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

of 3 October 2002

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

(OJ L 273, 10.10.2002, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 808/2003 of 12 May 2003	L 117	1	13.5.2003
►M2	Commission Regulation (EC) No 668/2004 of 10 March 2004	L 112	1	19.4.2004
►M3	Commission Regulation (EC) No 92/2005 of 19 January 2005	L 19	27	21.1.2005
►M4	Commission Regulation (EC) No 93/2005 of 19 January 2005	L 19	34	21.1.2005
►M5	Commission Regulation (EC) No 416/2005 of 11 March 2005	L 66	10	12.3.2005
►M6	Commission Regulation (EC) No 181/2006 of 1 February 2006	L 29	31	2.2.2006
►M7	Commission Regulation (EC) No 208/2006 of 7 February 2006	L 36	25	8.2.2006
►M8	Commission Regulation (EC) No 2007/2006 of 22 December 2006	L 379	98	28.12.2006
►M9	Commission Regulation (EC) No 829/2007 of 28 June 2007	L 191	1	21.7.2007
►M10	Commission Regulation (EC) No 1432/2007 of 5 December 2007	L 320	13	6.12.2007
►M11	Commission Regulation (EC) No 399/2008 of 5 May 2008	L 118	12	6.5.2008
►M12	Commission Regulation (EC) No 437/2008 of 21 May 2008	L 132	7	22.5.2008
►M13	Commission Regulation (EC) No 523/2008 of 11 June 2008	L 153	23	12.6.2008
►M14	Commission Regulation (EC) No 777/2008 of 4 August 2008	L 207	9	5.8.2008
►M15	Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009	L 188	14	18.7.2009
►M16	Commission Regulation (EU) No 595/2010 of 2 July 2010	L 173	1	8.7.2010
►M17	Commission Regulation (EU) No 790/2010 of 7 September 2010	L 237	1	8.9.2010

Corrected by:

►C1 Corrigendum, OJ L 30, 3.2.2007, p. 3 (1774/2002)

►C2 Corrigendum, OJ L 109, 22.4.2006, p. 12 (668/2004)

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

of 3 October 2002

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission ([1]),

Having regard to the opinion of the Economic and Social Committee ([2]),

Having consulted the Committee of the Regions,

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

Whereas:

(1) Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedingstuffs of animal or fish origin and amending Directive 90/425/EEC ([4]) established the principle that all animal waste, regardless of its source, may be used for the production of feed material following appropriate treatment.

(2) The Scientific Steering Committee has adopted a number of opinions since the adoption of that Directive. Their main conclusion is that animal by-products derived from animals not fit for human consumption following health inspection should not enter the feed chain.

(3) In the light of those scientific opinions, a distinction should be drawn between the measures to be implemented, depending on the nature of animal by-products used. The possible uses of certain animal materials should be limited. Rules should be laid down for the use of animal by-products other than in feed and for their disposal.

([1]) OJ C 96 E, 27.3.2001, p. 40.
([2]) OJ C 193, 10.7.2001, p. 32.
([3]) Opinion of the European Parliament of 12 June 2001 (OJ C 53 E of 28.2.2002, p. 84), Council Common Position of 20 November 2001 (OJ C 45 E of 19.2.2002, p. 70) and Decision of the European Parliament of 13 March 2002 (not yet published in the Official Journal). Decision of the European Parliament of 24 September 2002 and Council Decision of 23 September 2002.
([4]) OJ L 363, 27.12.1990, p. 51. Directive as last amended by the 1994 Act of Accession.

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(4) In the light of the experience gained in recent years, it is appropriate to clarify the relationship between Directive 90/667/EEC and Community environmental legislation. This Regulation should not affect the application of existing environmental legislation or hinder the development of new rules on environmental protection, particularly as regards biodegradable waste. In this regard, the Commission has given a commitment that by the end of the year 2004 a Directive on biowaste, including catering waste, will be prepared with the aim of establishing rules on safe use, recovery, recycling and disposal of this waste and of controlling potential contamination.

(5) The International Scientific Conference on Meat-and-Bone Meal organised by the Commission and the European Parliament, held in Brussels on 1 and 2 July 1997, initiated a debate concerning the production and feeding of meat-and-bone meal. The Conference called for further reflection on the future policy in this area. In November 1997, to launch the widest possible public debate about the future of the Community's feed legislation, the Commission finalised a consultation paper on meat-and-bone meal. Following that consultation, it appears that there is a general recognition of the need to amend Directive 90/667/EEC to bring it in line with the new scientific information.

(6) The European Parliament, in its resolution of 16 November 2000 on BSE and safety of animal feed ([1]), called for a ban on the use of animal protein in feed until the present Regulation enters into force.

(7) Scientific advice suggests that the practice of feeding an animal species with proteins derived from the bodies, or parts of bodies, of the same species presents a risk of spreading disease. As a precautionary measure, this practice should therefore be prohibited. Implementing rules should be adopted to ensure the necessary separation of animal by-products destined for use in feed at every stage of processing, storage and transport. However, there should be scope to establish derogations from this general prohibition in relation to fish and fur animals if justified by scientific advice.

(8) Catering waste containing products of animal origin can also be a vector for the spread of disease. All catering waste generated from means of transport operating internationally should be disposed of safely. Catering waste produced within the Community should not be used for the feeding of farmed animals other than fur animals.

([1]) OJ C 223, 8.8.2001, p. 281.

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(9) From October 1996, the Food and Veterinary Office of the Commission (FVO) carried out a number of rounds of inspections in Member States, to assess the presence and management of main risk factors and surveillance procedures with regard to BSE. Part of the assessment covered the systems of commercial rendering and other methods of animal waste disposal. General conclusions and a number of recommendations were drawn up following those inspections, with particular reference to the traceability of animal by-products.

(10) To avoid any risk of dispersal of pathogens and/or residues, animal by-products should be processed, stored and kept separated in an approved and supervised plant designated by the Member State concerned or be disposed of in a suitable manner. In certain circumstances, especially when it is justified by distance, time of transport, or capacity problems, the designated processing, incineration or co-incineration plant could be located in another Member State.

(11) Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste [1] does not apply to incineration plants if the waste treated consists solely of animal carcases. It is necessary to lay down minimum requirements for such incineration plants to protect animal and public health. Pending the adoption of Community requirements, Member States may adopt environmental legislation for such plants. Less strict requirements should apply to low-capacity incineration plants, such as those located on farms and at pet crematoria, to reflect the lower risk posed by the material treated and to avoid unnecessary transport of animal by-products.

(12) Specific rules should be laid down on controls for processing plants, with particular reference to detailed procedures for the validation of processing methods and for self-supervision of production.

(13) Derogations from the rules on the use of animal by-products may be appropriate to facilitate the feeding of animals not destined for human consumption. The competent authorities should control such uses.

[1] OJ L 332, 28.12.2000, p. 91.

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(14) Derogations may also be appropriate to permit the disposal of animal by-products on site in controlled circumstances. The Commission should receive the information necessary to enable it to monitor the situation and to lay down implementing rules if appropriate.

(15) Community inspections should be carried out in the Member States to ensure uniform implementation of the health requirements. Such inspections should also include audit procedures.

(16) The basis for Community legislation on health issues is sound science. To this end, the relevant scientific committees set up by Commission Decisions 97/404/EC ([1]) and 97/579/EC ([2]) should be consulted wherever necessary. In particular, further scientific advice is required on the use of products of animal origin in organic fertilisers and soil improvers. Pending the adoption of Community rules in the light of this advice, Member States may maintain or adopt national rules that are stricter than those envisaged in this Regulation, provided that such rules comply with other applicable Community legislation.

(17) A wide variety of approaches exists in Member States as regards the financial support for processing, collection, storage and disposal of animal by-products. To ensure that the conditions of competition between agricultural products are not affected, it is necessary to carry out an analysis and, if necessary, to take appropriate measures at Community level.

(18) In the light of the above, a fundamental revision of the Community rules applicable to animal by-products appears to be necessary.

(19) Animal by-products not destined for human consumption (in particular processed animal protein, rendered fats, petfood, hides and skins and wool) are included in the list of products in Annex I to the Treaty. The placing on the market of such products constitutes an important source of income for part of the farming population. To ensure rational development in this sector and increase productivity, animal health and public health rules for the products in question should be laid down at Community level. Given the significant risks of the spread of diseases to which animals are exposed, particular requirements should apply to the placing on the market of certain animal by-products, particularly in regions with a high health status.

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

([2]) OJ L 237, 28.8.1997, p. 18. Decision as amended by Decision 2000/443/EC.

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(20) To ensure that products imported from non-member countries are of a hygiene standard which is at least equal or equivalent to the hygiene standard applied by the Community, a system of approval should be introduced for non-member countries and their establishments, together with a Community inspection procedure to ensure that the conditions for such approval are observed. The importation from third countries of petfood and raw material for petfood can take place subject to conditions different from those applicable to such material produced in the Community, in particular as regards the guarantees required concerning the residues of substances prohibited in accordance with Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC ([1]). To ensure that such petfood and raw material are used only for their intended purpose, it is necessary to lay down appropriate control measures on importation of material covered by such derogations.

(21) Animal by-products that pass through the Community in transit, and those originating in the Community and destined for export, can create a risk for animal and public health within the Community. Certain requirements laid down by this Regulation should therefore apply to such movements.

(22) The accompanying document for products of animal origin is the best way of satisfying the competent authority of the place of destination that a consignment complies with the provisions of this Regulation. The health certificate should be maintained for the purposes of verifying the destination of certain imported products.

(23) Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC ([2]) pursues the abovementioned objectives.

(24) The Council and the Commission have adopted several Decisions implementing Directives 90/667/EEC and 92/118/EEC. Furthermore, Directive 92/118/EEC has been substantially amended and further amendments are to be made. Consequently, a great number of Community acts currently regulate the animal by-products sector and there is a need for simplification.

([1]) OJ L 125, 23.5.1996, p. 3.
([2]) OJ L 62, 15.3.1993, p. 49. Directive as last amended by Commission Decision 2001/7/EC (OJ L 2, 5.1.2001, p. 27).

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(25) Such simplification will lead to more transparency with regard to specific health rules for products of animal origin not destined for human consumption. Simplification of the specific health legislation must not lead to deregulation. It is therefore necessary to maintain and, to ensure public and animal health protection, to tighten the detailed health rules for products of animal origin not destined for human consumption.

(26) The products concerned should be subject to the rules for veterinary checks, including checks by experts from the Commission, and any protective measures laid down by Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ([1]).

(27) Effective checks should be carried out on products imported into the Community. This can be achieved by implementing the controls laid down in Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from non-member countries ([2]).

(28) Directive 90/667/EEC, Council Decision 95/348/EC of 22 June 1995 laying down the veterinary and animal health rules applicable in the United Kingdom and Ireland to the treatment of certain types of waste intended to be marketed locally as feedstuffs for certain animal categories ([3]) 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 ([4]) should therefore be repealed.

(29) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([5]).

([1]) OJ L 224, 18.8.1990, p. 29. Directive as last amended by Directive 92/118/EEC.
([2]) OJ L 24, 30.1.1998, p. 9.
([3]) OJ L 202, 26.8.1995, p. 8.
([4]) OJ L 204, 4.8.1999, p. 37.
([5]) OJ L 31, 1.2.2002, p. 1.

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(30) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]),

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down animal and public health rules for:

(a) the collection, transport, storage, handling, processing and use or disposal of animal by-products, to prevent these products from presenting a risk to animal or public health;

(b) the placing on the market and, in certain specific cases, the export and transit of animal by-products and those products derived therefrom referred to in Annexes VII and VIII.

2. This Regulation shall not apply to:

(a) raw petfood originating from retail shops or in premises adjacent to sale points, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot;

(b) liquid milk and colostrum disposed of or used on the farm of origin;

(c) entire bodies or parts of wild animals not suspected of being infected with diseases communicable to humans or animals, except for fish landed for commercial purposes and bodies or parts of wild animals used to produce game trophies;

(d) raw petfood for use on site derived from animals slaughtered on the farm of origin for use as foodstuffs by the farmer and his family only, in accordance with national legislation;

([1]) OJ L 184, 17.7.1999, p. 23.

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(e) catering waste, unless:

(i) from means of transport operating internationally,

(ii) destined for animal consumption, or

(iii) destined for use in a biogas plant or for composting;

(f) ova, embryos and semen intended for breeding purposes; and

(g) transit by sea or by air.

3. This Regulation shall not affect veterinary legislation having as its objective the eradication and control of certain diseases.

Article 2

Definitions

1. For the purpose of this Regulation, the following definitions shall apply:

(a) **animal by-products:** entire bodies or parts of animals or products of animal origin referred to in Articles 4, 5 and 6 not intended for human consumption, including ova, embryos and semen;

(b) **Category 1 material:** animal by-products referred to in Article 4;

(c) **Category 2 material:** animal by-products referred to in Article 5;

(d) **Category 3 material:** animal by-products referred to in Article 6;

(e) **animal:** any vertebrate or invertebrate animal (including fish, reptiles and amphibians);

(f) **farmed animal:** any animal that is kept, fattened or bred by humans and used for the production of food (including meat, milk and eggs), wool, fur, feathers, skins or any other product of animal origin;

(g) **wild animal:** any animal not kept by humans;

(h) **pet animal:** any animal belonging to species normally nourished and kept, but not consumed, by humans for purposes other than farming;

(i) **competent authority:** the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that central authority has delegated that competence, in particular for the control of feeding-stuffs; it shall also include, where appropriate, the corresponding authority of a non-member country;

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(j) **placing on the market:** any operation the purpose of which is to sell animal by-products, or products derived therefrom covered by this Regulation, to a third party in the Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;

(k) **trade:** trade between Member States in goods within the meaning of Article 23(2) of the Treaty;

(l) **transit:** a movement through the Community from one non-member country to another;

(m) **producer:** any person whose activity produces animal by-products;

(n) **TSEs:** all transmissible spongiform encephalopathies, except those occurring in humans;

(o) **specified risk material:** material referred to in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ([1]).

2. The specific definitions set out in Annex I shall also apply.

Article 3

General obligations

1. Animal by-products, and products derived therefrom, shall be collected, transported, stored, handled, processed, disposed of, placed on the market, exported, carried in transit and used in accordance with this Regulation.

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2. However, Member States may regulate under national law the importation and placing on the market of products not referred to in Annexes VII and VIII, pending the adoption of a decision by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Member States shall immediately inform the Commission of the use that they make of this possibility.

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

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

CHAPTER II

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

Article 4

Category 1 material

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

(a) all body parts, including hides and skins, of the following animals:

(i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed,

(ii) animals killed in the context of TSE eradication measures,

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

(iv) experimental animals as defined by Article 2 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes ([1]), and

(v) wild animals, when suspected of being infected with diseases communicable to humans or animals;

(b) (i) specified risk material, and

(ii) where, at the time of disposal, specified risk material has not been removed, entire bodies of dead animals containing specified risk material;

(c) products derived from animals to which substances prohibited under Directive 96/22/EC have been administered and products of animal origin containing residues of environmental contaminants and other substances listed in Group B(3) of Annex I to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC ([2]), if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;

([1]) OJ L 358, 18.12.1986, p. 1.
([2]) OJ L 125, 23.5.1996, p. 10.

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(d) all animal material collected when treating waste water from Category 1 processing plants and other premises in which specified risk material is removed, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises, unless such material contains no specified risk material or parts of such material;

(e) catering waste from means of transport operating internationally; and

(f) mixtures of Category 1 material with either Category 2 material or Category 3 material or both, including any material destined for processing in a Category 1 processing plant.

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

(a) directly disposed of as waste by incineration in an incineration plant approved in accordance with Article 12;

(b) processed in a processing plant approved under Article 13 using any of processing methods 1 to 5 or, where the competent authority so requires, processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and finally disposed of as waste by incineration or by co-incineration in an incineration or co-incineration plant approved in accordance with Article 12;

(c) with the exclusion of material referred to in paragraph 1(a)(i) and (ii), processed in a processing plant approved in accordance with Article 13 using processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and finally disposed of as waste by burial in a landfill approved under Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste ([1]);

(d) in the case of catering waste referred to in paragraph 1(e), disposed of as waste by burial in a landfill approved under Directive 1999/31/EC; or

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(e) in the light of developments in scientific knowledge, disposed of by other means that are approved by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means may either supplement or replace those provided for in points (a) to (d) of this paragraph.

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

([1]) OJ L 182, 16.7.1999, p. 1.

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4. ►M15 Category 1 material shall not be imported or exported except in accordance with this Regulation or with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). ◄ However, the import or export of specified risk material shall take place only in accordance with Article 8(1) of Regulation (EC) No 999/2001.

Article 5

Category 2 material

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

(a) manure and digestive tract content;

(b) all animal materials collected when treating waste water from slaughterhouses other than slaughterhouses covered by Article 4(1)(d) or from Category 2 processing plants, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises;

(c) products of animal origin containing residues of veterinary drugs and contaminants listed in Group B(1) and (2) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation;

(d) products of animal origin, other than Category 1 material, that are imported from non-member countries and, in the course of the inspections provided for in Community legislation, fail to comply with the veterinary requirements for their importation into the Community, unless they are returned or their importation is accepted under restrictions laid down under Community legislation;

(e) animals and parts of animals, other than those referred to in Article 4, that die other than by being slaughtered for human consumption, including animals killed to eradicate an epizootic disease;

(f) mixtures of Category 2 material with Category 3 material, including any material destined for processing in a Category 2 processing plant; and

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

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

(a) directly disposed of as waste by incineration in an incineration plant approved in accordance with Article 12;

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(b) processed in a processing plant approved in accordance with Article 13 using any of processing methods 1 to 5 or, where the competent authority so requires, processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and:

(i) disposed of as waste either by incineration or by coincineration in an incineration or co-incineration plant approved in accordance with Article 12, or

(ii) in the case of rendered fats, further processed into fat derivatives for use in organic fertilizers or soil improvers or for other technical uses, other than in cosmetics, pharmaceuticals and medical devices, in a Category 2 oleochemical plant approved in accordance with Article 14;

(c) processed in a processing plant approved in accordance with Article 13 using processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and:

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(i) in the case of resulting proteinaceous material, used as an organic fertiliser or soil improver in compliance with requirements, if any, laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3),

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(ii) transformed in a biogas plant or in a composting plant approved in accordance with Article 15, or

(iii) disposed of as waste by burial in a landfill approved under Directive 1999/31/EC;

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(d) in the case of material of fish origin, ensiled or composted in compliance with rules adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

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(e) in the case of manure, digestive tract content separated from the digestive tract, milk and colostrum, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease:

(i) used without processing as raw material in a biogas plant or in a composting plant approved in accordance with Article 15 or treated in a technical plant approved for this purpose in accordance with Article 18,

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(ii) applied to land in accordance with this Regulation, or

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(iii) transformed in a biogas plant or composted in accordance with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

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(f) in the case of entire bodies or parts of wild animals not suspected of being infected with diseases communicable to humans or animals, used to produce game trophies in a technical plant approved for this purpose in accordance with Article 18; or

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(g) disposed of by other means, or used in other ways, in accordance with rules laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means or ways may either supplement or replace those provided for in points (a) to (f) of this paragraph.

