silos, or
- properly sealed packs (plastic bags or 'big bags').

#### Importation of processed manure and processed manure products

6. Member States shall authorise importation of processed manure and processed manure products only if:

- they come from third countries which appear on the list of Part IX of Annex XI;
- they come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;
- they satisfy the requirements under 5 above;
- they are accompanied by a health certificate as provided for in Article 29(5).

#### III. Guano

7. Marketing of 'guano' is not subject to any animal health conditions.

### CHAPTER IV

#### **Blood and blood products used for technical or pharmaceutical purpose, *in vitro* diagnosis or laboratory agents, 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 conditions laid down in Article 18 of this Regulation.

##### B. Importation of blood and blood products used for technical or pharmaceutical purpose, *in vitro* diagnosis or laboratory agents, excluding serum of equidae

2. Imports of blood are subject to the conditions laid down in Chapter XI to this Annex.

3. Member States shall authorise importation of blood products only if:

- they come from third countries which appear on the list of Part VI of Annex XI;
- they 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

- in the case of blood products derived from bovine animals, they originate in an area of a third countries fulfilling the conditions set out in the first indent 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 countries and must have been collected:

(i) in slaughterhouses approved in accordance with Community legislation,

or

(ii) in slaughterhouses approved and supervised by the competent authorities of the third country. The Commission and Member States must be notified of the address and approval number of such slaughterhouse or it must be indicated in the certificate.

or

— in the case of blood products derived from bovine animals, they have undergone one of the following treatment guaranteeing the absence of pathogens of the bovine diseases referred to in the first indent:

- (i) heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,
- (ii) irradiation at 2,5 magarads or by gamma rays, followed by an effectiveness check,
- (iii) change in pH to pH 5 for two hours, followed by an effectiveness check,
- (iv) heat treatment of at least 90 °C throughout their substance, followed by an effectiveness check,
- (v) any other treatment provided for in accordance with the procedure referred to in Article 33(2),

or

— in the case of blood products derived from bovine animals, they fulfil the conditions laid down in Chapter X of this Annex. In such cases, the packaging may not be opened during storage and the processing undertaking must carry out one of the treatment listed in the above indent;

and

— they comes from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation; and

— they are accompanied by a health certificate as provided for in Article 29(5).

4. The specific conditions relating to imports of products for use in *in vitro* diagnosis and laboratory reagents shall be established, where necessary, in accordance with the procedure referred to in Article 33(2).

## CHAPTER V

### Serum of equidae

1. Serum must come from equidae which show none of the serious transmissible diseases referred to in Directive 90/426/EEC or if the serious transmissible diseases to which equidae are susceptible and have been obtained in bodies or centres not subject to health restrictions pursuant to that Directive.

#### *Importation of serum of equidae*

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

- it comes from equidae born and raised in a third country from which the importation of horses for slaughter is authorised;
- it was obtained, processed and dispatched in conformity with the following conditions:
  - (a) it comes from a country where the following diseases are compulsory notifiable: African horse sickness, dourine, glanders, equine encephalomyelitis (all types including VEE), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;
  - (b) 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;
  - (c) it was obtained from equidae, which 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:
    - (i) venezuelan equine encephalomyelitis has not occurred during the last two years;
    - (ii) dourine has not occurred during the last six months;
    - (iii) glanders has not occurred during the last six months;
  - (d) it was obtained from equidae, which, at the moment of collection, did not come from a holding and have not been present on a holding which was subject to prohibition for animal health reasons:
    - (i) within the previous six months in the case of equine encephalomyelitis, beginning on the date on which the equidae suffering from the disease are slaughtered;
    - (ii) in the case of infectious anaemia, until the date on which, the infected animals having been slaughtered, the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart;
    - (iii) within the previous six months in the case of vesicular stomatitis;

(iv) within the previous 15 days of the last recorded case, in the case of anthrax.

If all the animals of species susceptible to the disease located on the holding have been slaughtered and premises disinfected, the period of prohibition shall be 30 days, beginning on the day on which the animals were destroyed and the premises disinfected, except in the case of anthrax, where the period of prohibition is 15 days;

- (e) it has undergone all precautions to avoid contamination with pathogenic agents during production, handling and packaging;
  - (f) it was packed in sealed impermeable containers clearly labelled 'serum from equidae' and bearing the registration number of the establishment of collection.
- they come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;
- It is accompanied by an health certificate as laid down in Chapter 4 of Annex X.