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3. Intermediate handling or storage of Category 2 material, other than manure, shall take place only in Category 2 intermediate plants approved in accordance with Article 10.

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4. Category 2 material shall not be placed on the market or exported except in accordance with this Regulation or with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

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Article 6

Category 3 material

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

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

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

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(c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

(d) blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

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

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

(g) raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals;

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

(i) fresh by-products from fish from plants manufacturing fish products for human consumption;

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

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

(l) catering waste other than as referred to in Article 4(1)(e).

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

(a) directly disposed of as waste by incineration in an incineration plant approved in accordance with Article 12;

▼B

(b) processed in a processing plant approved in accordance with Article 13 using any of processing methods 1 to 5, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and disposed of as waste either by incineration or by co-incineration in an incineration or co-incineration plant approved in accordance with Article 12 or in a landfill approved under Directive 1999/31/EC;

(c) processed in a processing plant approved in accordance with Article 17;

(d) transformed in a technical plant approved in accordance with Article 18;

(e) used as raw material in a petfood plant approved in accordance with Article 18;

(f) transformed in a biogas plant or in a composting plant approved in accordance with Article 15;

▼M15

(g) in the case of catering waste referred to in paragraph 1(l), transformed in a biogas plant or composted in accordance with rules laid down by the Commission, or, pending the adoption of such rules, in accordance with national law. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

(h) in the case of material of fish origin, ensiled or composted in accordance with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3); or

(i) disposed of by other means, or used in other ways, in accordance with rules laid down by the Commission after consultation of the appropriate scientific committee; those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means or ways may either supplement or replace those provided for in points (a) to (h).

▼B

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

Article 7

Collection, transportation and storage

1. Animal by-products and processed products, with the exception of Category 3 catering waste shall be collected, transported and identified in accordance with Annex II.

▼B

2. During transportation, a commercial document or, when required by this Regulation, a health certificate, shall accompany animal by-products and processed products. Commercial documents and health certificates shall satisfy the requirements, and be kept for the period, specified in Annex II. They shall, in particular, include information concerning the quantity and a description of the material and its marking.

3. Member States shall ensure that adequate arrangements exist to guarantee the collection and transportation of Category 1 and Category 2 material in accordance with Annex II.

4. In accordance with Article 4 of Council Directive 75/442/EEC of 15 July 1975 on waste ([1]), Member States shall take the necessary measures to ensure that Category 3 catering waste is collected, transported and disposed of without endangering human health and without harming the environment.

5. The storage of processed products shall take place only in storage plants approved in accordance with Article 11.

6. However, Member States may decide not to apply the provisions of this Article to manure transported between two points located on the same farm or between farms and users located in the same Member State.

Article 8

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

1. Animal by-products and processed products shall be sent to other Member States only subject to the conditions laid down in paragraphs 2 to 6.

2. The Member State of destination must have authorised the receipt of Category 1 material, Category 2 material, processed products derived from Category 1 or Category 2 material and processed animal protein. Member States may make the application of processing method 1 prior to dispatch a condition of authorisation.

3. Animal by-products, and processed products referred to in paragraph 2, shall be:

(a) accompanied by a commercial document or, when required by this Regulation, a health certificate, and

(b) conveyed directly to the plant of destination, which must have been approved in accordance with this Regulation.

4. When Member States send Category 1 material, Category 2 material, processed products derived from Category 1 or Category 2 material and processed animal protein to other Member States, the competent authority of the place of origin shall inform the competent authority of the place of destination of each consignment by means of the ANIMO system, or by another method by mutual agreement. The message shall contain the information specified in Annex II, Chapter I, paragraph 2.

([1]) 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).

▼B

5. When informed of its dispatch in accordance with paragraph 4, the competent authority of the place of destination shall inform the competent authority of the place of origin of the arrival of each consignment by means of the ANIMO system, or by another method by mutual agreement.

6. Member States of destination shall ensure, through regular checks, that the designated plants on their territory use consignments only for authorised purposes and keep full records demonstrating compliance with this Regulation.

Article 9

Records

1. Any person consigning, transporting or receiving animal by-products shall keep a record of consignments. Records shall contain the information, and be kept for the period, specified in Annex II.

2. However, this Article shall not apply to manure transported between two points located on the same farm or locally between farms and users located in the same Member State.

CHAPTER III

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

Article 10

Approval of intermediate plants

1. Category 1, 2 and 3 intermediate plants shall be subject to approval by the competent authority.

2. To be approved, Category 1 or Category 2 intermediate plants must:

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

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

(c) undergo the plant's own checks provided for in Article 25; and

(d) be checked by the competent authority in accordance with Article 26.

3. To be approved, Category 3 intermediate plants must:

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

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

▼B

(c) undergo the plant's own checks provided for in Article 25; and

(d) be checked by the competent authority in accordance with Article 26.

Article 11

Approval of storage plants

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

2. To be approved, storage plants must:

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

(b) be checked by the competent authority in accordance with Article 26.

Article 12

Approval of incineration and co-incineration plants

1. The incineration and co-incineration of processed products shall take place in accordance with the provisions of Directive 2000/76/EC. The incineration and co-incineration of animal by-products shall take place either in accordance with the provisions of Directive 2000/76/EC or, when that Directive does not apply, in accordance with the provisions of this Regulation. Incineration and co-incineration plants shall be approved under that Directive or in accordance with paragraph 2 or 3.

2. To be approved by the competent authority for the purpose of disposing of animal by-products, a high-capacity incineration or co-incineration plant to which Directive 2000/76/EC does not apply must fulfil:

(a) the general conditions laid down in Annex IV, Chapter I;

(b) the operating conditions laid down in Annex IV, Chapter II;

(c) the requirements laid down in Annex IV, Chapter III, concerning water discharges;

(d) the requirements laid down in Annex IV, Chapter IV, concerning residues;

(e) the temperature measurement requirements laid down in Annex IV, Chapter V; and

(f) the conditions concerning abnormal operating laid down in Annex IV, Chapter VI.

▼B

3. To be approved by the competent authority for the purpose of disposing of animal by-products, a low-capacity incineration or co-incineration plant to which Directive 2000/76/EC does not apply must:

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

▼B

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

(c) fulfil the general conditions laid down in Annex IV, Chapter I;

(d) fulfil the applicable operating conditions laid down in Annex IV, Chapter II;

(e) fulfil the requirements laid down in Annex IV, Chapter IV, concerning residues;

(f) fulfil the applicable temperature measurement requirements laid down in Annex IV, Chapter V;

(g) fulfil the conditions concerning abnormal operating laid down in Annex IV, Chapter VI; and

▼M1

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

▼B

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

▼M15

5. The requirements of paragraphs 2 and 3 may be amended by the Commission in the light of developments in scientific knowledge, after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼B

Article 13

Approval of Category 1 and Category 2 processing plants

1. Category 1 and Category 2 processing plants shall be subject to approval by the competent authority.

2. To be approved, Category 1 and Category 2 processing plants must:

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

(b) handle, process and store Category 1 or Category 2 material in accordance with Annex V, Chapter II and Annex VI, Chapter I;

▼B

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

(d) undergo the plant's own checks provided for in Article 25;

(e) be checked by the competent authority in accordance with Article 26; and

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

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

Article 14

Approval of Category 2 and Category 3 oleochemical plants

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

2. To be approved, Category 2 oleochemical plants must:

(a) process rendered fats derived from Category 2 material in accordance with the standards laid down in Annex VI, Chapter III;

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

(c) keep a record of the information obtained pursuant to point (b) for presentation to the competent authority; and

(d) be checked by the competent authority in accordance with Article 26.

3. To be approved, Category 3 oleochemical plants must process rendered fats derived only from Category 3 material and meet the relevant requirements referred to in paragraph 2.

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

Article 15

Approval of biogas plants and composting plants

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

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

(a) meet the requirements of Annex VI, Chapter II, Part A;

(b) handle and transform animal by-products in accordance with Annex VI, Chapter II, Parts B and C;

▼B

(c) be checked by the competent authority in accordance with Article 26;

(d) establish and implement methods of monitoring and checking the critical control points; and

(e) ensure that digestion residues and compost, as appropriate, comply with the microbiological standards laid down in Annex VI, Chapter II, Part D.

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

CHAPTER IV

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

Article 16

General animal health provisions

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

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

(a) come from a holding, territory or part of a territory or, in the case of aquaculture products, from a farm, zone or part of a zone, not subject to animal health restrictions applicable to the animals and products concerned, and in particular restrictions under disease control measures imposed by Community legislation or by virtue of a serious transmissible disease listed in Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease ([1]);

(b) were not slaughtered in a plant in which animals infected, or suspected of being infected, with one of the diseases covered by the rules referred to in (a) were present at the time of slaughter.

([1]) OJ L 62, 15.3.1993, p. 69. Directive as last amended by the 1994 Act of Accession.

▼B

3. Subject to compliance with the disease control measures referred to in paragraph 2(a), the placing on the market of animal by-products, and products derived therefrom referred to in Annexes VII and VIII, that come from a territory or part of a territory subject to animal health restrictions but are not infected or suspected of being infected shall be permitted provided that, as appropriate, the products:

(a) are obtained, handled, transported and stored separately from or at different times from products fulfilling all animal health conditions;

(b) have undergone a treatment sufficient to eliminate the animal health problem concerned in accordance with this Regulation at a plant approved for that purpose by the Member State where the animal health problem occurred;

(c) are properly identified;

▼M15

(d) comply with the requirements laid down in Annexes VII and VIII, or with detailed rules to be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).

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►M15 Conditions alternative to those set out in the first subparagraph may be laid down in specific situations by decisions adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4). ◄ Such decisions shall take account of any measures concerning the animals or tests to be carried out on them and the specific characteristics of the disease in the species concerned and shall specify any measures needed to ensure the protection of animal health in the Community.

Article 17

Approval of Category 3 processing plants

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

2. To be approved, Category 3 processing plants must:

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

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

▼B

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

(d) undergo the plant's own checks provided for in Article 25;

(e) be checked by the competent authority in accordance with Article 26; and

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

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

Article 18

Approval of petfood plants and technical plants

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

2. To be approved, the petfood plant or the technical plant must:

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

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

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

(iii) depending on the products, to take samples for analyses in a laboratory recognised by the competent authority for the purposes of checking compliance with the standards established by this Regulation;

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

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

(b) to be checked by the competent authority in accordance with Article 26.

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

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Article 19

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

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

(a) have been prepared in a Category 3 processing plant approved and supervised in accordance with Article 17;

(b) have been prepared exclusively with Category 3 material, as specified in Annex VII;

(c) have been handled, processed, stored and transported in accordance with Annex VII and in such a manner as to ensure compliance with Article 22; and

(d) meet the specific requirements laid down in Annex VII.

Article 20

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

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

(a) meet either:

(i) the specific requirements laid down in Annex VIII, or

(ii) when a product could be used both as a technical product and as feed material, and Annex VIII contains no specific requirements, the specific requirements laid down by the relevant Chapter of Annex VII; and

(b) come from plants approved and supervised in accordance with Article 18 or, in the case of animal by-products referred to in Annex VIII, from other plants approved in accordance with Community veterinary legislation.

▼M15

2. Member States shall ensure that organic fertilisers and soil improvers produced from processed products, other than those produced from manure and digestive tract content, are placed on the market or exported only if they meet requirements, if any, laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

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

(a) have been prepared in a Category 2 oleochemical plant approved in accordance with Article 14 from rendered fats resulting from the processing of Category 2 material in a Category 2 processing plant approved in accordance with Article 13 following the application of any of processing methods 1 to 5;

(b) have been handled, processed, stored and transported in accordance with Annex VI; and

(c) meet any specific requirements laid down in Annex VIII.

Article 21

Safeguard measures

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

Article 22

Restrictions on use

1. The following uses of animal by-products and processed products are prohibited:

(a) the feeding of a species with processed animal protein derived from the bodies or parts of bodies of animals of the same species;

(b) the feeding of farmed animals other than fur animals with catering waste or feed material containing or derived from catering waste; and

(c) the application to pasture land of organic fertilizers and soil improvers, other than manure.

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2. The Commission shall establish rules concerning control measures. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Other rules for the implementation of this Article shall be adopted in accordance with the regulatory procedure referred to in Article 33(2).

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Derogations from paragraph 1(a) may be granted in relation to fish and fur animals, after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

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CHAPTER V

DEROGATIONS

Article 23

Derogations regarding the use of animal by-products

1. Member States may authorise, under the supervision of the competent authorities:

(a) the use of animal by-products for diagnostic, educational and research purposes; and

(b) the use of animal by-products for taxidermy purposes in technical plants approved for this purpose in accordance with Article 18.

2. (a) Member States may also authorise the use of the animal by-products specified in subparagraph (b) for the feeding of the animals specified in subparagraph (c), under the supervision of the competent authorities and in accordance with the rules laid down in Annex IX.

(b) The animal by-products referred to in subparagraph (a) are:

(i) Category 2 material, provided that it comes from animals which were not killed or did not die as a result of the presence or suspected presence of a disease communicable to humans or animals, and

(ii) Category 3 material referred to in Article 6(1)(a) to (j) and, subject to Article 22, in Article 6(1)(l);

(c) The animals referred to in subparagraph (a) are:

(i) zoo animals,

(ii) circus animals,

(iii) reptiles and birds of prey other than zoo or circus animals,

(iv) fur animals,

(v) wild animals the meat of which is not destined for human consumption,

(vi) dogs from recognised kennels or packs of hounds, and

(vii) maggots for fishing bait.

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(d) In addition, Member States may authorise the use, under the supervision of the competent authorities, of Category 1 material referred to in Article 4(1)(b)(ii) for the feeding of endangered or protected species of necrophagous birds in accordance with rules laid down by the Commission after consultation of the European Food Safety Authority. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

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3. Member States shall inform the Commission of:

(a) the use made of the derogations referred to in paragraph 2; and

(b) the verification arrangements introduced to ensure that the animal by-products concerned are used only for authorised purposes.

4. Each Member State shall draw up a list of users and collection centres authorised and registered pursuant to paragraph 2(c)(iv), (vi) and (vii) within its territory. Each user and collection centre shall be assigned an official number for inspection purposes and to be able to trace the origin of the products concerned.

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

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

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5. Detailed rules concerning verification measures may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

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Article 24

Derogations regarding the disposal of animal by-products

1. The competent authority may, where necessary, decide that:

(a) dead pet animals may be directly disposed of as waste by burial;

(b) the following animal by-products originating in remote areas may be disposed of as waste by burning or burial on site:

(i) Category 1 material referred to in Article 4(1)(b)(ii),

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(ii) Category 2 material, and

(iii) Category 3 material; and

(c) animal by-products may be disposed of as waste by burning or burial on site in the event of an outbreak of a disease mentioned in List A of the International Office of Epizootic Diseases (OIE), if the competent authority rejects transport to the nearest incineration or processing plant because of the danger of propagation of health risks or because a widespread outbreak of an epizootic disease leads to a lack of capacity at such plants.

2. No derogation may be granted in respect of Category 1 material referred to in Article 4(1)(a)(i).

3. In the case of Category 1 material referred to in Article 4(1)(b)(ii), burning or burial may take place in accordance with paragraph 1(b) or (c) only if the competent authority authorises and supervises the method used and is satisfied that it precludes all risk of transmission of TSEs.

4. Member States shall inform the Commission of:

(a) the use they make of the possibilities provided for in paragraph 1(b) in respect of Category 1 and Category 2 material; and

(b) the areas that they categorise as remote areas for the purpose of applying paragraph 1(b) and the reasons for that categorisation.

5. The competent authority shall take the measures necessary:

(a) to ensure that the burning or burial of animal by-products does not endanger animal or human health; and

(b) to prevent the abandonment, dumping or uncontrolled disposal of animal by-products.

6. Detailed arrangements for implementing this Article may be laid down under the procedure referred to in Article 33(2).

CHAPTER VI

CONTROLS AND INSPECTIONS

Article 25

Plants' own-checks

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

(a) identify and control the critical control points in the plants;

(b) establish and implement methods for monitoring and checking such critical control points;

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(c) in the case of processing plants, take representative samples to check compliance:

(i) of each processed batch with the standards for the products established by this Regulation, and

(ii) with the maximum permitted levels of physicochemical residues laid down in Community legislation;

(d) record the results of the checks and tests referred to in points (b) and (c) and keep them for a period of at least two years for presentation to the competent authorities;

(e) introduce a system ensuring the traceablility of each batch dispatched.

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

(a) notify the competent authority immediately of the full details of the nature of the sample and the batch from which it was derived;

(b) establish the causes of failures of compliance;

(c) reprocess or dispose of the contaminated batch under the supervision of the competent authority;

(d) ensure that no material suspected or known to be contaminated is moved from the plant before being reprocessed under the supervision of the competent authority and re-sampled officially in order to comply with the standards laid down in this Regulation, unless destined for disposal;

(e) increase the frequency of sampling and testing of production;

(f) investigate animal by-products records appropriate to the finished sample; and

(g) instigate appropriate decontamination and cleaning procedures within the plant.

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3. The Commission may lay down rules concerning the frequency of checks and reference methods for microbiological analyses. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Any other detailed arrangements for implementing this Article may be laid down under the regulatory procedure referred to in Article 33(2).

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Article 26

Official controls and lists of approved plants

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

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

3. If the inspection carried out by the competent authority reveals that one or more of the requirements of this Regulation are not being met, the competent authority shall take appropriate action.

4. Each Member State shall draw up a list of plants approved in accordance with this Regulation within its territory. It shall assign an official number to each plant, which identifies the plant with respect to the nature of its activities. Member States shall send copies of the list and updated versions to the Commission and other Member States.

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5. The Commission may lay down rules concerning the frequency of checks and reference methods for microbiological analyses. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Any other detailed arrangements for implementing this Article may be laid down under the regulatory procedure referred to in Article 33(2).

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CHAPTER VII

COMMUNITY CONTROLS

Article 27

Community controls in Member States

1. Experts from the Commission may make on-the-spot checks, in cooperation with the competent authorities of Member States, in so far as is necessary for the uniform application of this Regulation. The Member State on whose territory checks are made shall provide the experts with all the assistance necessary for carrying out their duties. The Commission shall inform the competent authority of the results of the checks made.

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2. Rules for the implementation of this Article, in particular those governing the procedure for cooperation with national competent authorities, shall be laid down under the procedure referred to in Article 33(2).

CHAPTER VIII

PROVISIONS APPLICABLE TO THE IMPORTATION AND TRANSIT OF CERTAIN ANIMAL BY-PRODUCTS AND PRODUCTS DERIVED THEREFROM

Article 28

General provisions

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

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However, the importation from third countries of petfood and raw material for petfood production, derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC, shall be permitted provided that such raw material is permanently marked and under specific conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

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Article 29

Prohibitions and compliance with Community rules

1. The importation and transit of animal by-products and processed products shall be prohibited, except in accordance with this Regulation.

2. The importation into, and the transit through, the Community of the products referred to in Annexes VII and VIII may take place only if such products satisfy the requirements set out in paragraphs 3 to 6.

3. Products referred to in Annexes VII and VIII shall, save as otherwise specified in those Annexes, come from a third country or parts of third countries on a list to be drawn up and updated in accordance with the procedure referred to in Article 33(2).

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;

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(b) the organisation of the competent authority and its inspection services in the third country, the powers of those services, the supervision to which they are subject, and their authority to monitor effectively the application of their legislation;

(c) the actual health conditions applied to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community;

(d) the assurances the third country can give regarding compliance with the relevant health conditions;

(e) experience of marketing the product from the third country and the results of import checks carried out;

(f) the result of any Community inspections in the third country;

(g) the health status of the livestock, other domestic animals and 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 OIE or, in the case of diseases of aquaculture animals, the notifiable diseases as listed in the Aquatic Animal Health Code of the OIE;

(i) the regulations on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on imports from other countries.

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

Approved lists shall be amended as follows:

(a) the Commission shall inform the Member States of the modifications proposed by the third country concerned to the lists of plants within five working days of the receipt of the proposed modifications;

(b) the Member States shall have seven working days, from receipt of the modifications to the lists of plants referred to in (a), to send any written comments to the Commission;

(c) when at least one Member State makes written comments, the Commission shall inform the Member States within five working days and include the point on the agenda of the next meeting of the Standing Committee on the Food Chain and Animal Health for decision under the procedure referred to in Article 33(2);

▼B

(d) when the Commission receives no comments from the Member States within the time limit referred to in subparagraph (b), Member States shall be considered to have accepted the modifications to the list. The Commission shall inform the Member States within five working days, and imports shall be authorised from such plants five working days after receipt of this information by the Member States.

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

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

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

Article 30

Equivalence

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

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

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

(a) the nature and content of the health certificate that must accompany the product;

(b) specific health requirements applicable to importation into, and/or transit through, the Community; and

(c) where necessary, procedures for drawing up and amending lists of regions or plants from which imports and/or transit are permitted.

▼B

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

Article 31

Community inspections and audits

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

(a) drawing up the list of third countries or parts thereof and determining conditions for importation and/or transit;

(b) verifying compliance with:

(i) the conditions for inclusion in a Community list of third countries,

(ii) import and/or transit conditions,

(iii) the conditions for recognising equivalence of measures,

(iv) any emergency measures applied under Community legislation.

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

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

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

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

CHAPTER IX

FINAL PROVISIONS

Article 32

Amendments to Annexes and transitional measures

▼M15

1. After consultation of the appropriate scientific committee on any question that could have an impact on animal or public health, the Annexes may be amended or supplemented and any appropriate transitional measures may be adopted by the Commission.

Transitional measures and measures amending or supplementing the Annexes, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, in particular further specifications of the requirements laid down in this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).

▼M15

Other transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 33(2).

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2. With regard to the ban on the feeding of catering waste referred to in Article 22, where appropriate control systems are in place in Member States prior to the application of this Regulation, transitional measures shall be adopted, in accordance with paragraph 1, to permit the continued use in feed of certain types of catering waste under strictly controlled circumstances for a period of not more than four years as from 1 November 2002. These measures shall ensure that there is no undue risk to animal or public health during the transitional period.

▼M15

Article 33

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, hereinafter referred to as 'the Committee'.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

▼B

Article 34

Consultation of scientific committees

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

Article 35

National provisions

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

▼B

2. In particular, Member States shall inform the Commission of the measures taken to ensure compliance with this Regulation within one year of its entry into force. On the basis of the information received, the Commission shall submit a report to the European Parliament and the Council accompanied, if appropriate, by legislative proposals.

3. Member States may adopt or maintain national rules restricting the use of organic fertilizers and soil improvers further than envisaged in this Regulation pending the adoption of Community rules for their use in accordance with Article 20(2). Member States may adopt or maintain national rules restricting the use of fat derivatives produced from Category 2 material further than envisaged in this Regulation pending the addition to Annex VIII of Community rules for their use in accordance with Article 32.

Article 36

Financial arrangements

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

Article 37

Repeal

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

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

Article 38

Entry into force

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

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

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

▼B

ANNEX I

SPECIFIC DEFINITIONS

For the purpose of this Regulation:

▼M9

1. ‘apiculture by-products’ means honey, beeswax, royal jelly, propolis or pollen not intended for human consumption;

▼B

2. ‘batch’ means a unit of production produced in a single plant using uniform production parameters — or a number of such units, when stored together — and that can be identified for the purposes of recall and re-treatment or disposal should tests show that to be necessary;

3. ‘biogas plant’ means a plant in which biological degradation of products of animal origin is undertaken under anaerobic conditions for the production and collection of biogas;

4. ‘blood products’ means products derived from blood or fractions of blood, excluding blood meal; they include dried/frozen/liquid plasma, dried whole blood, dried/frozen/liquid red cells or fractions thereof and mixtures;

5. ‘blood’ means fresh whole blood;

▼M14

6. ‘blood meal’ means products derived from the heat treatment of blood or fractions of blood in accordance with Annex VII, Chapter II, and intended for animal consumption or organic fertilisers;

▼B

7. ‘canned petfood’ means heat-processed petfood contained within a hermetically sealed container;

8. ‘Category 1 or Category 2 intermediate plant’ means a plant in which unprocessed Category 1 or Category 2 material is handled and/or temporarily stored for the purpose of further transportation to its final destination and where certain preliminary activities, such as removal of hides and skins and performing post-mortem examinations, may take place;

9. ‘Category 1 processing plant’ means a plant in which Category 1 material is processed before its final disposal;

10. ‘Category 2 oleochemical plant’ means a plant processing rendered fats derived from Category 2 material under conditions set out in Annex VI, Chapter III;

11. ‘Category 2 processing plant’ means a plant in which Category 2 material is processed before its final disposal, further transformation or use;

12. ‘Category 3 intermediate plant’ means a plant in which unprocessed Category 3 material is sorted and/or cut and/or chilled or deep-frozen into blocks and/or temporarily stored for the purpose of further transporting to its final destination;

13. ‘Category 3 oleochemical plant’ means a plant processing rendered fats derived from Category 3 material;

14. ‘Category 3 processing plant’ means a plant in which Category 3 material is processed into processed animal protein and other processed products that could be used as feed material;

▼M1

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

▼B

16. ‘co-incineration plant’ means a disposal site as defined in Article 3(5) of Directive 2000/76/EC;

17. ‘co-incineration’ means the disposal of animal by-products or products derived therefrom in a co-incineration plant;

18. ‘collection centres’ means premises collecting and treating certain animal by-products intended to be used for the feeding of the animals specified in Article 23(2)(c);

19. ‘composting plant’ means a plant in which biological degradation of products of animal origin is undertaken under aerobic conditions;

20. ‘digestion residues’ means residues resulting from the transformation of animal by-products in a biogas plant;

21. ‘digestive tract content’ means the content of the digestive tract of mammals and ratites, whether or not separated from the digestive tract;

22. ‘dogchews’ means untanned products for pet animals to chew, produced from hides and skins of ungulates or other animal material;

23. ‘feed material’ means those feed materials, as defined in Directive 96/25/EC ([1]), that are of animal origin including processed animal proteins, blood products, rendered fats, fish oil, fat derivatives, gelatin and hydrolysed proteins, dicalcium phosphate, milk, milk-based products and colostrum;

24. ‘fishmeal’ means processed animal protein derived from sea animals, except sea mammals;

25. ‘fur animals’ means animals kept or reared for the production of fur and not used for human consumption;

26. ‘gelatin’ means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry);

27. ‘greaves’ means the protein-containing residue of rendering, after partial separation of fat and water;

28. ‘hermetically sealed container’ means a container that is designed and intended to be secure against the entry of micro-organisms;

29. ‘hides and skins’ means all cutaneous and subcutaneous tissues;

30. ‘high-capacity incineration plant’ means an incineration plant other than a low-capacity incineration plant;

31. ‘hydrolysed proteins’ means polypeptides, peptides and aminoacids, and mixtures thereof, obtained by the hydrolysis of animal by-products;

32. ‘incineration plant’ means a disposal site as defined in Article 3(4) of Directive 2000/76/EC;

33. ‘incineration’ means the disposal of animal by-products or products derived therefrom in an incineration plant;

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

▼B

34. ‘laboratory reagent’ means a packaged product, ready for use by the end user, containing a blood product, and intended for laboratory use as reagent or reagent product, whether used alone or in combination;

35. ‘landfill’ means a disposal site as defined by Directive 1999/31/EC;

36. ‘low-capacity incineration plant’ means an incineration plant with a throughput of less than 50 kg of animal by-products per hour;

▼M1

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

▼B

38. ‘organic fertilizers’ and ‘soil improvers’ mean materials of animal origin used to maintain or improve plant nutrition and the physical and chemical properties and biological activity of soils, either separately or together; they may include manure, digestive tract content, compost and digestion residues;

▼M6

39. ‘pasture land’means land covered with grass or other herbage grazed by or used as feedingstuffs for farmed animals, excluding land to which organic fertilisers and soil improvers have been applied in accordance with Commission Regulation (EC) No 181/2006 ([1]);

▼B

40. ►M2 ‘petfood plant’ means a plant producing petfood or dogchews or flavouring innards and in which certain animal by-products are used in the preparation of such petfood, dogchews or flavouring innards; ◄

41. ‘petfood’ means food for pet animals containing Category 3 material;

▼M9

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

▼B

43. ‘processed petfood’ means petfood, other than raw petfood, that has undergone treatment in accordance with the requirements of Annex VIII;

44. ‘processed products’ means animal by-products that have undergone one of the processing methods or another treatment required by Annex VII or VIII;

45. ‘processing methods’ means the methods listed in Annex V, Chapter III;

46. ‘processing plant’ means an animal by-products processing plant;

([1]) OJ L 29, 2.2.2006, p. 31.

▼B

47. ‘product used for *in vitro* diagnosis’ means a packaged product, ready for use by the end user, containing a blood product, and used as a reagent, reagent product, calibrator, kit or any other system, whether used alone or in combination, intended to be used *in vitro* for the examination of samples of human or animal origin, with the exception of donated organs or blood, solely or principally with a view to the diagnosis of a physiological state, state of health, disease or genetic abnormality or to determine safety and compatibility with reagents;

48. ‘raw petfood’ means petfood which has not undergone any preserving process other than chilling, freezing or quick freezing to ensure preservation;

49. ‘remote areas’ means areas where the animal population is so small, and where facilities are so far away, that the arrangements necessary for collection and transport would be unacceptably onerous compared to local disposal;

50. ‘rendered fats’ means fats derived from processing of Category 2 material or Category 3 material;

51. ‘storage plant’ means a plant, other than establishments and intermediaries covered by Directive 95/69/EC ([1]), in which processed products are temporarily stored before their final use or disposal;

52. ‘tanning’ means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents;

53. ‘technical plant’ means a plant in which animal by-products are used to produce technical products;

54. ‘technical products’ means products directly derived from certain animal by-products, intended for purposes other than human or animal consumption, including tanned and treated hides and skins, game trophies, processed wool, hair, bristles, feathers and parts of feathers, serum of equidae, blood products, pharmaceuticals, medical devices, cosmetics, bone products for china, gelatin and glue, organic fertilizers, soil improvers, rendered fats, fat derivatives, processed manure and milk and milk-based products;

▼M1

55. ‘unprocessed feathers and parts of feathers’ means feathers and parts of feathers that have not been treated with a steam current or by some other method that ensures that no pathogens remain;

56. ‘unprocessed wool’ means sheep's wool that has not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;

57. ‘unprocessed hair’ means ruminant hair that has not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;

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

▼**M1**

58. ‘unprocessed pig bristles’ means pig bristles that have not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;

59. ‘collagen’ means protein-based products derived from hides, skins and tendons of animals, including bones in the case of pigs, poultry and fish;

60. ‘screenings’ means visible solid animal materials retained in the waste water screen where a pre-treatment process as referred to in Annex II, Chapter IX, is required;

61. ‘grease and oil mixture’ means floating animal materials collected at the surface of waste water grease remover systems where a pre-treatment process as referred to in Annex II, Chapter IX, is required;

62. ‘sludge’ means visible solid animal materials or sediments retained in the waste water drains where a pre-treatment process as referred to in Annex II, Chapter IX, is required;

63. ‘material from desanding’ means visible solid animal materials or sediments retained in desanding systems where these constitute a pre-treatment process referred to in Annex II, Chapter IX;

▼**M2**

64. ‘flavouring innard’ means a liquid or dehydrated processed product of animal origin used to enhance the palatability values of petfood;

▼**M10**

65. ‘colour-coding’ means the systematic use of colours as defined in Chapter I of Annex II for displaying information as provided for in this Regulation on the surface or part of the surface of a packaging, container or vehicle, or on a label or symbol applied to them.

▼B

ANNEX II

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

▼M10

CHAPTER I

Identification

1. All necessary measures must be taken to ensure that:

   (a) Category 1, Category 2 and Category 3 materials are identifiable and kept separate and identifiable during collection and transportation;

   (b) processed products are identifiable and kept separate and identifiable during transportation;

   (c) a marking substance for the identification of animal by-products or processed products of a specific category is only used for the category for which its use is required under this Regulation, or is established or laid down pursuant to point 4; and

   (d) animal by-products and processed products are dispatched from one Member State to another Member State in packaging, containers or vehicles which are prominently and, at least for the period of transport, indelibly colour-coded as follows:

      (i) in the case of Category 1 materials, using the colour black;

      (ii) in the case of Category 2 materials (other than manure and digestive tract content), using the colour yellow;

      (iii) in the case of Category 3 materials, using the colour green with a high content of blue to ensure that it is clearly distinguishable from the other colours.

2. During transport, a label attached to the packaging, container or vehicle must:

   (a) clearly indicate the category of the animal by-products or, in the case of processed products, the category of animal by-products from which the processed products were derived; and

   (b) bear the following words:

      (i) in the case of Category 3 material, ‘not for human consumption’;

      (ii) in the case of Category 2 material (other than manure and digestive tract content) and processed products derived therefrom, ‘not for animal consumption’; however, when Category 2 material is intended for the feeding of animals referred to in Article 23(2)(c) under the conditions provided for in that Article, the label shall instead indicate ‘for feeding to …’ completed with the name of the specific species of those animals for the feeding of which the material is intended;

      (iii) in the case of Category 1 material and processed products derived therefrom, ‘for disposal only’;

      (iv) in the case of manure and digestive tract content, ‘manure’.

3. Member States may establish systems or lay down rules for the colour-coding of packaging, containers or vehicles used for the transport of animal by-products and processed products originating in and remaining on their territory, provided that those systems or rules do not confuse the colour-coding system provided for in point 1(d).

▼M10

4. Without prejudice to point 3 of Annex V to Regulation (EC) No 999/2001, Member States may establish systems or lay down rules for the marking of animal by-products originating in and remaining on their territory provided that those systems or rules do not conflict with the marking requirements laid down for processed products in Chapter I of Annex VI to this Regulation.

5. By way of derogation from points 3 and 4, Member States may use the systems or rules referred to in those points for animal by-products originating in but not intended to remain on their territory if the Member State or third country of destination has communicated its agreement.

▼B

CHAPTER II

Vehicles and containers

1. Animal by-products and processed products must be collected and transported in sealed new packaging or covered leak-proof containers or vehicles.

2. Vehicles and reusable containers, and all reusable items of equipment or appliances that come into contact with animal by-products or processed products, must be:

(a) cleaned, washed and disinfected after each use;

(b) maintained in a clean condition; and

(c) clean and dry before use.

3. Reusable containers must be dedicated to the carriage of a particular product to the extent necessary to avoid cross-contamination.

▼M1

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

▼B

CHAPTER III

Commercial documents and health certificates

▼M1

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

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2. Commercial documents must specify:

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

(b) the description of the material, including the information referred to in Chapter I, the animal species for Category 3 material and processed products derived therefrom destined for use as feed material and, if applicable, the ear-tag number;

(c) the quantity of the material;

(d) the place of origin of the material;

(e) the name and the address of the carrier;

▼B

(f) the name and the address of the receiver and, if applicable, its approval number; and

(g) if appropriate:

(i) the approval number of the plant of origin, and

(ii) the nature and the methods of the treatment.

3. The commercial document must be produced at least in triplicate (one original and two copies). The original must accompany the consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the carrier the other.

4. A model for the commercial document may be laid down under the procedure referred to in Article 33(2).

5. Health certificates must be issued and signed by the competent authority.

CHAPTER IV

Records

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

(a) the information referred to in subparagraphs (b) and (c); and

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

(c) in the case of records kept by any person transporting animal by-products, the information referred to in subparagraphs (a), (d) and (f); or

(d) in the case of records kept by any person receiving animal by-products, the date of reception and the information referred to in subparagraphs (d) and (e).

CHAPTER V

Retention of documents

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

CHAPTER VI

Temperature conditions

1. The transport of animal by-products must take place at an appropriate temperature, to avoid any risk to animal or public health.

2. Unprocessed Category 3 material destined for the production of feed material or pet food must be transported chilled or frozen, unless processed within 24 hours of departure.

3. The design of vehicles used for refrigerated transport must ensure the maintenance of an appropriate temperature throughout transport.

▼B

CHAPTER VII

Specific rules for transit

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

CHAPTER VIII

Control measures

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

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

▼M1

CHAPTER IX

Collection of animal material when treating waste water

1. Category 1 processing plants and other premises where specified risk material is removed, slaughterhouses and Category 2 processing plants shall have a pre-treatment process for the retention and collection of animal material as an initial step in the treatment of waste water. The equipment used in the pre-treatment process shall consist of drain traps or screen with apertures or a mesh size of no more than 6 mm in the down-stream end of the process or equivalent systems that ensures that the solid particles in the waste water passing through them are no more than 6 mm.