#### CHAPTER VI

##### **Hides and skins of ungulates**

1. The provisions of this chapter shall not apply to:

- Hides and skins of ungulates fulfilling the requirements of Directive 64/433/EEC;
- Hides and skins of ungulates having undergone the complete process of tanning,
- 'wet blue',
- 'pickled pelts',
- 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 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 which have been:

- dried, or
- dry-salted or wet-salted for at least 14 days prior to dispatch, or
- salted for seven days in sea salt with the addition of sodium carbonate to 2 %, or
- drying for 42 days at a temperature of at least 20 °C, or
- preserved by a process other than tanning, to be determined in accordance with the procedure referred to in Article 33(2).

##### *Trade*

3. Trade in fresh or chilled hides and skins are subjected to the same health conditions as those applicable to fresh meat pursuant Directive 72/461/EEC.
4. Trade in treated hides and skins is authorised on condition that each consignment is accompanied by the commercial document as provided for in Annex II attesting that:
- (i) the hides and skins have been treated in accordance with point 2, and
  - (ii) the consignments has not been in contact with other animal products or live animals presenting a risk of spreading a serious transmissible disease.

##### *Importation of hides and skins*

5. Member States shall authorise the import of fresh or chilled hides and skins if:

- (a) they have been obtained from animals which have been slaughtered in a slaughterhouse and
- (b) they originate from third countries or in 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 for at least 12 months before dispatch has been free from the following diseases:
  - classical swine fever

- African swine fever
- rinderpest

and which 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;

(c) have been obtained from:

- animals which 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,
- in the case of hides and skins from bi-ungulates, animals 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,
- in the case of hides and skins from swine, animals which 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 disease for 30 days,
- animals which 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

(e) they are accompanied by an animal health certificate as laid down in Chapter 5(A) of Annex X.

6. Member States shall authorise the import of treated hides and skins if:

- (a) they are accompanied by an animal health certificate as laid down in Chapter 5(B) of Annex X;
- (b) either the hides and skins come from animals originating in a region of a third country or in a third country not subject, pursuant to Community regulations, 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 point 2

or

the hides and skins come from animals originating from other regions of a third country or other third countries and they have been treated in accordance with point 2, third and fourth indents

or

the hides and skins come from ruminant animals and have been treated in accordance with point 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 point 6(a) is replaced by a declaration laid down in Chapter 5(C) of Annex X, to the effect that or proving that those requirements have been met;

- (c) 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
- (d) 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, trucks, trainwagons or bales sealed by the competent authority of third country of dispatch.

## CHAPTER VII

### Game trophies

1. Without prejudice to the measures adopted pursuant to Regulation (EEC) 3626/82, game trophies:

- (i) of ungulates and birds having undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures;
- (ii) of species other than ungulates and birds;

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

2. Without prejudice to the measures adopted pursuant to Regulation (EEC) 3626/82, game trophies of ungulates and birds not having undergone the treatment mentioned in (i) shall be subject to the following conditions:

- 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

- comply with the conditions laid down in (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:
- 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,
  - have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned,
  - 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,
  - be accompanied by a document or certificate certifying that the above conditions have been met.
4. In respect of game trophies consisting solely of hide or skin, the trophies must
- 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 to be fixed according to the procedure referred to in Article 33(2);
  - 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,
  - be accompanied by a document or certificate certifying that the above conditions have been met.

*Importation of game trophies*

5. Member States shall 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 only if:
- they are accompanied by a certificate/document as laid down in Chapter 6(A) of Annex X, and
  - in the case of dry-salted or wet-salted skins transported by ship, the skins have been salted a minimum of 14 days before importation.
6. Member States shall 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 appearing on the list of Commission Decision 94/86/EC from which the importation of all categories of fresh meat of the corresponding species is authorised if they are accompanied by a veterinary certificate as laid down in Chapter 6(B) of Annex X.

CHAPTER VIII

**Unprocessed wool, hair, pig bristles, feathers and parts of feathers**

1. Unprocessed wool, hair, pig bristles, feathers and parts of feathers (the goods) must be securely enclosed in packaging and dry. However, movements of pig bristles from regions in which African swine fever is endemic are prohibited except for pig bristles which:
- (a) have been boiled, dyed or bleached; or
  - (b) have 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 shall not be regarded as a form of treatment for the purposes of this provision.

2. The provisions of the above paragraph shall 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.

*Importation of pig bristles*

3. Member States shall authorise the importation of pig bristles from third countries or, in case of regionalisation according to Community legislation, regions thereof, where no cases of African swine fever has occurred during the previous 12 months, and if the a consignment is accompanied by an animal health certificate as laid down in Chapter 7(A) of Annex X.
4. Member States shall authorise the importation of pig bristles from third countries or, in case of regionalisation according to Community legislation, regions thereof, where one or more cases of African swine fever has occurred during the previous 12 months, if the a consignment is accompanied by an animal health certificate as laid down in Chapter 7(B) of Annex X.
5. Member States shall authorise the importation of unprocessed wool, hair, feathers and parts of feathers only if securely enclosed in packaging and dry.
6. Unprocessed wool, hair, bristles, feathers and parts of feathers must be sent directly to the plant of destination or to the intermediate storage plant in conditions such that any spread of pathogenic agents is avoided.