2. Waste water from the premises as referred to in paragraph 1 must enter a pre-treatment process which shall ensure that all waste water has been filtered through the process before being drained off the premises. No grinding or maceration shall take place which could facilitate the passage of animal material through the pre-treatment process.

3. All animal material retained in the pre-treatment process in premises as referred to in paragraph 1 shall be collected and transported as Category 1 or Category 2 material, as appropriate, and disposed of in accordance with this Regulation.

4. Waste water having passed the pre-treatment process in premises referred to in paragraph 1 and waste water from premises only receiving Category 3 material shall be treated in accordance with other relevant Community legislation.

▼M9

CHAPTER X

Commercial document

▼M10

1. A commercial document in accordance with the model set out in this Chapter shall accompany animal by-products and processed products during transportation. However, for the transport of animal by-products and processed products on their own territory Member States may require:

   (a) to use a different commercial document, in paper or in electronic form, provided that such commercial document complies with the requirements laid down in point 2 of Chapter III;

▼M10

(b) that the quantity of the material referred to in point 2(c) of Chapter III is expressed in weight of the material in the commercial document;

(c) that a copy of the commercial document is returned by the receiver to the producer to be kept by that producer in accordance with Chapter V as proof of arrival of the consignment.

▼M9

2. Where more than one transporter is involved, each transporter shall fill in a declaration as referred to in point 7 of the commercial document, which shall be part of the document.

MODEL COMMERCIAL DOCUMENT FOR THE TRANSPORTATION WITHIN THE EUROPEAN COMMUNITY OF ANIMAL BY-PRODUCTS AND PROCESSED PRODUCTS

Notes

(a) Commercial documents shall be produced, according to the layout of the model appearing in this Annex. It shall contain, in the numbered order that appears in the model, the attestations that are required for the transportation of animal by-products and processed products derived there from.

(b) It shall be drawn up in one of the official languages of the MemberState of origin or the MemberState of destination, as appropriate. However, it may also be drawn up in other official Community languages, if accompanied by an official translation or if previously agreed by the competent authority of the MemberState of destination.

(c) The commercial document must be produced at least in triplicate (one original document and two copies). The original document must accompany the consignment to its final destination. The receiver must retain it. The producer must retain one of the copies and the carrier the other.

(d) The original of each commercial document shall consist of a single page, both sides, or, where more text is required it shall be in such a form that all pages needed are part of an integrated whole and indivisible.

(e) If for reasons of identification of the items of the consignment, additional pages are attached to the commercial document, these pages shall also be considered as forming part of the original document by the application of the signature of the person responsible for the consignment, on each of the pages.

(f) When the commercial document, including additional pages referred to in (e), comprises more than one page, each page shall be numbered — (*page number*) of (*total number of pages*) — at the bottom and shall bear the code number of the document that has been designated by the responsible person at the top.

(g) The original of the commercial document must be completed and signed by the responsible person. In doing so, the responsible person shall ensure that the principles of documentation as laid down in Chapter III of Annex II to Regulation (EC) No 1774/2002 are followed. The commercial document must specify:

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

(ii) the description of the material, including the identification of the material, the animal species for Category 3 material and processed products derived therefrom destined for use as feed material and, if applicable, the ear-tag number of the animal;

(iii) the quantity of the material;

(iv) the place of origin of the material;

▼**M9**

(v) the name and the address of the carrier of the material;

(vi) the name and the address of the receiver and, if applicable, its approval number; and

(vii) if appropriate, the approval number of the plant of origin, and the nature and the methods of the treatment.

(h) The colour of the signature of the responsible person shall be different to that of the printing.

(i) The commercial document must be kept for a period of at least two years for presentation to the competent authority to verify the records referred to in Article 9 of Regulation (EC) No 1774/2002.

(j) Where Member States decide to use a commercial document in electronic form, the requirements listed in points (a) to (i) shall be complied with as appropriate for such electronic form.

▼M9

Commercial document

For the transportation within the European Community of animal by-products and processed products not intended for human consumption in accordance with Regulation (EC) No 1774/2002 ([2])

EUROPEAN COMMUNITY **Commercial document**

Part I : Details of consignment presented

I.1. Consignor
Name
Address
Postal code

I.2. Document reference number

I.2.a. Local reference number:

I.3. Central competent authority

I.4. Local competent authority

I.5. Consignee
Name
Address
Postal code

I.6.

I.7.

I.8. Country of origin ISO code

I.9. Region of origin Code

I.10. Country of destination ISO code

I.11. Region of destination Code

I.12. Place of origin
Establishment ☐
Name Approval number
Address
Postal code

I.13. Place of destination
Establishment ☐ Other ☐
Name Approval number
Address
Postal code

I.14. Place of loading
Postal code

I.15. Date and time of departure

I.16. Means of transport
Aeroplane ☐ Ship ☐
Road vehicle ☐ Other ☐ Railway wagon ☐
Identification:

I.17. Transporter
Name Approval number
Address
Postal code Member State

I.18. Description of commodity

I.19. Commodity code (CN code)

I.20. Number/quantity

I.21. Temperature of products
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. Transit through third country ☐
Third country ISO code
Exit point Code
Entry point BIP unit No:

I.27. Transit through Member States ☐
Member State ISO code
Member State ISO code
Member State ISO code

I.28. Export ☐
Third country ISO code
Exit point Code

I.29.

I.30.

I.31. Identification of the commodities

Species (Scientific name)	Nature of commodity	Category	Treatment type	Approval number of establishments: Manufacturing plant	Batch number

▼M9

EUROPEAN COMMUNITY **Animal by-products/processed products not intended for human consumption**

Part II: Declaration

II.a. Document reference number	II.b. Local reference number

II.1. **Declaration by the consignor**

I, the undersigned, declare that:

II.1.1. A label attached to the container/carton/other packaging material carries the following indication ([1]):

(a) the Category of the animal by-products (see box reference I.31: Category);

(b) in the case of processed products, the Category of animal by-products from which the processed products were derived (see box reference I.31: Category);

(c) (i) in the case of Category 3 material, the words 'not for human consumption';

(ii) in the case of Category 2 material, other than manure and digestive tract content and processed products derived therefrom, the words 'not for animal consumption';

(iii) in the case of Category 2 material intended for feeding of animals referred to in point (c) of Article 23(2) under the conditions provided for in that Article of Regulation (EC) No 1774/2002 ([2]), the words "for feeding to …" completed with the name of the specific species of those animal(s) for the feeding of which the material is intended;

(iv) in the case of manure and digestive tract content, the word "manure"; or

(v) in the case of Category 1 material and processed products derived therefrom, the words "for disposal only";

II.1.2. in the case where the packaging is done by the consignor the animal by-products and/or processed products are:

([1]) *either* [in sealed new packaging;]

([1]) *or* [transported in bulk in covered leak-proof containers or vehicles or other means of transport that were thoroughly cleaned and dry before use;]

II.1.3. in the case of treatment,

(a) hides and skins have been treated in accordance with "note Part I, box reference I.31: Treatment type" to this document;

(b) the consignment has not been in contact with other animal products or live animals presenting a risk of spreading a serious transmissible disease;

II.1.4. the animal by-products and/or processed products were stored properly prior to loading and dispatch;

II.1.5. all precautions have been taken to avoid contamination of the animal by-products or processed products with pathogenic agents and cross-contamination between various Categories.

Notes

Part I:

— Box reference I.9 and I.11: if appropriate.

— Box reference I.14: complete if different from "I.1. Consignor".

— Box reference I.31:

Animal species: For Category 3 material and processed products derived therefrom destined for use as feed material.

Nature of commodity: Enter unprocessed animal by-product or processed product chosen among the following list: "apiculture products", "blood products", "blood", "bloodmeal", "canned petfood", "digestion residues", "digestive tract content", "dogchews", "fishmeal", "gelatin", "greaves", "hides and skins", "hydrolysed proteins", "organic fertilizers", "petfood", "processed animal protein", "processed petfood", "processed products", "raw petfood", "rendered fats".

Category: Categories 1, 2 or 3. In case of Category 3, specify which letter from a to k (as under Article 6, paragraph 1 of Regulation (EC) No 1774/2002):

In the case of animal by-product for use in raw petfood indicate 3a or 3b whether the animal by-products derive from:

Category 3a, Article 6(1)(a) i.e. parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons; or

Category 3b, Article 6(1)(b) i.e. parts of slaughtered animals, which are rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that are fit for human consumption in accordance with Community legislation;

In the case of hides and skins and processed products derived there from, indicate 3c or 3k whether the animal by-products derive from:

Category 3c, Article 6(1)(c) i.e. hides and skins originating from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation; or

Category 3k, Article 6(1)(k) i.e. hides and skins originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals.

▼M9

Where the consignment is made of more than one Category, indicate the quantity and if applicable the number of containers per Category of materials.

Treatment type: For treated hides and skins, which (a) are not fulfilling the requirements of Regulation (EC) No 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ No L226, 25.6.2004, p. 22) or (b) have not undergone the complete process of tanning or (c) are not 'wet blue'; or (d) are not 'pickled pelts' or (e) are not limed (treated with lime and in brine at a pH of 12 to 13 for at least eight hours): enter treatment among the following: (a) dried; (b) dry-salted or wet-salted for at least 14 days prior to dispatch; (c) salted for seven days in sea salt with the addition of 2 % sodium carbonate; or (d) preserved by a process other than tanning specified in accordance with the procedure referred to in Article 33(2) of Regulation (EC) No 1774/2002.

For Category 3 materials and processed products derived therefrom destined for use as feed: if appropriate describe the nature and the methods of the treatment.

Batch number: enter batch number or ear tag number if applicable.

Part II:

(1) Delete as appropriate.

(2) OJ L 273, 10.10.2002, p. 1.

The signature must be in a different colour to that of the printing

Signature

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

.....
(signature of the responsible person/consignor)

.....
(name, in capital letters)

Declaration by the transporter

I, the undersigned, declare that:

II.2.1. in the case where the packaging is done by the transporter, the animal by-products and/or processed products are:

(1) *either* [in sealed new packaging;]

(1) *or* [transported in bulk in covered leak-proof containers or vehicles or other means of transport that were clean and dry before use and cleaned, washed and disinfected after each use;]

II.2.2. all precautions have been taken:

— to avoid contamination of the animal by-products or processed products with pathogenic agents and cross-contamination between various Categories during transportation, and

— to ensure transportation under appropriate temperature to avoid risk to animal or public health.

Notes

Part II:

(1) Delete as appropriate.

— The signature must be in a different colour to that of the printing.

— Note for the transporters: This document must accompany the consignment (*) from the place of loading for dispatch until it reaches the point of destination.

(*) "Consignment" means "a quantity of products of the same type, which may contain different Categories of animal by-products, coming from the same consignor and covered by the same commercial document conveyed by the same means of transport to the same recipient."

Signature

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

.....
(signature of the responsible person/transporter)

.....
(name, in capital letters)'

▼B

ANNEX III

HYGIENE REQUIREMENTS FOR INTERMEDIATE AND STORAGE PLANTS

CHAPTER I

Requirements for the approval of intermediate plants

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

   (a) The premises must be adequately separated from the public highway and other premises such as slaughterhouses. The layout of plants must ensure the total separation of Category 1 and Category 2 material from Category 3 material from reception until dispatch.

   (b) The plant must have a covered space to receive animal by-products.

   (c) The plant must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids.

   (d) The plant must have adequate lavatories, changing rooms and wash-basins for staff.

   (e) The plant must have appropriate arrangements for protection against pests, such as insects, rodents and birds.

   (f) The plant must have a waste-water disposal system which meets hygiene requirements.

   (g) Where it is necessary for the purpose of achieving the objectives of this Regulation, plants must have suitable temperature-controlled storage facilities of sufficient capacity for maintaining animal by-products at appropriate temperatures and designed to allow the monitoring and recording of those temperatures.

2. The plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the vehicles, other than ships, in which they are transported. Adequate facilities must be provided for the disinfecting of vehicle wheels.

CHAPTER II

General hygiene requirements

A. *Category 3 intermediate plants*

1. The plant must not engage in activities other than the importation, collection, sorting, cutting, chilling, freezing into blocks, temporary storage and dispatching of Category 3 material.

2. The sorting of Category 3 material must be carried out in such a way as to avoid any risk of the propagation of animal diseases.

3. All the time during sorting or storage, Category 3 material must be handled and stored separately from goods other than other Category 3 material and in such a way as to prevent any propagation of pathogens and to ensure compliance with Article 22.

▼B

4. Category 3 material must be stored properly, and, where appropriate, chilled or frozen, until re-dispatched.

▼M1

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▼B

B. *Category 1 or Category 2 intermediate plants*

6. The plant must not engage in activities other than the collection, handling, temporary storage and dispatching of Category 1 or Category 2 material.

7. The sorting of the Category 1 or Category 2 material must be carried out in such a way as to avoid any risk of the propagation of animal diseases.

8. All the time during storage, the Category 1 or Category 2 material must be handled and stored separately from other goods and in such a way as to prevent any propagation of pathogens.

9. Category 1 or Category 2 material must be stored properly, including under appropriate temperature conditions, until re-dispatched.

▼M1

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▼M15

11. Waste water must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from Category 1 and Category 2 intermediate plants may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼B

CHAPTER III

Requirements for the approval of storage plants

Premises and facilities must meet at least the following requirements.

1. Premises storing processed products derived from Category 3 material must not be at the same site as premises storing processed products derived from Category 1 or Category 2 material, unless in a completely separate building.

2. The plant must:

   (a) have a covered space to receive the products;

   (b) be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids;

   (c) have adequate lavatories, changing rooms and washbasins for staff; and

   (d) have appropriate arrangements for protection against pests, such as insects, rodents and birds.

3. The plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which the products are received and the vehicles, other than ships, in which they are transported. Adequate facilities must be provided for the disinfecting of vehicle wheels.

4. Products must be stored properly until re-dispatched.

▼B

ANNEX IV

REQUIREMENTS FOR INCINERATION AND CO-INCINERATION PLANTS TO WHICH DIRECTIVE 2000/76/EC DOES NOT APPLY

CHAPTER I

General conditions

▼M1

1. Incineration or co-incineration plants must be designed, equipped and operated in such a manner as to fulfil the requirements of this Regulation. The following hygiene conditions must be met:

   (a) Animal by-products must be disposed of as soon as possible after arrival. They must be stored properly until disposal.

   (b) Containers, receptacles and vehicles used for transporting unprocessed material must be cleaned in a designated area, thereby ensuring that waste water is treated during the storage referred to in Chapter III.

   (c) Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest control programme must be used for that purpose.

   (d) Cleaning procedures must be established and documented for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.

   (e) Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and maintained for at least two years.

▼B

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

CHAPTER II

Operating conditions

3. Incineration or co-incineration plants must be designed, equipped, built and operated in such a way that the gas resulting from the process is raised in a controlled and homogeneous fashion, even under the most unfavourable conditions, to a temperature of 850 °C, as measured near the inner wall or at another representative point of the combustion chamber as authorised by the competent authority, for two seconds.

4. Each line of high-capacity incineration plants must be equipped with at least one auxiliary burner. This burner must be switched on automatically when the temperature of the combustion gases after the last injection of combustion air falls below 850 °C. It must also be used during plant start-up and shut-down operations to ensure that the temperature of 850 °C is maintained at all times during these operations and as long as unburned material is in the combustion chamber.

5. High-capacity incineration or co-incineration plants must have and operate an automatic system to prevent feed with animal by-products:

   (a) at start-up, until the temperature of 850 °C has been reached; and

   (b) whenever the temperature of 850 °C is not maintained.

▼B

6. Animal by-products should, where practicable, be placed straight in the furnace without direct handling.

CHAPTER III

Water discharges

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

8. The storage capacity must be adequate to ensure that such waters can be tested and treated before discharge where necessary.

CHAPTER IV

Residues

9. For the purposes of this Chapter, 'residues' means any liquid or solid material generated by the incineration or co-incineration process, the waste-water treatment or other processes within the incineration or co-incineration plant. They include bottom ash and slag, fly ash and boiler dust.

10. Residues resulting from the operation of the incineration or co-incineration plant must be minimised in their amount and harmfulness. Residues must be recycled, where appropriate, directly in the plant or outside in accordance with relevant Community legislation.

11. Transport and intermediate storage of dry residues in the form of dust must take place in such a way as to prevent dispersal in the environment (e.g., in closed containers).

CHAPTER V

Temperature measurement

12. Techniques must be used to monitor the parameters and conditions relevant to the incineration or co-incineration process. High-capacity incineration and co-incineration plants must have and use temperature measurement equipment.

13. The approval issued by the competent authority, or conditions attached to it, must lay down temperature measurement requirements.

14. The appropriate installation and the functioning of any automated monitoring equipment must be subject to control and to an annual surveillance test. Calibration must be carried out by means of parallel measurements with the reference methods at least every three years.

15. Temperature measurement results must be recorded and presented in an appropriate fashion to enable the competent authority to verify compliance with the permitted operating conditions laid down in this Regulation in accordance with procedures to be decided upon by that authority.

▼B

CHAPTER VI

Abnormal operating

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

▼M1

CHAPTER VII

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

1. The low-capacity incineration plant must be located on a well-drained hard standing.

2. Livestock must not have access to the low-capacity incineration plant, animal by-products that are awaiting incineration or ash resulting from the incineration of animal by-products. If the low-capacity incineration plant is located on a livestock holding:

   (a) there must be total physical separation between the incinerator and the livestock and their feed and bedding, with fencing where necessary;

   (b) equipment must be dedicated entirely to the operation of the incinerator and not used elsewhere on the farm;

   (c) the operators must change their outer clothing and footwear before handling livestock or livestock feed.

3. The storage of animal by-products and of ashes must be covered, labelled and leak proof.

4. The operator must check that animal by-products are incinerated in such a way that they are completely reduced to ash. Ash must be disposed of to a landfill approved under Directive 1999/31/EC.

5. Incompletely incinerated animal by-products must not be disposed of to a landfill, but must be re-incinerated or otherwise disposed of in accordance with this Regulation.

6. The low-capacity incineration plant must be equipped with an afterburner.

7. The operator must keep records of the quantities, category and species of animal by-products incinerated and the date of incineration.

8. The competent authority must inspect the low-capacity incineration plant before approval, and at least once a year to monitor compliance with this Regulation.

▼B

ANNEX V

GENERAL HYGIENE REQUIREMENTS FOR THE PROCESSING OF CATEGORY 1, 2 AND 3 MATERIAL

CHAPTER I

General requirements for the approval of Category 1, 2 and 3 processing plants

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

▼M14

(a) Processing plants shall not be situated on the same site as slaughterhouses, unless the risks to public and animal health, resulting from the processing of animal by-products which originate from such slaughterhouses, are mitigated by compliance with at least the following conditions:

(i) the processing plant must be physically separated from the slaughterhouse; where appropriate by locating the processing plant in a building that is completely separated from the slaughterhouse;

(ii) the following must be installed and operated:

— a conveyer system which links the processing plant to the slaughterhouse,

— separate entrances, reception bays, equipment and exits for the processing plant and the slaughterhouse;

(iii) measures must be taken to prevent the spreading of risks through the operation of personnel which is employed in the processing plant and in the slaughterhouse;

(iv) unauthorised persons and animals must not have access to the processing plant.

By way of derogation from points (i) to (iv), in the case of Category 3 processing plants, the competent authority may authorise other conditions instead of those set out in those points, aimed at mitigating the risks to public and animal health, including the risks arising from the processing of Category 3 material, which originates from off-site establishments approved under Regulation (EC) No 853/2004. Member States shall inform the Commission and the other Member States in the framework of the Committee referred to in Article 33(1) of the use made of this derogation by their competent authorities;

▼B

(b) the processing plant must have a clean and unclean sector, adequately separated. The unclean sector must have a covered place to receive animal by-products and must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid in such a way as to facilitate the draining of liquids. The processing plant must have adequate lavatories, changing rooms and washbasins for staff;

(c) the processing plant must have sufficient production capacity for hot water and steam for the processing of animal by-products;

(d) the unclean sector must, if appropriate, contain equipment to reduce the size of animal by-products and equipment for loading the crushed animal by-products into the processing unit;

▼B

(e) all installations in which animal by-products are processed must operate in accordance with the requirements of Chapter II. Where heat treatment is required, all installations must be equipped with:

(i) measuring equipment to monitor temperature against time and, if necessary, pressure at critical points;

(ii) recording devices to record continuously the results of these measurements; and

(iii) an adequate safety system to prevent insufficient heating;

(f) to prevent recontamination of the finished product by incoming animal by-products, there must be a clear separation between the area of the plant where incoming material for processing is unloaded and the areas set aside for the processing of that product and the storage of the processed product.

2. The processing plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the vehicles, other than ships, in which they are transported.

3. Adequate facilities must be provided for the disinfecting of vehicle wheels, on leaving the unclean sector of the processing plant.

4. All processing plants must have a waste-water disposal system meeting the competent authority's requirements.

5. The processing plant must have its own laboratory or make use of the services of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority.

CHAPTER II

General hygiene requirements

1. Animal by-products must be processed as soon as possible after arrival. They must be stored properly until processed.

2. Containers, receptacles and vehicles used for transporting unprocessed material must be cleaned in a designated area. That area must be situated or designed to prevent the risk of contamination of processed products.

3. Persons working in the unclean sector must not enter the clean sector without changing their working clothes and footwear or without disinfecting the latter. Equipment and utensils must not be taken from the unclean sector into the clean sector, unless first cleaned and disinfected. Personnel movement procedures must be established to control the movement of personnel between areas and to prescribe the proper use of foot baths and wheel baths.

▼M15

4. Waste water originating in the unclean sector must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from processing plants may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼B

5. Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest control programme must be used for that purpose.

6. Cleaning procedures must be established and documented for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.

7. Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and maintained for at least two years.

8. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.

9. Processed products must be handled and stored at the processing plant in such a way as to preclude recontamination.

CHAPTER III

Processing methods

Method 1

Reduction

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

Time, temperature and pressure

2. After reduction the animal by-products must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars produced by saturated steam ([1]); the heat treatment may be applied as the sole process or as a pre- or post-process sterilisation phase.

3. The processing may be carried out in batch or continuous systems.

Method 2

Reduction

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

Time, temperature and pressure

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

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

([1]) 'Saturated steam' means that all air is evacuated and replaced by steam in the whole sterilisation chamber.

▼M1

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

▼B

Method 3

Reduction

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

Time, temperature and pressure

2. After reduction the animal by-products must be heated to a core temperature greater than 100 ºC for at least 95 minutes, a core temperature greater than 110 ºC for at least 55 minutes and a core temperature greater that 120 ºC for at least 13 minutes.

3. The processing may be carried out in batch or continuous systems.

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

Method 4

Reduction

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

Time, temperature and pressure

2. After reduction the animal by-products must be placed in a vessel with added fat and heated to a core temperature greater than 100 ºC for at least 16 minutes, a core temperature greater than 110 ºC for at least 13 minutes, a core temperature greater that 120 ºC for at least eight minutes and a core temperature greater that 130 ºC for at least three minutes.

3. The processing may be carried out in batch or continuous systems.

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

Method 5

Reduction

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

▼B

Time, temperature and pressure

2. After reduction the animal by-products must be heated until they coagulate and then pressed so that fat and water are removed from the proteinaceous material. The proteinaceous material must then be heated to a core temperature greater than 80 ºC for at least 120 minutes and a core temperature greater than 100 ºC 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 in such a manner that the time-temperature requirements are achieved at the same time.

▼M4

Method 6

(For Category 3 animal by-products of fish origin only)

Reduction

1. The animal by-products must be reduced to at least:

   (a) 50 mm in case of heat treatment in accordance with paragraph 2(a); or

   (b) 30 mm in case of heat treatment in accordance with paragraph 2(b).

   They must then be mixed with formic acid to reduce and maintain the pH to 4,0 or lower. The mixture must be stored for at least 24 hours pending further treatment.

Time and temperature

2. Following reduction, the mixture must be heated to:

   (a) a core temperature of at least 90 °C for at least 60 minutes; or

   (b) a core temperature of at least 70 °C for at least 60 minutes.

   When using a continuous flow system, the progression of the product through the heat converter must be controlled by means of mechanical commands limiting its displacement in such a way that at the end of the heat treatment operation the product has undergone a cycle which is sufficient in both time and temperature.

▼B

Method 7

1. Any processing method approved by the competent authority where it has been demonstrated to that authority that the final product has been sampled on a daily basis over a period of one month in compliance with the following microbiological standards:

   (a) Samples of material taken directly after heat treatment:

   Clostridium perfringens absent in 1 g of the products

   (b) Samples of material taken during or upon withdrawal from storage at the processing plant:

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

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

   where:

   n = number of samples to be tested;

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

▼B

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

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

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

3. This information must be made available to the Commission on request.

CHAPTER IV

Supervision of production

1. The competent authority must supervise processing plants to ensure compliance with the requirements of this Regulation. It must in particular:

(a) check:

(i) the general conditions of hygiene of the premises, equipment and staff;

(ii) the efficacy of the own checks carried out by the plant, in accordance with Article 25, particularly by examining the results and taking samples;

(iii) the standards of the products after processing. The analyses and tests must be carried out in accordance with scientifically-recognised methods (in particular, those laid down in Community legislation or, where none exist, recognised international standards or, in their absence, national standards); and

(iv) the storage conditions;

(b) take any samples required for laboratory tests; and

(c) make any other checks it considers necessary to ensure compliance with this Regulation.

2. To allow it to carry out its responsibilities under paragraph 1, the competent authority must have free access at all times to all parts of the processing plant and to records, commercial documents and health certificates.

CHAPTER V

Validation procedures

1. The competent authority must validate the processing plant in accordance with the following procedures and indicators:

(a) description of the process (by a process flow diagram);

(b) identification of critical control points (CCPs) including the material process rate for continuous systems;

▼B

(c) compliance with the specific process requirements laid down by this Regulation; and

(d) achievement of the following requirements:

(i) particle size for batch-pressure and continuous processes — defined by the mincer hole or the anvil gap size, and

(ii) temperature, pressure, processing time and material processing rate (for continuous system only) as specified in paragraphs 2 and 3.

2. In the case of a batch pressure system:

(a) the temperature must be monitored with a permanent thermocouple and it must be plotted against real time;

(b) the pressure stage must be monitored with a permanent pressure gauge. Pressure must be plotted against real time;

(c) the processing time must be shown by time/temperature and time/-pressure diagrams.

At least once a year the thermocouple and the pressure gauge must be calibrated.

3. In the case of a continuous pressure system:

(a) the temperature and the pressure must be monitored with thermocouples, or an infrared temperature gun, and pressure gauges used at defined positions throughout the process system in such a way that temperature and pressure comply with the required conditions inside the whole continuous system or in a section of it. The temperature and pressure must be plotted against real time;

(b) measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the required conditions, must be provided to the competent authorities, using insoluble markers (for example, manganese dioxide) or a method which offers equivalent guarantees. Accurate measurement and control of the material process rate is essential and must be measured during the validation test in relation to a CCP that can be continuously monitored such as:

(i) feed screw revolutions per minute (rev./min.),

(ii) electric power (amps at given voltage),

(iii) evaporation/condensation rate, or

(iv) number of pump strokes per unit time.

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

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

▼M15

5. Validation procedures based on testing methods may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼B

ANNEX VI

▼M10

SPECIFIC REQUIREMENTS FOR THE PROCESSING OF CATEGORY 1 AND 2 MATERIAL, FOR BIOGAS AND COMPOSTING AND FOR THE MARKING OF CERTAIN PROCESSED PRODUCTS

▼B

CHAPTER I

▼M10

Specific requirements for the processing of Category 1 and 2 materials and for the marking of certain processed products

▼B

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

A. *Premises*

1. The layout of Category 1 and Category 2 processing plants must ensure the total separation of Category 1 material from Category 2 material from reception of the raw material until dispatch of the resulting processed product.

2. However, the competent authority may authorise the temporary use of a Category 2 processing plant for the processing of Category 1 material when a widespread outbreak of an epizootic disease or other extraordinary and unforeseeable circumstances leads to a lack of capacity at a Category 1 processing plant.

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

B. *Processing standards*

3. The critical control points that determine the extent of the heat treatments applied in processing must be identified for each processing method as specified in Annex V, Chapter III. The critical control points may include:

   (a) raw material particle size;

   (b) temperature achieved in the heat treatment process;

   (c) pressure applied to the raw material; and

   (d) duration of the heat treatment process or feed rate to a continuous system.

   Minimum process standards must be specified for each applicable critical control point.

4. Records must be maintained for at least two years to show that the minimum process values for each critical control point are applied.

5. Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept to show the date of calibration of gauges/recorders.

▼B

6. Material that may not have received the specified heat treatment (e.g. material discharged at start up, or leakage from cookers) must be recirculated through the heat treatment or collected and reprocessed.

7. Animal by-products must be processed in accordance with the following processing standards.

(a) Processing method 1 must be applied to:

▼M1

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

▼B

(ii) Category 1 and Category 2 material destined for landfill.

(b) Any of processing methods 1 to 5 must be applied to:

(i) Category 2 material from which the resulting protein is destined for incineration or co-incineration,

(ii) Category 2 material from which the rendered fat is destined for a Category 2 oleochemical plant, and

(iii) Category 1 or Category 2 material destined for incineration or co-incineration.

▼M1

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▼B

C. *Processed products*

▼M15

8. Processed products derived from Category 1 or 2 material, with the exception of liquid products destined for biogas or composting plants, must be permanently marked, where technically possible with smell, using a system approved by the competent authority. Detailed rules for such marking may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼B

9. Samples of processed products destined for biogas or composting plants or landfill, taken directly after heat treatment, must be free from heat-resistant pathogenic bacteria spores (*Clostridium perfringens* absent in 1 g of the products).

▼M10

10. In processing plants approved in accordance with Article 13, processed products as referred to in Article 4(2)(b) and (c) and Article 5(2)(b) and (c) shall be permanently marked with:

(a) smell, where technically possible; and

(b) glyceroltriheptanoate (GTH) in such a way that:

(i) GTH is added to processed products that have undergone a preceding sanitising thermal treatment at a core temperature of at least 80 °C and remain subsequently protected from re-contamination; and

▼M10

(ii) all processed products contain homogenously throughout the substance a minimum concentration of at least 250 mg GTH per kg fat.

11. The operators of processing plants approved in accordance with Article 13 shall have in place a system of constant monitoring and recording of parameters suitable to demonstrate to the competent authority that the required homogeneous minimum concentration of GTH as referred to in point 10(b) is achieved in the processed products referred to in point 10.

That monitoring and recording system shall include the determination of the content of intact GTH as triglyceride in a cleaned petroleum-ether 40-70 extract of GTH from samples taken at regular intervals.

12. The competent authority shall carry out a performance check of the monitoring and recording system referred to in point 11 to ascertain compliance with this Regulation and may, where necessary, request the testing of additional samples in accordance with the method referred to in the second paragraph of point 11.

13. The marking with GTH shall not be required for processed products as referred to in Article 4(2)(b) and (c) and Article 5(2)(b) and (c), where such products are:

(a) moved by a closed conveyer system, where such a system has been authorised by the competent authority, from the processing plant for:

(i) immediate direct incineration or co-incineration; or

(ii) immediate use in accordance with a method approved for Category 1 and 2 animal by-products in accordance with Articles 1 and 2 of Regulation (EC) No 92/2005; or

(b) intended for research or for scientific use authorised by the competent authority.

▼B

CHAPTER II

Specific requirements for the approval of biogas and composting plants

A. *Premises*

▼M7

1. A biogas plant must be equipped with:

(a) a pasteurisation/hygienisation unit, which cannot be by-passed, with:

(i) installations for monitoring temperature against time;

(ii) recording devices to record continuously the results of the monitoring measurements referred to in (i); and

(iii) an adequate safety system to prevent insufficient heating;

(b) adequate facilities for the cleaning and disinfecting of vehicles and containers upon leaving the biogas plant.

However, a pasteurisation/hygienisation unit shall not be mandatory for biogas plants that transform only:

(i) animal by-products that have undergone processing Method 1;

(ii) Category 3 material that has undergone pasteurisation/-hygienisation elsewhere; or

▼M7

(iii) animal by-products which may be used as raw material without processing.

If the biogas plant is located on premises where farmed animals are kept and does not only use manure which accrues from those animals, the plant shall be located at an adequate distance from the area where such animals are kept and there must be, in any case, total physical separation between that plant and those animals and their feed and bedding, with fencing where necessary.

2. A composting plant must be equipped with:

(a) a closed composting reactor, which cannot be by-passed, with:

(i) installations for monitoring temperature against time;

(ii) recording devices to record, where appropriate continuously, the results of the monitoring measurements referred to in (i); and

(iii) an adequate safety system to prevent insufficient heating;

(b) adequate facilities for cleaning and disinfecting of vehicles and containers transporting untreated animal by-products.

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

(i) ensure adequate measures to control vermin;

(ii) are managed in such a way that all the material in the system achieves the required time and temperature parameters, including, where appropriate, continuous monitoring of the parameters;

(iii) comply with all other requirements of this Regulation.

If the composting plant is located on premises where farmed animals are kept and does not only use manure which accrues from those animals, the composting plant shall be located at an adequate distance from the area where animals are kept and there must, in any case, be total physical separation between that composting plant and the animals and their feed and bedding, with fencing where necessary.

▼B

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

B. *Hygiene requirements*

4. Only the following animal by-products may be transformed in a biogas or composting plant:

(a) Category 2 material, when using processing method 1 in a Category 2 processing plant;

▼M1

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

▼B

(c) Category 3 material.

▼M3

However, resulting materials from the processing of Category 1 material may be transformed in a biogas plant, provided that the processing was done pursuant to an alternative method approved in accordance with Article 4(2)(e) and, except as otherwise specified, the biogas production is part of that alternative method and the resulting material is disposed of in accordance with the conditions laid down for the alternative method.

▼B

5. Animal by-products referred to in paragraph 4 must be transformed as soon as possible after arrival. They must be stored properly until treated.

6. Containers, receptacles and vehicles used for transporting untreated material must be cleaned in a designated area. This area must be situated or designed to prevent risk of contamination of treated products.

7. Preventive measures against birds, rodents, insects or other vermin must be taken systematically. A documented pest-control programme must be used for that purpose.

8. Cleaning procedures must be documented and established for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.

9. Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented.

10. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.

▼M7

11. Digestion residues and compost must be handled and stored at the biogas respective composting plant in such way as to prevent recontamination.

▼B

C. *Processing standards*

▼M7

12. Category 3 material used as raw material in a biogas plant equipped with a pasteurisation/hygienisation unit must be submitted to the following minimum requirements:

(a) maximum particle size before entering the unit: 12 mm;

(b) minimum temperature in all material in the unit: 70 °C; and

(c) minimum time in the unit without interruption: 60 minutes.

However, category 3 milk, colostrums and milk products may be used without pasteurisation/hygienisation as raw material in a biogas plant, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease.

13. Category 3 material used as raw material in a composting plant must be submitted to the following minimum requirements:

(a) maximum particle size before entering the composting reactor: 12 mm;

(b) minimum temperature in all material in the reactor: 70 °C; and

▼M7

(c) minimum time in the reactor at 70 °C (all material): 60 minutes.

13a. However, the competent authority may authorise the use of other standardised process parameters provided an applicant demonstrates that such parameters ensure minimising of biological risks. That demonstration shall include a validation, which shall be carried out in accordance with points (a) to (f):

(a) Identification and analysis of possible hazards, including the impact of input material, based on a full definition of the processing conditions.

(b) A risk assessment, which evaluates how the specific processing conditions referred to in (a) are achieved in practice under normal and atypical situations.

(c) Validation of the intended process by measuring the reduction of viability/infectivity of:

(i) endogenous indicator organisms during the process, where the indicator is:

— consistently present in the raw material in high numbers,

— not less heat resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor,

— relatively easy to quantify and relatively easy to identify and to confirm;

or

(ii) a well-characterised test organism or virus, during exposure, introduced in a suitable test body into the starting material.

(d) The validation of the intended process referred to in (c) must demonstrate that the process achieves the following overall risk reduction:

(i) for thermal and chemical processes by:

— reduction of 5 log10 of *Enterococcus faecalis or Salmonella Senftenberg (775W, H2S negative),*

— reduction of infectivity titre of thermo resistant viruses such as *parvovirus* by at least 3 log10, whenever they are identified as a relevant hazard;

and

(ii) as regards chemical processes also by:

— reduction of resistant parasites such as eggs of *ascaris sp.* by at least 99,9 % (3 log10) of viable stages.

(e) Designing a complete control programme including procedures for monitoring the functioning of the process referred to in (c).

(f) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a biogas or composting plant as well as other critical control points must be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant. Records must be made available to the competent authority on request.

▼M7

Information relating to a process authorised under this point must be made available to the Commission on request.

▼M1

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

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

(a) does not consider that those material present a risk of spreading any serious transmissible disease;

▼M7

(b) considers that the residues or compost are unprocessed material.