CHAPTER IX

**Apiculture products**

1. Apiculture products intended exclusively for use in apiculture:
  - (a) must not come from an area which is subject of a prohibition order associated with an occurrence of American foulbrood or acariosis, if, in the case of acariosis, the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/68/EEC;
  - (b) must meet the requirements imposed by Article 8(a) of Directive 92/65/EEC.

Any derogation must be established, as necessary, under the procedure referred to in Article 33(2).

*Importation of apiculture products*

2. Member States shall only authorise the importation of apiculture products intended for use in apiculture if the commercial document accompanying the consignment includes the following information and it is stamped by the competent authorities supervising the registered establishment of production:

- country of origin
- name of the establishment of production
- registration number of the establishment of production
- nature of the products.

'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.'

CHAPTER X

**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 different from animal consumption or fertilisers**

1. Member States shall 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) intended for further processing but not for any use in human or animal food or as fertilisers provided that:

- (i) the products are dried before export and not chilled or frozen;
  - (ii) the products are conveyed only by land and sea from their country of origin directly to a border inspection post in the Community and are not transhipped at any port or place outside the Community;
  - (iii) following the document checks provided for in Directive 97/78/EC, the products are conveyed directly to the manufactured plant.
2. Each consignment must be accompanied by
- (i) A commercial document stamped by the competent authority supervising the establishment of origin, including the following information:  
 Country of origin,  
 Name of the establishment of production,  
 Nature of the product (dried bone/dried bone product/dried horns/dried horn products/dried hooves/dried hoof products) which:
    - Were derived from healthy animals slaughtered in a slaughterhouse; or
    - Were dried for 42 days at an average temperature of at least 20 °C; or
    - Were heated for one hour to at least 80 °C to the core before drying; or
    - Were ashed for one hour to at least 80 °C to the core before drying; or
    - Have undergone an acidification process such that the pH has been maintained at less than six to the core for at least one hour before drying;
 And are not intended at any stage to be diverted for any use in human food or animal feed or fertilisers  
 And
  - (ii) by 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 OF DECLARATION

I, the undersigned, declare that the following products: bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) 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 human food or animal feed or as fertilisers and will be conveyed directly to the following proceeding 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 letter)

3. On dispatch to the Community territory, the material shall be enclosed in lead-sealed containers units or trucks or in bulk in a vessel. If transported in containers, the containers and in all case all the accompanying documents shall bear the name and the address of the processing establishments.
4. The material shall be transported direct to the processing establishment from the point of arrival in Community territory in containers or means of transports which are sealed.
5. On arrival in the territory of the Community and before dispatch of the material to the processing plant, notification of intended dispatch shall be made as quickly as possible to the local official veterinarian or competent authority by Animo message or, when this is not possible, by telex or telefax.
6. Records shall 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

##### **Unprocessed animal by-products for the manufacture of petfood and pharmaceutical or technical products**

Member States shall authorise the importation of unprocessed animal by-products intended for the manufacture of petfood, pharmaceutical or technical products only if:

- they come from third countries which appear on the list of Part VII of Annex XI;
- they are accompanied by a health certificate as laid down in Chapter 8 of Annex X;
- following the border check provided for in Directive 97/78/EC and in accordance with the rules laid down in Article 8(4) of that Directive, they are transported either
  - (i) directly to a petfood or technical plant which has given the guarantee that the unprocessed animal by-products will be used only for the permitted purpose and that they will not leave the plant untreated, or
  - (ii) to an intermediate animal by-products plant.

#### CHAPTER XII

##### **Rendered fats for oleo-chemical purpose**

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

- The product is conveyed only by land and sea from their country of origin direct to a border inspection post in the Community;
- Following the document checks provided for in Directive 97/78/EC and in accordance with the rules laid down in Article 8(4) of that Directive, the products are conveyed to the oleo-chemical plants where they will be processed;
- each consignment must be accompanied by a declaration from the importer that products imported under this paragraph will not be diverted for any other use than further processing by a method which at least meets the standards of one of the processes described in Annex IV, Chapter III.

This declaration must be presented to the official veterinarian at the border inspection post, at first point of entry of the goods into the Community and be annotated by him, and thereafter shall accompany the consignment up to the manufacturing plant.

---

ANNEX VII

HEALTH CERTIFICATE

For processed animal by-products intended to be incinerated or co-incinerated in another Member State

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

Member State of destination: .....