▼B

D. *Digestion residues and compost*

▼M7

15. Representative samples of the digestion residues or compost taken during or immediately after processing at the biogas or composting plant in order to monitor the process must comply with the following standards:

Escherichia coli: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;

or

Enterococaceae: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;

and

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

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

where:

n = number of samples to be tested;

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

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

▼M7

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

Digestion residues or compost, which does not comply with the requirements set out in this Chapter shall be reprocessed, in the case of Salmonella handled or disposed of in accordance with the instructions of the competent authority.

▼B

CHAPTER III

Treatment standards for the further processing of rendered fats

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

1. transesterification or hydrolysis at least 200 ºC, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); or

2. saponification with NaOH 12M (glycerol and soap):

   (a) in a batch process at 95 ºC for three hours; or

▼M15

   (b) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes, or under equivalent conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼M3

However, other processes may be used for further processing of animal fats derived from Category 1 material, provided these processes are approved as alternative method in accordance with Article 4(2)(e).

▼B

ANNEX VII

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

CHAPTER I

Specific requirements for the approval of Category 3 processing plants

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

A. *Premises*

1. Premises for the processing of Category 3 material must not be at the same site as premises processing Category 1 or Category 2 material, unless in a completely separate building.

2. However, the competent authority may authorise the temporary use of a Category 3 processing plant for the processing of Category 1 or Category 2 material when a widespread outbreak of an epizootic disease or other extraordinary and unforeseeable circumstances lead to a lack of capacity at a Category 1 or Category 2 processing plant.

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

3. Category 3 processing plants must have:

   (a) an installation to check the presence of extraneous matter, such as packaging material, metallic pieces, etc. in the animal by-products; and

   (b) if the volume of products treated requires regular or permanent presence of the competent authority, an adequately equipped lockable room for the exclusive use of the inspection service.

B. *Raw material*

▼M1

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

▼B

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

C. *Processing standards*

6. The critical control points that determine the extent of the heat treatments applied in processing must be identified for each processing method as specified in Annex V, Chapter III. The critical control points must at least include:

   — raw material particle size,

   — temperature achieved in the heat treatment process,

▼B

— pressure applied to the raw material, if applicable, and

— duration of the heat treatment process or feed rate to a continuous system.

Minimum process standards must be specified for each applicable critical control point.

7. Records must be maintained for at least two years to show that the minimum process values for each critical control point are applied.

8. Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept for at least two years to show the date of calibration of gauges/recorders.

9. Material that may not have received the specified heat treatment (for example, material discharged at start up, or leakage from cookers) must be recirculated through the heat treatment or collected and reprocessed.

D. *Processed products*

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

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

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

where:

n = number of samples to be tested;

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

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

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

▼M1

11. Unused or surplus processed products may after they have been permanently marked:

(a) be disposed of as waste by incineration or co-incineration in an incineration or co-incineration plant approved in accordance with Article 12;

(b) be disposed of in a landfill approved under Directive 1999/31/EC; or

(c) be transformed in a biogas plant or in a composting plant approved in accordance with Article 15.

▼B

CHAPTER II

Specific requirements for processed animal protein

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

A. *Processing standards*

▼M1

1. ►M14 Mammalian processed animal protein must have been submitted to processing method 1. However, porcine blood or fractions of porcine blood may be submitted instead to any of processing methods 1 to 5 or processing method 7 provided that in the case of processing method 7, a heat treatment throughout its substance at a minimum temperature of 80 ° C has been applied. ◄

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

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

▼B

2. Non-mammalian processed animal protein, with the exclusion of fishmeal, must have been submitted to any of processing methods 1 to 5 or 7.

3. Fishmeal must have been submitted:

(a) to any of the processing methods; or

(b) to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I, paragraph 10.

B. *Storage*

4. Processed animal protein must be packed and stored in new or sterilised bags or stored in properly constructed bulk bins.

5. Sufficient measures must be taken to minimise condensation inside bins, conveyors or elevators.

6. Products in conveyors, elevators and bins must be protected from casual contamination.

7. Processed animal protein handling equipment must be maintained in a clean and dry condition and should have adequate inspection points so that equipment can be examined for cleanliness. All storage facilities must be emptied and cleaned regularly, as production requirements require.

8. Processed animal protein must be kept dry. Leakages and condensation in the storage area must be prevented.

▼B

C. *Importation*

9. Member States must authorise the importation of processed animal protein:

(a) if it comes from third countries that appear on the list in Part II of Annex XI or, in the case of fishmeal, that appear on the list in Part III of Annex XI;

(b) if it comes from a processing plant that appears on the list referred to in Article 29(4);

(c) if it has been produced in accordance with this Regulation; and

▼M2

(d) if it is accompanied by a health certificate that conforms to the model set out in Chapter 1 of Annex X.

▼B

10. Before consignments are released for free circulation within the Community, the competent authority must sample imports of processed animal protein at the border inspection post to ensure compliance with the requirements of Chapter I, paragraph 10. The competent authority must:

(a) sample each consignment of products carried in bulk; and

(b) carry out random sampling of consignments of products packaged in the manufacturing plant of origin.

11. However, when six consecutive tests on bulk consignments originating in a given third country prove negative, the competent authority may carry out random sampling of subsequent bulk consignments from that third country. If one of these random samples proves positive, the competent authority carrying out the sampling must inform the competent authority of the country of origin so that it can take appropriate measures to remedy the situation. The competent authority of the country of origin must bring these measures to the attention of the competent authority carrying out the sampling. In the event of a further positive result from the same source, the competent authority must sample each consignment from the same source until six consecutive tests again prove negative.

12. Competent authorities must keep a record for at least two years of the results of sampling carried out on all consignments that have undergone sampling.

13. Where a consignment proves to be positive for *salmonella*, it must either:

(a) be dealt with in accordance with the procedure laid down by Article 17(2)(a) of Directive 97/78/EC ([1]); or

([1]) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

▼M15

(b) reprocessed in a processing plant approved pursuant to this Regulation or decontaminated by a treatment authorised by the competent authority. A list of permitted treatments may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). The consignment must not be released until it has been treated, tested for salmonella by the competent authority in accordance with Chapter I, paragraph 10, and a negative result obtained.

▼B

CHAPTER III

Specific requirements for blood products

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

A. *Raw material*

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

B. *Processing standards*

2. Blood products must have been submitted:

(a) to any of processing methods 1 to 5 or 7; or

(b) to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I, paragraph 10.

C. *Importation*

3. Member States must authorise the importation of blood products if they:

▼M2

(a) come from third countries that appear on the list of part V and part VI of Annex XI as appropriate;

▼B

(b) come from a processing plant that appears on the list referred to in Article 29(4);

(c) have been produced in accordance with this Regulation; and

▼M2

(d) if it is accompanied by a health certificate that conforms to the model set out in Chapter 4(B) of Annex X.

▼B

CHAPTER IV

Specific requirements for rendered fats and fish oil

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

A. *Processing standards*

▼M1

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

([1]) OJ L 26, 31.1.1977, p. 85.
([2]) OJ L 62, 15.3.1993, p. 49.

▼M1

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

▼B

B. *Importation of rendered fats*

2. Member States must authorise the importation of rendered fats if they:

(a) come from third countries appearing on the list in Part IV of Annex XI;

(b) come from a processing plant that appears on the list referred to in Article 29(4);

(c) have been produced in accordance with this Regulation;

(d) either:

(i) are entirely or partly derived from swine raw material and come from a country or a part of the territory of a country free from foot-and-mouth disease for the previous 24 months and free from classical swine fever and African swine fever for the previous 12 months,

(ii) are entirely or partly derived from poultry raw material and come from a country or a part of the territory of a country free from Newcastle disease and avian influenza for the previous six months,

(iii) are entirely or partly derived from ruminant raw material and come from a country or a part of the territory of a country free from foot-and-mouth disease for the previous 24 months and free from Rinderpest for the previous 12 months, or

(iv) where there has been an outbreak of one of the abovementioned diseases during the relevant period mentioned above, have been subjected to one of the following heat treatment processes:

— at least 70 ºC for at least 30 minutes, or

— at least 90 ºC for at least 15 minutes,

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

▼M2

(e) are accompanied by a health certificate that conforms to the model set out in Chapter 10(A) of Annex X.

▼B

C. *Importation of fish oil*

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

(a) comes from third countries appearing on the list in Part III of Annex XI;

(b) comes from a processing plant that appears on the list referred to in Article 29(4);

▼B

(c) has been produced in accordance with this Regulation; and

▼M2

(d) is accompanied by a health certificate that conforms to the model set out in Chapter 9 of Annex X.

▼B

D. *Hygiene requirements*

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

▼M17

CHAPTER V

Specific requirements for milk, milk products, colostrum and colostrum products

▼M12

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

A. *Processing standards*

1. Milk must be subjected to one of the following treatments:

1.1. sterilisation at an F_0 ([1]) value of three or more;

1.2. UHT ([2]) combined with one of the following:

(a) a subsequent physical treatment, by:

(i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

(ii) lowering the pH below 6 for at least 1 hour;

(b) the condition that the milk or milk product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin;

([1]) F_0 is the calculated killing effect on bacterial spores. An F_0 value of 3,00 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250 °F) in three minutes with instantaneous heating and chilling.

([2]) *UHT* = Ultra High Temperature treatment at 132 °C for at least one second.

▼M12

1.3. HTST ([1]) applied twice;

1.4. HTST ([1]) in combination with one of the following:

(a) a subsequent physical treatment, by:

(i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

(ii) lowering the pH below 6 for at least 1 hour;

(b) the condition that the milk or milk product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin.

2. Milk products must either be subjected to at least one of the treatments provided for in paragraph 1 or be produced from milk treated in accordance with paragraph 1.

▼M17

3. Whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with paragraph 1 must:

(a) either be collected at least 16 hours following milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings; or

(b) have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin.

▼M12

4. In addition to the requirements laid down in paragraphs 1, 2 and 3, milk and milk products must meet the following requirements:

4.1. after completion of the processing, every precaution must be taken to prevent contamination of the products;

4.2. the final product must be labelled so as to indicate that it contains Category 3 material and is not intended for human consumption, and

(a) packed in new containers; or

(b) transported in bulk in containers or other means of transport that before use were thoroughly cleansed and disinfected using a disinfectant approved for the purpose by the competent authority.

▼M15

5. Raw milk and colostrum must be produced under conditions offering adequate guarantees as regards animal health. Such conditions may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼M17

6. Colostrum and colostrum products must:

6.1. be obtained from bovine animals kept on a holding on which all bovine herds are recognised as officially tuberculosis-free, officially brucellosis-free and officially enzootic-bovine-leukosis-free as defined in Article 2(2)(d), (f) and (j) of Directive 64/432/EEC;

([1]) HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.

▼M17

6.2. have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin;

6.3. have undergone a single HTST treatment [1];

6.4. comply with the requirements set out in paragraph 4.

▼M12

B. *Importation*

1. Member States shall authorise imports of milk and milk products subject to compliance with the following conditions:

▼M17

1.1. they come from third countries appearing on the list in Part I(A) of Annex XI;

▼M12

1.2. they come from a processing plant which appears on the list referred to in Article 29(4);

1.3. they are accompanied by a health certificate conforming to the model laid down in Chapter 2 of Annex X;

1.4. they have undergone at least one of the treatments provided for in paragraphs 1.1, 1.2, 1.3 and point (a) of paragraph 1.4 of Part A;

1.5. they comply with paragraphs 2 and 4, and, in the case of whey, paragraph 3 of Part A.

▼M17

2. By way of derogation from paragraph 1.4, Member States shall authorise imports of milk and milk products from third countries so authorised in Column 'A' of Annex I to Commission Decision 2004/438/EC [2] provided that the milk and milk products have undergone a single HTST treatment and:

(a) have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country; or

(b) have been presented at an EU border inspection post at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country.

2a. Member States shall authorise imports of colostrum or colostrum products of bovine animals provided that:

2a.1. they come from a third country appearing on the list in Part I(B) of Annex XI;

2a.2. they comply with the conditions set out in paragraphs 1.2 and 1.3;

2a.3. they have undergone a single HTST treatment [1] and:

(a) have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country; or

(b) have been presented at an EU border inspection post at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country;

[1] HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test in bovine milk.

[2] OJ L 154, 30.4.2004, p. 72.

▼M17

2a.4. they have been obtained from bovine animals subject to regular veterinary inspections to ensure that animals come from holdings on which all bovine herds are:

(a) either recognised as officially tuberculosis free and officially brucellosis free as defined in Article 2(2)(d) and (f) of Directive 64/432/EEC or not restricted under the national legislation of the third country of origin of the colostrum regarding eradication of tuberculosis and brucellosis; and

(b) either recognised as official enzootic-bovine-leukosis-free as defined in Article 2(2)(j) of Directive 64/432/EEC or included in an official system for the control of enzootic-bovine-leukosis and there has been no evidence as a result of clinical and laboratory testing of this disease in the herd during the past two years;

2a.5. after completion of the processing, every precaution has been taken to prevent contamination of the colostrum or colostrum products;

2a.6. the final product has been labelled so as to indicate that it contains Category 3 material and is not intended for human consumption, and that it has been:

(a) packed in new containers; or

(b) transported in bulk in containers or other means of transport that before use were thoroughly cleansed and disinfected using a disinfectant approved for the purpose by the competent authority.

▼M15

3. 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 by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼B

CHAPTER VI

Specific requirements for gelatin and hydrolysed protein

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

A. *Processing standards for gelatin*

1. (a) Gelatin must be produced by a process that ensures that unprocessed Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatin must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

(b) After having been subjected to the processes referred to in subparagraph (a), gelatin may undergo a drying process and, where appropriate, a process of pulverisation or lamination.

(c) The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.

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

(a) a room must be provided for storing materials for wrapping and packaging;

▼B

(b) wrapping and packaging must take place in a room or in a place intended for that purpose;

and

(c) wrappings and packages containing gelatin must carry the words 'gelatin suitable for animal consumption'.

B. *Processing standards for hydrolysed protein*

▼M1

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

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

(a) exposure of the material to a pH of more than 11 for more than three hours at a temperature of more than 80 ºC and subsequently by heat treatment at more than 140 ºC for 30 minutes at more than 3,6 bar;

(b) exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140 ºC for 30 minutes at 3 bar; or

▼M15

(c) an equivalent production process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼B

C. *Importation*

▼M1

4. Member States must authorise the importation of gelatine and hydrolysed proteins if they:

(a) come from third countries that appear on the list in Part XI of Annex XI;

(b) come from a processing plant that appears on the list referred to in Article 29(4);

(c) have been produced in accordance with this Regulation; and

▼M2

(d) are accompanied by a health certificate that conforms to the models set out in Chapter 11 and Chapter 12 of Annex X as appropriate.

▼M1

CHAPTER VII

Specific requirements for dicalcium phosphate

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

A. *Processing standards*

▼M15

1. Dicalcium phosphate must be produced by a process that:

(a) ensures that all Category 3 bone-material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;

▼M15

(b) following the procedure provided for in point (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and

(c) finally, air-dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C, or

by an equivalent process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼M1

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

B. *Importation*

3. Member States must authorise the importation of dicalcium phosphate if it:

(a) comes from third countries that appear on the list in Part XI of Annex XI;

(b) comes from a processing plant that appears on the list referred to in Article 29(4);

(c) has been produced in accordance with this Regulation; and

▼M2

(d) is accompanied by a health certificate that conforms to the model set out in Chapter 12 of Annex X.

▼M1

CHAPTER VIII

Specific requirements for tricalcium phosphate

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

A. *Processing standards*

▼M15

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

(a) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);

(b) continuous cooking with steam at 145 °C during 30 minutes at 4 bars;

(c) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation; and

(d) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200 °C; or

by an equivalent production process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

▼M1

B. *Importation*

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

(a) comes from third countries that appear on the list in Part XI of Annex XI;

▼M1

(b) comes from a processing plant that appears on the list referred to in Article 29(4);

(c) has been produced in accordance with this Regulation; and

▼M2

(d) is accompanied by a health certificate that conforms to the model set out in Chapter 12 of Annex X.

CHAPTER IX

Specific requirements for collagen

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

A. *Processing standards*

1. Collagen must be produced by a process ensuring that unprocessed category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion. After that treatment collagen may undergo a drying process.

2. The use of preservatives, other than those permitted under Community legislation shall be prohibited.

3. Collagen must be wrapped, packaged, stored and transported under satisfactory hygiene conditions. In particular:

(a) a room must be provided for storing materials for wrapping and packaging;

(b) wrapping and packaging must take place in a room or in a place intended for that purpose; and

(c) wrapping and packages containing collagen must be labelled with the words ‘collagen suitable for animal consumption’.

B. *Importation*

4. Member States must authorise the importation of collagen if it:

(a) comes from a third country that appears on a Community list set out in Part XI of Annex XI;

(b) comes from a plant that appears on the list referred to in Article 29(4);

(c) has been produced in accordance with this Regulation; and

(d) is accompanied by a health certificate that conforms to the model set out in Chapter 11 of Annex X.

CHAPTER X

Specific requirements for egg products

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

A. *Processing standards*

1. Egg products must have been:

(a) submitted to any of processing Methods 1 to 5 or 7; or

(b) submitted to a method and parameters which ensure that the products comply with the microbiological standards set in Chapter I, paragraph 10; or

▼**M2**

(c) treated in accordance with Chapter V of the Annex to Council Directive 89/437/EC ([1]) laying down hygiene and health problems affecting the production and the placing on the market of egg products.

B. *Importation*

2. Member States must authorise the importation of egg products if they:

(a) come from a third country that appears on a Community list set out in Part XVI of Annex XI;

(b) come from a plant that appears on the list referred to in Article 29(4);

(c) have been produced in accordance with this Regulation; and

(d) are accompanied by a health certificate that conforms to the model set out in Chapter 15 of Annex X.

([1]) OJ L 212, 22.7.1989, p. 87.

▼B

ANNEX VIII

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

CHAPTER I

Requirements for the approval of petfood and technical plants

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

1. they must have adequate facilities for storing and treating incoming material in complete safety; and

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

CHAPTER II

Requirements for petfood and dogchews

A. *Raw material*

▼M9

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

▼B

B. *Processing standards*

2. Canned petfood must be subjected to heat treatment to a minimum Fc value of 3.

▼M11

3. Processed petfood other than canned petfood must:

(a) be subjected to a heat treatment of at least 90 °C throughout the substance of the final product;

(b) be subjected to a heat treatment to at least 90 °C of the ingredients of animal origin; or

(c) be produced as regards ingredients of animal origin exclusively using:

(i) meat or meat products which have been subject to a heat treatment of at least 90 °C throughout their substance;

(ii) the following animal by-products or processed products which have been processed in accordance with the requirements of this Regulation: milk and milk based products, gelatine, hydrolysed protein, egg products, collagen, blood products, processed animal protein including fishmeal, rendered fat, fish oils, dicalcium phosphate, tricalcium phosphate or flavouring innards.

▼M11

After the heat treatment, every precaution must be taken to ensure that such processed petfood is not exposed to contamination.

The processed petfood must be packaged in new packaging.

▼M9

4. Dogchews must be subjected to a treatment during processing sufficient to destroy pathogenic organisms, including salmonella. After that treatment, every precaution must be taken to ensure that such dogchews are not exposed to contamination. The dogchews must be packed in new packaging.

▼B

5. Raw petfood must be packed in new packaging preventing any leakage. Effective steps must be taken to ensure that the product is not exposed to contamination throughout the production chain and up to the point of sale. The wording 'petfood only' must be visibly and legibly displayed on the packaging.

▼M1

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

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

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

Where:

n = number of samples to be tested;

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

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

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

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

▼B

C. *Importation*

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

(a) come from third countries that appear on the list in Part X of Annex XI;

(b) come from petfood plants approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;

(c) have been produced in accordance with this Regulation;

(d) are accompanied:

(i) in the case of canned petfood, by a certificate that conforms to the model laid down in Chapter 3(A) of Annex X,

▼B

(ii) in the case of processed petfood other than canned petfood, by a certificate that conforms to the model laid down in Chapter 3(B) of Annex X,

(iii) in the case of dogchews, by a certificate that conforms to the model laid down in Chapter 3(C) of Annex X, or

(iv) in the case of raw petfood, by a certificate that conforms to the model laid down in Chapter 3(D) of Annex X.

CHAPTER III

Requirements for manure, processed manure and processed manure products

I. *Unprocessed manure*

A. Trade

1. (a) Trade in unprocessed manure of species other than poultry or equidae is prohibited, except for manure:

(i) from an area which is not subject to restrictions by virtue of a serious transmissible disease, and

(ii) intended for application, under the supervision of the competent authorities, to land forming part of a single holding located on both sides of the border of two Member States.

(b) However, the competent authority may grant specific approval for the introduction on to its territory of:

(i) manure intended for processing in a technical plant or a biogas plant or in a composting plant approved by the competent authority in accordance with this Regulation with a view to the manufacture of the products referred to under Section II below. The competent authority must take account of the origin of the manure when approving such plants; or

(ii) manure intended for applying to land on a holding. Such trade can only occur with the consent of the competent authorities of both the Member States of origin and destination. When considering giving consent, the competent authorities must have particular regard to the origin of the manure, its destination and animal health and safety considerations.

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

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

(a) the manure must originate in an area which is not subject to restrictions by virtue of Newcastle disease or avian influenza;

▼B

(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 15(2) of Directive 90/539/EEC ([1]); and

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

▼M9

3. Unprocessed manure of equidae which is traded must not originate from a holding subject to animal health restrictions pertaining to glanders, vesicular stomatitis, anthrax or rabies in accordance with Article 4 (5) of Directive 90/426/EEC.

▼B

B. Importation

▼M9

4. The importation of unprocessed manure is prohibited.

▼B

II. *Processed manure and processed manure products*

A. Placing on the market

▼M7

5. The placing on the market of processed manure and processed manure products shall be subject to the following conditions set out in points (a) to (e):

(a) They must come from a technical plant, a biogas plant or a composting plant approved by the competent authority in accordance with this Regulation.

(b) They must have been subjected to a heat treatment process of at least 70 °C for at least 60 minutes and they must have been subjected to reduction in spore-forming bacteria and toxic formation.

(c) However, the competent authority may authorise the use of other standardised process parameters than those described in (b) provided an applicant demonstrates that such parameters ensure minimising of biological risks. This demonstration shall include a validation, which shall be carried out as follows:

(i) Identification and analysis of possible hazards including the impact of input material, based on a full definition of the processing conditions, and a risk assessment, which evaluates how the specific processing conditions are achieved in practice under normal and atypical situations.

(ii) Validation of the intended process

(ii-1) by measuring the reduction of viability/infectivity of endogenous indicator organisms during the process, where the indicator is:

— consistently present in the raw material in high numbers,

— not less heat resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor,

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

▼M7

— relatively easy to quantify and relatively easy to identify and confirm;

or

(ii-2) by measuring the reduction of viability/infectivity, during exposure, of a well-characterised test organism or virus introduced in a suitable test body into the starting material.

(iii) The validation referred to in point (ii) must demonstrate that the process achieves the following overall risk reduction:

— for thermal and chemical processes by reduction of *Enterococcus faecalis* by at least 5 log10 and by reduction of infectivity titre of thermo resistant viruses such as *parvovirus*, where they are identified as a relevant hazard, by at least 3 log10,

— for chemical processes also by reduction of resistant parasites such as eggs of *ascaris sp.* by at least 99,9 % (3 log10) of viable stages.

(iv) Designing a complete control programme including procedures for monitoring the process.

(v) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a plant as well as other critical control points must be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant. Records must be made available to the competent authority on request.

Information relating to a process authorised under this point must be made available to the Commission on request.

(d) Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards:

Escherichia coli: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

or

Enterococcaceae: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

and

Representative samples of the manure taken during or on withdrawal from storage at the technical, biogas or composting plant must comply with the following standards:

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

where:

n = number of samples to be tested;

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

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

▼M7

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

Processed manure or processed manure products not complying with the above requirements shall be regarded as unprocessed;

(e) They must be stored in such a way that once processed contamination or secondary infection and dampness is minimised. They must therefore be stored in:

(i) well-sealed and insulated silos, or

(ii) properly sealed packs (plastic bags or 'big bags').

▼B

B. Importation

6. Member States must authorise importation of processed manure and processed manure products if they:

(a) come from third countries that appear on the list in Part IX of Annex XI;

(b) come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in this Regulation;

(c) satisfy the requirements of paragraph 5 above; and

▼M9

(d) are accompanied by a health certificate that conforms to the model laid down in Chapter 17 of Annex X.

▼B

III. *Guano*

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

▼M13

CHAPTER IV

Requirements for blood and blood products, excluding from equidae, for the manufacture of technical products

A. *Importation*

1. Imports of blood are subject to the requirements laid down in Chapter XI.

2. Member States must authorise imports of blood products for the manufacture of technical products, including material originating from animals to which substances prohibited pursuant to Directive 96/22/EC have been administered, if they:

(a) come from third countries that appear on the list in Part VI (A) of Annex XI as applicable;

(b) come from a technical plant meeting the specific conditions laid down in this Regulation or from the establishment of collection;

(c) are accompanied by a health certificate that conforms to the model set out in Chapter 4(C) or Chapter 4(D) of Annex X as appropriate.

3. The blood from which blood products for the manufacture of technical products are produced must have been collected:

(a) in slaughterhouses approved in accordance with Community legislation;

▼**M13**

(b) in slaughterhouses approved and supervised by the competent authority of the third country; or

(c) from live animals in facilities approved and supervised by the competent authority of the third country.

4. In the case of blood products for the manufacture of technical products which have been derived from animals belonging to the *taxa Artiodactyla, Perissodactyla* and *Proboscidea*, including their crossbreeds, they must comply with the conditions of either points (a) or (b):

(a) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in point (b):

(i) heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,

(ii) irradiation at 25 kGy by gamma rays, followed by an effectiveness check,

(iii) heat treatment of at least 80 °C throughout their substance, followed by an effectiveness check,

(iv) in the case of animals other than *Suidae* and *Tayassuidae* only: change in pH to pH 5 for two hours, followed by an effectiveness check;

(b) in case of blood products not treated in accordance with point (a) the products originate from a country or region:

(i) where no case of rinderpest, *peste des petits* ruminants and Rift Valley fever has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months,

(ii) where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination has not been carried out against this disease for at least 12 months, or

where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination programmes against foot-and-mouth disease are being officially carried out and controlled in domestic ruminant animals for at least 12 months; in this case, following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the technical plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

In addition to points (i) and (ii), in the case of animals other than *Suidae* and *Tayassuidae*, one of the following conditions must be complied with:

— in the country or region of origin no case of vesicular stomatitis and bluetongue (including the presence of seropositive animals) has been recorded for 12 months and vaccination has not been carried out against those diseases for at least 12 months in the susceptible species,

▼**M13**

— following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the technical plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

In addition to points (i) and (ii), in the case of *Suidae* and *Tayassuidae*, in the country or region of origin no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for at least 12 months, vaccination has not been carried out against those diseases for at least 12 months and one of the following conditions are complied with:

— in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for 12 months and vaccination has not been carried out against this disease for at least 12 months in the susceptible species,

— following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the technical plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

5. In the case of blood products for the manufacture of technical products which have been derived from poultry and other avian species, they must comply with the conditions of either points (a) or (b):

(a) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in point (b):

(i) heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,

(ii) irradiation at 25 kGy by gamma rays, followed by an effectiveness check,

(iii) heat treatment of at least 70 °C throughout their substance, followed by an effectiveness check;

(b) in case of blood products not treated in accordance with point (a) the products originate from a country or region:

(i) which has been free from Newcastle disease and highly pathogenic avian influenza as defined in the Terrestrial Animal Health Code of the OIE,

(ii) which during the last 12 months has not carried out vaccination against avian influenza,

(iii) where the poultry or other avian species from which the products derive have not been vaccinated against Newcastle disease with vaccines prepared from a Newcastle disease master strain showing a higher pathogenicity than lentogenic virus strains.

▼M16

CHAPTER V

Requirements for blood and blood products from equidae for technical purposes

A. *Placing on the market*

The placing on the market for technical purposes of blood and blood products from equidae shall be subject to the following conditions:

1. Blood may be placed on the market provided that:

(a) it has been collected from equidae which:

(i) at inspection on the date of blood collection do not show clinical signs of any of the compulsorily notifiable diseases listed in Annex A to Directive 90/426/EEC and of Equine influenza, Equine piroplasmosis, Equine rhinopneumonitis and Equine viral arteritis listed in point 4 of Article 1.2.3. of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), 2009 Edition;

(ii) have been kept for at least 30 days prior to the date of and during blood collection on holdings under veterinary supervision which were not subject to a prohibition order pursuant to Article 4(5) of Directive 90/426/EEC or restrictions pursuant to Article 5 thereof;

(iii) for the periods laid down in Article 4(5) of Directive 90/426/EEC had no contact with equidae from holdings which were subject to a prohibition order for animal health reasons pursuant to that Article and for at least 40 days prior to the date of and during blood collection had no contact with equidae from a Member State or third country not considered free of African horse sickness in accordance with Article 5(2)(a) of that Directive;

(b) it has been collected under veterinary supervision either:

(i) in slaughterhouses approved in accordance with Regulation (EC) No 853/2004; or

(ii) in facilities approved, furnished with a veterinary approval number and supervised by the competent authority for the purpose of collecting blood from equidae for the production of blood products for technical purposes.

2. Blood products may be placed on the market provided that:

(a) all precautions have been taken to avoid contamination of the blood products with pathogenic agents during production, handling and packaging;

(b) the blood products have been produced from blood which:

(i) either fulfils the conditions set out in paragraph 1(a); or

(ii) has been subjected to at least one of the following treatments, followed by an effectiveness check, for the inactivation of possible causative pathogens for African horse sickness, equine encephalomyelitis of all types including Venezuelan equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and glanders (*Burkholderia mallei*):

— heat treatment at a temperature of 65 °C for at least three hours;

— irradiation at 25 kGy by gamma rays;

▼**M16**

— change in pH to pH 5 for two hours;

— heat treatment of at least 80 °C throughout their substance.

3. Blood and blood products from equidae must be packed in sealed impermeable containers which:

(a) are clearly labelled 'BLOOD AND BLOOD PRODUCTS FROM EQUIDAE, NOT FOR HUMAN OR ANIMAL CONSUMPTION';

(b) bear the approval number of the establishment of collection referred to in paragraph 1(b).

B. *Importation*

Member States shall authorise imports of blood and blood products from equidae for technical purposes subject to the following conditions:

1. The blood must comply with the conditions set out in paragraph 1(a) of Section A and must be collected under veterinary supervision either in:

(a) slaughterhouses

(i) approved in accordance with Regulation (EC) No 853/2004; or

(ii) approved and supervised by the competent authority of the third country; or

(b) facilities approved, furnished with a veterinary approval number and supervised by the competent authority of the third country for the purpose of collecting blood from equidae for the production of blood products for technical purposes.

2. The blood products must comply with the conditions set out in paragraph 2 of Section A.

In addition, the blood products referred to in paragraph 2(b)(i) of Section A must have been produced from blood collected from equidae which have been kept for a period of at least three months, or since birth if less than three months old, prior to the date of collection on holdings under veterinary supervision in the third country of collection which during that period and the period of blood collection has been free of:

(a) African horse sickness in accordance with Article 5(2)(a) of Directive 90/426/EEC;

(b) Venezuelan equine encephalomyelitis for a period of at least two years;

(c) glanders:

(i) for a period of three years; or

(ii) for a period of six months where the animals have shown no clinical signs of glanders (*Burkholderia mallei*) during the post-mortem inspection in the slaughterhouse referred to in paragraph 1(a), including a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum;

(d) vesicular stomatitis for six months.

3. Blood products must come from a technical plant approved by the competent authority of the third country meeting the specific conditions laid down in Article 18 of Regulation (EC) No 1774/2002.

▼M16

4. Blood and blood products must come from a third country that appears on the list referred to in the following Parts of Annex XI:

(a) Part XIII(A) where blood has been collected in accordance with paragraph 1 of Section A or where blood products have been produced in accordance with paragraph 2(b)(i) of Section A; or

(b) Part XIII(B) where they have been treated in accordance with paragraph 2(b)(ii) of Section A.

5. Blood and blood products shall be packed and labelled in accordance with paragraph 3(a) of Section A and shall be accompanied by a health certificate that conforms to the model set out in Chapter 4(A) of Annex X, duly completed and signed by the official veterinarian.

▼B

CHAPTER VI

Requirements for hides and skins of ungulates

A. *Scope*

1. The provisions of this Chapter do not apply:

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(a) to hides and skins of ungulates complying with the requirements of Regulation (EC) No 853/2004 of 29 April 2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin ([1]);

▼B

(b) to hides and skins of ungulates having undergone the complete process of tanning;

(c) to ‘wet blue’;

(d) to ‘pickled pelts’; and

(e) to limed hides (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).

2. Within the scope defined in paragraph 1, the provisions of this Chapter apply to fresh, chilled and treated hides and skins. For the purpose of this Chapter, ‘treated hides and skins’ means hides and skins that have been:

(a) dried;

(b) dry-salted or wet-salted for at least 14 days prior to dispatch;

(c) salted for seven days in sea salt with the addition of 2 % of sodium carbonate;

(d) dried for 42 days at a temperature of at least 20 °C; or

▼M15

(e) preserved by a process other than tanning specified by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

([1]) OJ L 139, 30.4.2004, p. 55; corrected version (OJ L 226, 25.6.2004, p. 22).

▼B

B. *Trade*

▼M9

3. Trade in fresh or chilled hides and skins is subject to the same health conditions as those applicable to fresh meat pursuant to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ([1]).

▼B

4. Trade in treated hides and skins is authorised on condition that the commercial document provided for in Annex II accompanies each consignment and attests that:

(a) the hides and skins have been treated in accordance with paragraph 2; and

(b) the consignment has not been in contact with other animal products or live animals presenting a risk of spreading a serious transmissible disease.

C. *Importation*

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

(a) they have been obtained from animals referred to in Article 6(1)(b) or (c);

▼M9

(b) they come from a third country or, in the case of regionalisation in accordance with Community legislation, from a part of a third country, appearing on the list set out in Part XIV(A) of Annex XI and which, as appropriate to the species concerned:

▼M2

(i) for at least 12 months before dispatch, has been free from the following diseases:

— classical swine fever,

— African swine fever, and

— rinderpest, and

(ii) has been free for at least 12 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;

▼B

(c) they have been obtained from:

(i) animals that have remained in the territory of the country of origin for at least three months before being slaughtered or since birth in the case of animals less that three months old,

(ii) in the case of hides and skins from bi-ungulates, animals that come from holdings in which there has been no outbreak of foot-and-mouth disease in the previous 30 days, and around which within a radius of 10 km there has been no case of foot-and-mouth disease for 30 days,

(iii) in the case of hides and skins from swine, animals that come from holdings in which there has been no outbreak of swine vesicular disease in the previous 30 days, or of classical or African swine fever in the previous 40 days, and around which within a radius of 10 km there has been no case of these diseases for 30 days, or

([1]) OJ L 18, 23.1.2003, p. 11.

▼B

(iv) animals that have passed the ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter and have shown no evidence of foot-and-mouth disease, rinderpest, classical swine fever, African swine fever or swine vesicular disease;

(d) they have undergone all precautions to avoid recontamination with pathogenic agents; and

(e) a certificate conforming to the model laid down in Chapter 5(A) of Annex X accompanies them.

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

(a) they have been obtained from animals referred to in Article 6(1)(b), (c) or (k);

▼M9

(b) they come either from:

(i) a third country or, in the case of regionalisation in accordance with Community legislation, from a part of a third country, appearing on the list set out in Part XIV(B) of Annex XI from which imports of fresh meat of the corresponding species are authorised and they have been treated in accordance with paragraph 2(a), (b) and (c) of A; or

(ii) a third country appearing on the list set out in Part XIV(B) of Annex XI and they have been treated in accordance with paragraph 2(c) or (d) of A; or

(iii) equidae or ruminant animals from a third country appearing on the list set out in Part XIV(C) of Annex XI, which have been treated in accordance with paragraph 2(a), (b) and (c) of A and after treatment have been kept separate for at least 21 days;

(c) in the case of salted hides and skins transported by ship, they have been treated in accordance with paragraphs 2(b) or (c) of A and have been kept separated after treatment during transportation for at least 14 days in the case of paragraph (b) or seven days in the case of paragraph (c) before importation and the health certificate accompanying the consignment attests such treatment and the duration of the transportation; and

(d) a health certificate conforming to the model health certificate laid down in Chapter 5(B) of Annex X, or, in the case of hides and skins referred to in paragraph 6(b)(iii) of C of this Annex, an official declaration conforming to the model laid down in Chapter 5 (C) of Annex X, accompanies them.

▼B

7. Fresh, chilled or treated hides and skins of ungulates must be imported in containers, road vehicles, railway wagons or bales sealed by the competent authority of the third country of dispatch.