Member State of origin: .....

Responsible ministry: .....

Certifying department: .....

I. Identification of the consignment

Nature of packaging: .....

Number of packages: .....

Net weight: .....

II. Origin of the consignment

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

III. Destination of the consignment

The processed animal by-product will be sent

From: .....

(place of loading)

To: .....

(Country and place of destination)

By the following means of transport:

— Type .....

— Plate number or name of the vessel .....

Number of seal: .....

Name and address of consignor: .....

Name and address of consignee: .....

IV. Health attestation

I, the undersigned official veterinarian, certify that the product described above cannot be use for purposes other than incineration or co-incineration and it fulfil the conditions of Article 13 (B) (b) of Council and European Parliament Regulation .../EC.

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

(place)

(date)

Stamp (1)

(signature of the official veterinarian) (1)

(name, qualification and title, in capital letters)

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

## ANNEX VIII

**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;
  - (b) the plant must have a covered space to receive the 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, birds, etc.;
  - (f) the plant must have a waste water disposal system which meets hygiene requirements.
2. The plant must have adequate facilities for cleaning and disinfecting the containers or recipients in which the 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 conditions of hygiene***A. Category 3 intermediate plant*

1. The plant must have not other activities than importing, collecting, sorting, cutting, chilling, freezing into blocks, temporary storing and dispatching of Category 3 material;
2. The sorting of the Category 3 material must be done in way that any risk of introduction of animal diseases can be avoided;
3. All the time during sorting or storage, the Category 3 material must be handled and stored separately from other goods and in such a way as to prevent any propagation of epizootic diseases;
4. Category 3 material must be stored properly until re-dispatched;
5. The vehicles and containers used for the transport of unprocessed Category 3 material, together with all items of equipment or appliances which have come into contact with the unprocessed Category 3 material must be cleaned, washed and disinfected after each use. Packaging material must be incinerated or disposed of by some other means in accordance with instructions from the official veterinarian.

*B. Category 1 or Category 2 intermediate plant*

1. The plant must have not other activities than collecting, handling, temporary storing and dispatching of Category 1 or Category 2 material;
2. The sorting of the Category 1 or Category 2 material must be done in way that any risk of introduction of animal diseases can be avoided;
3. 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 epizootic diseases;
4. Category 1 or Category 2 material must be stored properly until re-dispatched;
5. The vehicles and containers used for the transport of Category 1 or Category 2 material, together with all items of equipment or appliances which have come into contact with the Category 1 or Category 2 material must be cleaned, washed and disinfected after each use. Packaging material must be incinerated or disposed of by some other means in accordance with instructions from the official veterinarian.

## CHAPTER III

**Requirements for the approval of storage plants**

1. Premises and facilities must meet at least the following requirements:
  - (a) the plant must have a covered space to receive the products;

- (b) 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;
  - (c) the plant must have adequate lavatories, changing rooms and washbasins for staff;
  - (d) the plant must have appropriate arrangements for protection against pests such as insects, rodents, birds, etc.
2. The plant must have adequate facilities for cleaning and disinfecting the containers or recipients 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.
  3. Products must be stored properly until re-dispatched.

---

ANNEX IX

**RULES APPLICABLE TO THE TREATMENT OF CERTAIN CATEGORY 2 AND CATEGORY 3 MATERIALS INTENDED TO BE USED AS FEEDSTUFFS FOR CATEGORIES OF ANIMALS LISTED IN ARTICLE 21**

1. Category 2 or Category 3 material must be transported to the users or to the collection centres in accordance with Annex II.
2. The premises must comply at least with the requirements of Annex III Chapter I points 1(a) (b) (c) (d) and (f), 2,3,4 and Chapter II points 1,2,4,5,9 and they must have adequate facilities for destroying unused unprocessed Category 2 or Category 3 material, or must send it to a processing plant or to an incinerator in accordance with this Regulation.
3. In addition to the records required in accordance to Article 8, the following records shall be kept:
  - (i) in the case of final users, the quantity of Category 2 or Category 3 material used and the date of use;
  - (ii) in the case of centres of collection supplying Category 2 or Category 3 material to final users:
    - (a) the quantity of Category 2 or Category 3 material treated in accordance with point 4 below;
    - (b) the name and address of each final user buying the processed Category 2 or Category 3 material;
    - (c) the premises to which the Category 2 or Category 3 material are to be taken for use;
    - (d) the quantity dispatched; and
    - (e) the date on which the material was dispatched.
4. In the case of centres of collection supplying Category 2 or Category 3 material to final users, Category 2 or Category 3 material, other than fish offals, must:
  - (i) undergo one of the following treatments:
    - (a) denaturing with the solution of a colouring agent approved by the competent authority; the solution is to be of such a strength that the colouring on the stained meat is clearly visible, and the whole surface of all pieces of meat have been covered with a solution as aforesaid either by immersing the meat in, or spraying or otherwise applying the solution;
    - (b) sterilisation, that is to say, boiling or steaming under pressure until every piece of meat is cooked throughout;
    - (c) any other treatment approved by the competent authority;
  - (ii) after treatment the Category 2 or Category 3 material must be packaged before distribution and the packaging must include the name and the address of the collection centre and be clear and legibly marked 'not for human consumption'.

ANNEX X

MODELS OF 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 this 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: .....

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 Council and European Parliament Regulation . . . /EC and certify that:

(a) the processed animal protein or product described above contains exclusively or partially processed animal protein not intended for human consumption which:

(i) has been prepared and stored in a processing plant approved, validated and supervised by the competent authority in accordance with Article 15 of Council and European Parliament Regulation . . . /EC;

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

- parts of animals slaughtered in a slaughterhouse which are declared fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reason;
- parts of animals slaughtered in a slaughterhouse rejected as unfit for human consumption, but not affected by any signs of diseases communicable to man or animals and which have been derived from carcasses passed fit for human consumption in accordance with Community legislation;
- hides and skins, hooves and horns, pig bristles and feathers originating from animals which have been slaughtered in a slaughterhouse and have undergone an *ante mortem* inspection and passed fit, as a result of such inspection, for slaughter in accordance with Community legislation;
- blood obtained from animals which have been slaughtered in a slaughterhouse and have undergone an *ante mortem* inspection and passed fit, as a result of such inspection, for slaughter in accordance with Community legislation;
- animal by-products derived from the production of products intended for human consumption, such as degreased bones, greaves; etc.;
- foodstuffs of animal origin or containing products of animal origin, originally intended for human consumption, but destined to animal consumption for commercial reason or due to problems of manufacturing or packaging defects or any other defects which do not present any risk to humans or animals;
- fish or other sea animals except sea mammals, caught in the open sea for the purposes of fishmeal production;
- fresh fish offal from plants manufacturing fish products for human consumption;
- 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 man or animals;

(iii) has been 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, with a particle size prior to processing of not more than 50 millimetres<sup>(1)</sup>, or
- in case of bloodmeal or non-mammalian protein other than fishmeal, according to the processing method . . . listed in Annex III, Chapter III of Council and European Parliament Regulation . . . /EC<sup>(1)</sup>, or

and

the random sample complies with following standards<sup>(2)</sup>:

- *clostridium perfringens*: absence in 1 g
- *salmonella*: absence in 25 grams, n = 5, c = 0, m = 0, M = 0
- *enterobacteriaceae*: n = 5, c = 2, n = 10, M 3 X 10<sup>2</sup> in 1 gram



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 products

Milk of: .....  
(species)

Description of milk/milk based products: .....

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 products

The milk/milk-based products 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: .....

Name and address of consignor: .....

Name and address of consignee: .....

IV. Health attestation

I, the undersigned official veterinarian, certify that:

- 1. . . . (exporting country), . . . (region) <sup>(3)</sup>, has been free from foot-and-mouth disease and rinderpest for 12 months immediately prior to export and has not practised vaccination against foot-and-mouth disease or rinderpest in the 12 months immediately prior to export.
- 2. The milk/milk-based product referred to in this certificate:
  - (a) has been prepared from raw milk which comes from animals:
    - not showing clinical signs of a diseases that can be transmitted through the milk to man or animals
    - belonging to holdings which 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.
- 3. Every precaution was taken to avoid contamination of the milk/milk-based product after processing.
- 4. The milk/milk-based product was packed in new container <sup>(1)</sup> or
  - where bulk containers were used, these were disinfected prior to loading using a product approved by the competent authorities <sup>(1)</sup> and
  - the containers are marked so to indicate the nature of the milk/milk-based product.

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

Stamp <sup>(4)</sup>

.....  
(signature of the official veterinarian) <sup>(4)</sup>

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

---

<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 should be included.  
<sup>(3)</sup> To be completed if the authorisation to import into the Community is restricted to certain regions of the third country concerned.  
<sup>(4)</sup> The signature and the stamp must be in a different colour to that of the printing.

(B)

HEALTH CERTIFICATE

For heat treated milk-based products with a pH reduced to less than 6 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-based products

Milk of: ..... (species)

Description of milk-based products: .....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

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

II. Origin

Address and registration number of treatment or processing establishment (1): .....

III. Destination of milk-based products

The milk-based products will be sent

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

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

By the following means of transport (2): .....

Number of seal: .....

Name and address of consignor: .....

Name and address of consignee: .....

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 which comes from animals:
    - not showing clinical signs of a disease that can be transmitted through the milk to man or animals
    - belonging to holdings which 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; 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 container <sup>(1)</sup> or
  - where bulk containers were used, these were disinfected prior to loading using a product approved by the competent authorities <sup>(1)</sup>, and
  - the containers are marked so to indicate the nature of the milk/milk-based product.

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

(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 products

Milk of: ..... (species)

Description of milk/milk based products: .....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

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

II. Origin

Address and registration number of treatment or processing establishment (1): .....

III. Destination of milk/milk-based products

The milk/milk-based products will be sent

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

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

By the following means of transport (2): .....

Number of seal: .....

Name and address of consignor: .....

Name and address of consignee: .....

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 which comes from animals:

- not showing clinical signs of a disease that can be transmitted through the milk to man or animals
- belonging to holdings which are not under official restriction due to foot-and-mouth disease or rinderpest; and

(b) has undergone:

either

(i) a sterilisation process whereby an  $F_0$  value equal to or greater than 3 was 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 by, in the case of dried milk or dried milk-based product, 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 container <sup>(1)</sup> or

- where bulk containers were used, these were disinfected prior to loading using a product approved by the competent authorities <sup>(1)</sup>, and
- the containers are marked so 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>(3)</sup>

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

<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 should be included.

<sup>(3)</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 approval 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: .....

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 Council and EP Regulation . . . and certify that the petfood described above:

(a) has been prepared and stored in a processing plant approved and supervised by the competent authority in accordance with Article 16 of Council and European Parliament Regulation . . . /EC;



(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 approval 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: .....

Name and address of consignor: .....

Name and address of consignee: .....

*IV. Health attestation*

I, the undersigned official veterinarian, declare to have read and understood Council and EP Regulation ... and certify that the petfood described above:

(a) has been prepared and stored in a processing plant approved and supervised by the competent authority in accordance with Article 16 of Council and European Parliament Regulation .../EC;

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

- parts of animals slaughtered in a slaughterhouse which are declared fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reason;



(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 approval 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: .....

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 Council and European Parliament Regulation . . . /EC and certify that the dogchews described above:

(a) has been prepared and stored in a processing plant approved and supervised by the competent authority in accordance with Article 16 of Council and European Parliament Regulation . . . /EC;

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

— parts of animals slaughtered in a slaughterhouse, which are declared fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reason;



(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 of the following species: .....

.....

Nature of packaging: .....

Number of packages: .....

Net weight: .....

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

*II. Origin of raw petfood*

Address and approval 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: .....

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 Council and European Parliament Regulation . . . /EC and certify that the raw petfood described above:

(a) Consists of animal by-products derived from species referred to in (I) above and satisfies the relevant animal health requirements laid down in Commission(s) Decision(s) . . . (!);



## 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 parts or 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 the seal: .....

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:

- (a) comes from a country where the following diseases are compulsory notifiable: African horse sickness, dourine, glanders, equine encephalomyelitis (of all types including VEE), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;
- (b) was obtained, under supervision of a veterinarian, from equidae which at the time of collection were free from clinical signs of infectious disease;
- (c) was obtained from equidae, which 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:
  - (i) Venezuelan equine encephalomyelitis has not occurred during the last two years;
  - (ii) Dourine has not occurred during the last six months;
  - (iii) Glanders has not occurred during the last six months;
- (d) was obtained from equidae, which at the moment of collection did not come from a holding and have not been present on a holding which was subject to prohibition for animal health reason:
  - (i) within the previous six months in the case of equine encephalomyelitis, beginning on the date on which the equidae suffering from the disease are slaughtered;
  - (ii) in the case of infectious anaemia, until the date on which, the infected animals having been slaughtered, the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart;
  - (iii) within the previous six months in the case of vesicular stomatitis;
  - (iv) within the previous month of the last recorded case, in the case of rabies;
  - (v) within the previous 15 days of the last recorded case, in the case of anthrax.

If all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected, the period of the prohibition shall be 30 days, beginning on the day on which the animals were destroyed and the premises disinfected, except in the case of anthrax, where the period of prohibition is 15 days;
- (e) has undergone all precautions to avoid contamination with pathogenic agents during production, handling and packaging;
- (f) was packed in sealed impermeable containers clearly labelled 'serum from equidae' and bearing the registration number of the establishment of collection.

Done at .....,  
(place)

on .....,  
(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 5

(A)

ANIMAL 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 parts or packages: .....

Net weight: .....

Number(s) of the seal(s) of the container(s), truck, trainwagons or bale(s): .....  
.....

II. Origin of the hides and skins

Address and veterinary registration 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: .....



(B)

ANIMAL HEALTH CERTIFICATE

For treated hides and skins of ungulates, intended for dispatch to the European Community, originating from third countries or parts of third countries, listed in part 1 of the Annex to Decision 79/542/EEC

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 parts or packages: .....

Net weight: .....

Number(s) of the seal(s) of the container(s), truck, trainwagons or bale(s): .....  
.....

II. Origin of the hides and skins

Address and veterinary registration 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 have been obtained from animals which have been slaughtered in a slaughterhouse and have undergone an *ante* and *post-mortem* inspection and have found to be free of serious diseases communicable to man or animals and were not killed in order to eradicate epizootic diseases and

1. Either <sup>(1)</sup>:

(a) originate in a country or from a part of a country in which no case of the following diseases, which are officially notifiable diseases in the country of origin, has occurred during the last 12 months

— rinderpest <sup>(2)</sup>,

— foot-and-mouth disease <sup>(2)</sup>,

— classical swine fever <sup>(2)</sup>,

— African swine fever <sup>(2)</sup>,

and have been

— dried <sup>(1)</sup>, or

— dry-salted or wet-salted for at least 14 days prior to dispatch <sup>(1)</sup>, or

— dry-salted or wet-salted on the following date . . . and, according to the declaration of the transporter, the hides and skins will be transported by ship and the duration of transport will be such that they will have undergone a minimum of 14 days salting before they reach the EC border inspection post <sup>(1)</sup>;

or

(b) have been

— salted for 7 days in sea salt with addition of sodium carbonate to 2 %,

or

— salted in sea salt with addition of sodium carbonate to 2 % on the following date . . . and, according to the declaration of the transporter, the hides and skins will be transported by ship and the duration of transport will be such that they will have undergone a minimum of 7 days salting before they reach the EC border inspection post <sup>(1)</sup>, or

— dried for 42 days at a temperature of at least 20 °C <sup>(1)</sup>;

2. have undergone all precautions to avoid recontamination with pathogenic agents.

Done at .....,  
(place)

on .....,  
(date)

Stamp <sup>(3)</sup>

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

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

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

<sup>(2)</sup> Delete diseases not applicable to the species concerned.

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

(C)

OFFICIAL DECLARATION

For hides and skins of ungulates, other than pigs and equidae, which are intended for dispatch to the European Community and which have been kept separate for 21 days or have been undergoing 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 parts or packages: .....

Net weight: .....

Number(s) of the seal(s) of the container(s), truck, trainwagons or bale(s): .....

II. Origin of the hides and skins

Address and official registration 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:

- (a) have been subjected
  - dried <sup>(1)</sup>, or
  - dry-salted or wet-salted for at least 14 days prior to dispatch <sup>(1)</sup>, or
  - salted for 7 days in (sea) salt with addition of sodium carbonate to 2 % <sup>(1)</sup>, or
  - dried for 42 days at a temperature of at least 20 °C <sup>(1)</sup>;
- (b) have undergone all precautions to avoid recontamination with pathogenic agents after treatment and have not been in contact with any other animal product or live animals;
- (c) — have been kept separate immediately before dispatch under official supervision for 21 days after the treatment described under point (a) <sup>(1)</sup>, or
  - following the declaration of the transporter, the duration of the transport period is foreseen to be at least 21 days <sup>(1)</sup>.

Done at ..... (place), on ..... (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 6

(A)

## CERTIFICATE/DOCUMENT

**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/document: .....

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: .....

Name and address of consignor: .....

Name and address of consignee: .....

III. *Health attestation*

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

- (a) 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;

(b) in the case of game trophies consisting solely of hides or skins have been <sup>(1)</sup>

- dried <sup>(1)</sup>,
- dry-salted or wet-salted for a minimum of 14 days before dispatch <sup>(1)</sup>,
- dry-salted or wet-salted on the following date . . . and, according to the declaration of the transporter, the hides and skins will be transported by ship and the duration of transport will be such that they will have undergone a minimum of 14 days of salting before they reach the EC border inspection post <sup>(1)</sup>;

(c) in the case of game trophies consisting solely of bones, horns, hooves, claws, antlers or teeth <sup>(1)</sup>:

- have been immersed in boiling water for an appropriate time so as to ensure that any matter other than of bones, horns, hooves, claws, antlers or teeth is removed,
- have been disinfected with a product authorised by the competent authority of the country of dispatch, in particular with hydrogen peroxide where parts consisting of bone are concerned.

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

## VETERINARY CERTIFICATE

**For 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: .....

Name and address of consignor: .....

Name and address of consignee: .....

III. *Health attestation*

I, the undersigned official veterinarian, certify that:

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 these diseases has taken place.

(b) The game trophies described above:

- were obtained from animals which were killed in the territory of . . . in the region . . . authorised for export of fresh meat of the corresponding susceptible domestic species, where during the last 60 days there have been no animal health restrictions because of outbreaks of disease to which the game animals are susceptible;
- originated from animals that were killed at least 20 km distance from the borders of another third country or part of a third country not authorised to export untreated game trophies of cloven hoofed animals other than swine to the Community.

2. With respect to game trophies of wild swine <sup>(1)</sup>:

(a) . . . during the last 12 months was free from classical swine fever, African swine fever, swine vesicular disease, foot-and-mouth disease and porcine enteroviral encephalomyelitis (Teschen disease) and no vaccination have been carried out against any these diseases during the last 12 months.

(b) The game trophies described above:

- were obtained from animals which were killed in the territory of . . . authorised for export of fresh meat of the corresponding susceptible domestic species, where during the last 60 days there have been no animal health restrictions because of outbreaks of disease to which the swine are susceptible;
- originated from animals that were killed at least 20 km distance from the borders of another third country or part of a third country not authorised to export untreated game trophies of wild swine to the Community.

3. With respect to game trophies of solipeds, the game trophies described above were obtained from wild solipeds that were killed in the territory of . . . <sup>(1)</sup> (exporting country)

4. With respect to game trophies of game birds <sup>(1)</sup>

- (a) . . . , region . . . is free from avian influenza and Newcastle disease;
- (b) the game trophies described above were obtained from wild game birds that were killed in the territory of . . . , region . . . Where during the last 30 days there have been no animal health restrictions because of outbreaks of disease to which the wild birds are susceptible.

5. The game trophies described above have been packaged 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.

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 7

(A)

ANIMAL HEALTH CERTIFICATE

**For pig bristles from third countries or regions thereof which 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 animal health 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: .....

Name and address of consignor: .....

Name and address of consignee: .....

IV. Health attestation

I, the undersigned official veterinarian, certify that:

- 1. the pig bristles described above have been obtained from pigs originating in 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 man or other animals and were not slaughtered in order to eradicate epizootic diseases.
- 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 ..... (place), on ..... (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.

(B)

ANIMAL HEALTH CERTIFICATE

For pig bristles from third countries or regions thereof which 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 animal health 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: .....

Name and address of consignor: .....

Name and address of consignee: .....

IV. Health attestation

I, the undersigned official veterinarian, certify that:

1. the pig bristles described above have been obtained from pigs originating in 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 man or other animals and were not slaughtered in order to eradicate epizootic diseases.
3. The pig bristles mentioned above have been:
  - boiled <sup>(1)</sup>,
  - dyed <sup>(1)</sup>,
  - bleached <sup>(1)</sup>.
4. The pig bristles are dry and securely enclosed in packaging.

Done at .....  
(place)

on .....  
(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 8

HEALTH CERTIFICATE

**For unprocessed animal by-products for the manufacture of petfood or technical products, including pharmaceutical, 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 unprocessed animal by-products*

Nature of unprocessed animal by-products: .....  
(species)

Nature of packaging: .....

Number of packages: .....

Net weight: .....

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

*II. Origin of unprocessed animal by-products*

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

*III. Destination of unprocessed animal by-products*

The unprocessed 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: .....

Name and address of consignor: .....

Name and address of consignee: .....

IV. Health attestation

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

- (a) Consists of animal by-products derived from species referred to in I above and satisfies the relevant animal health requirements laid down in Commission(s) Decision(s) ... <sup>(1)</sup>.
- (b) Consists only of parts of animals slaughtered in a slaughterhouse, which are declared fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reason;
- (c) Has been deep-frozen at the plant of origin;
- (d) has undergone all precautions to avoid recontamination with pathogenic agents after treatment;
- (e) was packed in new packaging material preventing any leakage.

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> No of the relevant and current Decision(s) for fresh meat of the corresponding susceptible domestic species must be included.  
<sup>(2)</sup> The signature and the stamp must be in a different colour to that of the printing.

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## ANNEX XI

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

The following lists are lists in principle and importation shall fulfil the relevant animal health and public health requirements

## PART I

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

Third countries listed in the Annex to Decision 97/296/EC, and the following countries:

- (EE) Estonia
- (PR) Puerto Rico
- (UA) Ukraine.

## PART IV

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

**List of third countries from which Member States authorise imports of unprocessed material for the manufacture of petfood and technical products**A. *unprocessed material from animals of bovine, ovine, caprine, porcine and equine species*

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 poultrymeat

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 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 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 poultrymeat.

PART X

**List of third countries from which Member States 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 authorise imports of gelatine, hydrolysed protein and dicalcium phosphate intended for animal consumption**

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>.

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

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

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