▼B

CHAPTER VII

Requirements for game trophies

A. *Raw material*

1. Without prejudice to the measures adopted pursuant to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein [1], game trophies:

(a) of ungulates and birds having undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures; and

(b) of species other than ungulates and birds,

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

2. Without prejudice to the measures adopted pursuant to Regulation (EC) No 338/97, game trophies of ungulates and birds not having undergone the treatment mentioned in paragraph 1(a) are subject to the following conditions. They must:

(a) come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible; or

(b) comply with the conditions laid down in paragraphs 3 or 4 if they come from animals originating in an area subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible.

3. In respect of game trophies consisting solely of bone, horns, hooves, claws, antlers or teeth, the trophies must:

(a) have been immersed in boiling water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

(b) have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned;

(c) be packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and

(d) be accompanied by a document or certificate certifying that the above conditions have been met.

4. In respect of game trophies consisting solely of hides or skin, the trophies must:

(a) have been either:

(i) dried, or

(ii) dry- or wet-salted for a minimum of 14 days before dispatch, or

▼M15

(iii) preserved by a treatment other than tanning approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

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

▼B

(b) be packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and

(c) be accompanied by a document or certificate certifying that the above conditions have been met.

B. *Importation*

5. Member States must authorise the importation of treated game trophies from birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, from third countries if:

(a) a certificate that conforms to the model laid down in Chapter 6(A) of Annex X accompanies them; and

(b) they comply with the requirements of paragraphs 3 and 4. However, in the case of dry-salted or wet-salted skins transported by ship, the skins need not be salted 14 days before dispatch, provided that they are salted for 14 days before importation;

▼M2

(c) they come from a third country appearing on the list set out in part XV (A) of Annex XI.

▼B

6. Member States must, in accordance with the requirements of paragraph 7, authorise the importation of game trophies from birds and ungulates consisting of entire anatomical parts, not having been treated in any way, from third countries:

▼M2

(a) that appear on the lists set out in part XV(B) and (C) of Annex XI as appropriate; and

▼B

(b) from which the importation of all categories of fresh meat of the corresponding species is authorised.

7. Member States must authorise importation of the game trophies referred to in paragraph 6 if:

(a) they come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible;

(b) they were packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and

(c) a certificate conforming to the model laid down in Chapter 6(B) of Annex X accompanies them.

▼B

CHAPTER VIII

Requirements for wool, hair, pig bristles, feathers and parts of feathers

A. *Raw material*

▼M1

1. (a) Unprocessed wool, unprocessed hair, unprocessed pig bristles and unprocessed feathers and parts of feathers must have been obtained from animals referred to in Article 6(1)(c) or (k). They must be securely enclosed in packaging and dry. However, in the case of unprocessed feather and part of feathers sent directly from the slaughterhouse to the processing plant, the competent authority may allow derogation from the dry requirement, provided that:

(i) all necessary measures are taken to avoid any possible spread of disease;

(ii) the transport takes place in leak-proof containers and/or vehicles which must be cleansed and disinfected immediately after each use; and

(iii) the Member State notifies the Commission when such derogation is given.

(b) Movements of pig bristles from regions in which African swine fever is endemic are prohibited except for pig bristles that have:

(i) been boiled, dyed or bleached; or

(ii) undergone some other form of treatment which is certain to kill pathogenic agents, provided that evidence to this effect is submitted in the form of a certificate from the veterinarian responsible for the place of origin. Factory washing may not be regarded as a form of treatment for the purposes of this provision.

▼B

2. The provisions of paragraph 1 do not apply to decorative feathers or feathers:

(a) carried by travellers for their private use; or

(b) in the form of consignments sent to private individuals for non-industrial purposes.

B. *Importation*

3. Member States must authorise the importation of pig bristles from third countries or, in case of regionalisation according to Community legislation, regions thereof, if:

(a) the pig bristles were obtained from animals originating, and slaughtered in a slaughterhouse, in the country of origin; and

(b) either:

(i) where no case of African swine fever has occurred during the previous 12 months, a certificate conforming to the model laid down in Chapter 7(A) of Annex X accompanies the consignment; or

(ii) where one or more cases of African swine fever have occurred during the previous 12 months, a certificate conforming to the model laid down in Chapter 7(B) of Annex X accompanies the consignment;

▼M2

(c) they come from a third country that appears on the list of part VIII of Annex XI as appropriate.

▼B

4. ►M9 Member States must authorise the importation of unprocessed wool and hair, if they are: ◄

(a) securely enclosed in packaging and dry; and

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

▼M9

5. The importation of unprocessed feathers and parts of feathers is prohibited.

Member States must authorise the importation of processed feathers and parts of feathers if:

(a) they are treated decorative feathers, treated feathers carried by travellers for their private use or consignments of treated feathers sent to private individuals for non-industrial purposes; or

(b) they are accompanied by a commercial document stating that the feathers or parts of feathers have been treated with a steam current or by another method ensuring the inactivation of pathogens and are securely enclosed in packaging and dry.

▼M2

CHAPTER IX

Requirements for apiculture products

A. *Raw material*

▼M9

1. Apiculture by-products intended exclusively for use in apiculture must:

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(a) not come from an area which is subject of a prohibition order associated with an occurrence of:

(i) American foulbrood (*Paenibacillus larvae larvae*), except where the competent authority has assessed the risk to be negligible, issued a specific authorisation for use only in that Member State, and taken all other necessary measures to ensure no spread of that disease;

(ii) acariosis (*Acarapis woodi* (Rennie), except where the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC [1];

(iii) small hive beetle (*Aethina tumida*); or

(iv) Tropilaelaps spp. (*Tropilaelaps* spp); and

(b) meet the requirements provided for in Article 8(a) of Directive 92/65/EEC.

B. *Importation*

2. As the small hive beetle and *Tropilaelaps* spp. are not present in the Community, the following additional safeguards concerning importation of apiculture products have to be laid down.

[1] Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

▼M9

3. Member States must authorise the importation of apiculture by-products, other than beeswax in the form of honeycomb, intended for use in apiculture if they:

(a) come from third countries that appear on the list in Part XII of Annex XI;

(b) either:

(i) have been subjected to a temperature of –12 °C or lower for at least 24 hours; or

(ii) in the case of wax, the material has been refined or rendered before importation; and

(c) are accompanied by a health certificate that conforms to the model set out in Chapter 13 of Annex X.

4. Member States must authorise the importation of beeswax for technical purposes, other than beeswax in the form of honeycomb, if it:

(a) has been refined or rendered before importation; and

(b) is accompanied by a commercial document attesting that refinement or rendering.

5. The importation of beeswax in the form of honeycomb shall be prohibited.

▼B

CHAPTER X

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

1. Member States must authorise the importation of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) to produce technical products if:

(a) the products are dried before export and not chilled or frozen;

(b) the products are conveyed only by land and sea from their country of origin direct to a border inspection post in the Community and are not transhipped at any port or place outside the Community;

(c) following the document checks provided for in Directive 97/78/EC, the products are conveyed directly to the technical plant;

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(d) they come from a third country appearing on the list set out in part XVII of Annex XI.

▼B

2. Each consignment must be accompanied by:

(a) a commercial document stamped by the competent authority supervising the establishment of origin, including the following information:

(i) the country of origin,

(ii) the name of the establishment of production,

(iii) the nature of the product (dried bone/dried bone product/dried horns/dried horn products/dried hooves/dried hoof products), and

▼B

(iv) the fact that the product was:

— derived from healthy animals slaughtered in a slaughterhouse, or

— dried for 42 days at an average temperature of at least 20 °C, or

— heated for one hour to at least 80 °C to the core before drying, or

▼M2

— ashed for one hour to at least 800 °C to the core before drying, or

▼B

— underwent an acidification process such that the pH was maintained at less than 6 to the core for at least one hour before drying, and

is not intended at any stage to be diverted for any use in food, feed material, organic fertilizers or soil improvers; and

▼M2

(b) a declaration of the importer that conforms to the model laid down in Chapter 16 of Annex X and that 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.

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3. On dispatch to the Community territory, the material must be enclosed in sealed containers or vehicles or carried in bulk in a ship. If transported in containers, the containers, and in all cases all the accompanying documents, must bear the name and the address of the technical plant.

▼M2

4. Following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the material must be transported direct to the technical plant.

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

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CHAPTER XI

▼M8

Requirements for animal by-products for the manufacture of feed including petfood, and of technical products, excluding intermediate products as referred to in Article 1 of Commission Regulation (EC) No 2007/2006

▼M2

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

1. come from third countries appearing on the lists set out in part VI and VII(A) and (B) of Annex XI as appropriate;

2. consist only of animal by-products referred to in Article 6(1)(a) to (j) and/or, when intended to be used for petfood, material derived from animals treated as referred to in the second paragraph of Article 28;

▼M9

however, animal by-products for use in feed for farmed fur animals or for use in raw petfood must consist of animal by-products referred to in Article 6(1)(a) and (b) only;

▼M2

3. have been deep-frozen at the plant of origin or have been preserved in accordance with Community legislation in such a way to prevent spoiling between dispatch and delivery to the plant of destination;

4. have undergone all precautions to avoid contamination with pathogenic agents;

5. were packed in new packaging preventing any leakage;

▼M9

6. are accompanied by a certificate that conforms to one of the models set out in Chapter 3(D), 3(F) or 8 of Annex X;

▼M2

7. following the border checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, they are transported directly either:

(a) to a petfood or technical plant, which has given the guarantee that the animal by-products shall be used only for the purpose of producing petfood or technical products as appropriate, as specified by the competent authority if necessary, and shall not leave the plant untreated other than for direct disposal; or

(b) to an intermediate plant; or

(c) to an authorised and registered user or collection centre, which has given the guarantee that the animal by-products shall be used only for permitted purposes, as specified by the Competent Authority if necessary;

and

8.1. in the case of raw material for petfood production derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC, as referred to in the second paragraph of Article 28 of this Regulation, it shall:

(a) be marked in the third country before entry into the territory of the Community by a cross of liquefied charcoal or activated carbon, on each outer side of each frozen block, in such a way that the marking covers at least 70 % of the diagonal length of the side of the frozen block and is at least 10 cm in width;

(b) in the case of material which is not frozen, be marked in the third country before entry into the territory of the Community by spraying it with liquefied charcoal or by applying charcoal powder in such a way that the charcoal is clearly visible on the material;

(c) be transported directly to:

(i) the petfood plant of destination in accordance with point 7(a) above;

or

(ii) an intermediate plant in accordance with point 7(b) above and from there directly to the petfood plant referred to under (i), provided that the intermediate plant:

— only handles material covered by this point 8.1, or

▼M2

— only handles material destined for a petfood plant as referred to under (i);

and

(d) be manipulated to remove the marking provided for in (a) and (b) only in the petfood plant of destination and only immediately prior to use of the material for the manufacture of petfood;

8.2. where a consignment is made up of raw material, which has been treated as referred to in 8.1 above and other non-treated raw material, all the raw materials in the consignment must be marked as laid down in point 8.1(a) and (b) above.

8.3. the marking provided for in point 8.1(a) and (b) and 8.2 shall remain visible from the dispatch and until the delivery to the petfood plant of destination.

CHAPTER XII

Rendered fats from category 2 materials for oleochemical purposes

A. *Processing standards*

1. Rendered fats derived from category 2 material for oleochemical purposes must be produced using methods 1 to 5 as referred to in Annex V, Chapter III.

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

B. *Importation of rendered fats*

3. Member States must authorise the importation of rendered fats derived from category 2 materials, intended to be processed using a method that at least meets the standards of one of the processes described in Annex VI, Chapter III, if it:

(a) comes from a third country that appears on a Community list set out in part IV of Annex XI;

(b) has been produced in accordance with this Regulation; and

(c) is accompanied by a health certificate that conforms to the model set out in Chapter 10(B) of Annex X.

4. The rendered fats must be conveyed by land and/or sea from the country of origin direct to a border inspection post in the Community.

5. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the rendered fats must be conveyed to a category 2 oleochemical plant where they are to be processed into fat derivatives.

6. The health certificate referred to in paragraph 3 must state that:

(i) the rendered fats will not be diverted for any use other than further processing by a method that at least meets the standards of one of the processes referred to in Chapter III of Annex VI; and

(ii) the resulting fat derivatives shall only be used in organic fertiliser or soil improvers or other technical uses, other than in cosmetics, pharmaceuticals and medical devices.

▼M2

7. The health certificate provided for in paragraph 3 must be presented to the competent authority at the border inspection post at the first point of entry of the goods into the Community, and thereafter a copy must accompany the consignment until their arrival at the plant of destination.

8. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the rendered fats shall be transported directly to the plant of destination.

CHAPTER XIII

Fat derivatives

A. *Processing standards*

1. If rendered fat produced from category 2 material is used for the production of fat derivatives a method that at least meets the standards of one of the processes referred to in Chapter III of Annex VI shall be used.

B. *Importation*

2. Member States shall authorise the importation of fat derivatives only if a health certificate that conforms to the model set out in Chapters 14(A) or 14(B) of Annex X accompanies each consignment.

3. The health certificate referred to in paragraph 2 must state:

(a) whether or not the fat derivatives derive from category 2 or 3 materials;

(b) in the case of fat derivatives produced from category 2 material, that the products:

(i) have been produced using a method that at least meets the standards of one of the processes referred to in Chapter III of Annex VI; and

(ii) shall only be used in organic fertiliser or soil improvers or other technical uses, other than in cosmetics, pharmaceuticals and medical devices.

4. The health certificate provided for in paragraph 2 must be presented to the competent authority at the border inspection post at the first point of entry of the goods into the Community, and thereafter a copy must accompany the consignment until its arrival at the plant of destination.

5. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the fat derivatives shall be transported directly to the plants of destination.

CHAPTER XIV

Specific requirements for flavouring innards for the manufacture of pet food

The following conditions apply in addition to the requirements for approval laid down in Chapter I.

A. *Raw Material*

1. Only animal by-products referred to in Article 6(1)(a) to (j) may be used for the production of liquid/dehydrated processed products of animal origin used to enhance the palatability values of pet food.

▼M2

B. *Processing standards*

2. Flavouring innards must have been submitted to a treatment method and parameters, which ensure that the product complies with the microbiological standards laid down in Annex VIII, paragraph 6 of Chapter II. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination.

3. The end product must:

(a) be packed in new or sterilised packaging; or

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

C. *Importation*

4. Member States must authorise the importation of flavouring innards if they:

(a) come from third countries that appear on the list set out in part VII(C) of Annex XI;

(b) come from petfood plants approved by the competent authority of the third country meeting the specific conditions laid down in Article 18;

(c) have been produced in accordance with this Regulation; and

(d) are accompanied by a health certificate that conforms to the model set out in Chapter 3(E) of Annex X.

▼M16

CHAPTER XV

Requirements for horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers

A. *Placing on the market*

The placing on the market of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers shall be subject to the following conditions:

1. they must originate from animals that:

(a) either have been slaughtered in a slaughterhouse, after undergoing an ante-mortem inspection, and were found fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation; or

(b) did not show clinical signs of any disease communicable through that product to humans or animals.

2. they must have undergone a heat treatment for one hour at a core temperature of at least 80° C;

3. the horns must have been removed without opening the cranial cavity;

4. at any stage of processing, storage or transport, every precaution shall have been taken to avoid cross-contamination;

5. they shall be packed either in new packaging or containers; or transported in vehicles or bulk containers which have been disinfected prior to loading using a product approved by the competent authority;

▼**M16**

6. the packaging or containers must:

   (a) indicate the type of product (horns, horn products, hooves or hoof products);

   (b) be clearly labelled 'NOT FOR HUMAN AND ANIMAL CONSUMPTION';

   (c) be marked with the name and address of the approved technical or storage plant of destination.

B. *Importation*

Member States shall authorise the importation of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers provided that they:

1. come from a third country appearing on the list referred to in Part XVIII of Annex XI;

2. have been produced in accordance with point A of this Chapter;

3. are accompanied by a health certificate that conforms to the model set out in Chapter 18 of Annex X, duly completed and signed by the official veterinarian;

4. are conveyed following the veterinary checks in the border inspection post at the point of entry into the Union provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, directly to an approved technical plant or an approved storage plant.

▼B

ANNEX IX

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

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

2. Relevant material must be transported to the users or to collection centres in accordance with Annex II.

▼M1

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

▼B

3. Collection centres must:

(a) comply at least with the following requirements of Annex V:

(i) Chapter I, paragraphs 1(a), (b), (c), (d) and (f), 2, 3 and 4, and

(ii) Chapter II, paragraphs 1, 2, 4, 5 and 9; and

(b) have adequate facilities for destroying unused unprocessed relevant material, or send it to a processing plant or to an incineration or co-incineration plant in accordance with this Regulation.

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

4. In addition to the records required in accordance with Annex II, the following records must be kept in relation to relevant material:

(a) in the case of final users, the quantity used and the date of use; and

(b) in the case of collection centres:

(i) the quantity treated in accordance with paragraph 5;

(ii) the name and address of each final user buying the material;

(iii) the premises to which the material is taken for use;

(iv) the quantity dispatched; and

(v) the date on which the material was dispatched.

▼B

5. Operators of collection centres supplying relevant material other than fish offal to final users, must ensure that:

(a) it undergoes one of the following treatments (either in the collection centre or in a slaughterhouse approved by the competent authority in accordance with Community legislation):

(i) denaturing with a solution of a colouring agent approved by the competent authority. The solution must be of such a strength that the colouring on the stained material is clearly visible, and the whole surface of all pieces of material have been covered with a solution as aforesaid either by immersing the material in, or spraying or otherwise applying the solution;

(ii) sterilisation, that is to say boiling or steaming under pressure until every piece of material is cooked throughout; or

(iii) any other treatment approved by the competent authority; and

(b) it is packaged after treatment and before distribution in packaging that is clearly and legibly marked with the name and the address of the collection centre and the indication ‘not for human consumption’.

▼M9

ANNEX X

MODEL HEALTH CERTIFICATES FOR THE IMPORTATION FROM THIRD COUNTRIES AND FOR THE TRANSIT THROUGH THE EUROPEAN COMMUNITY OF CERTAIN ANIMAL BY-PRODUCTS AND PRODUCTS DERIVED THEREFROM

Notes

(a) Veterinary certificates shall be produced by the exporting country, based on the models appearing in this Annex X, according to the layout of the model that corresponds to the animal by-products concerned. They shall contain, in the numbered order that appears in the model, the attestations that are required for any third country and, as the case may be, those supplementary guarantees that are required for the exporting third country or part thereof.

(b) The original of each certificate shall consist of a single page, both sides, or, where more text is required, it shall be in such a form that all pages needed are part of an integrated whole and indivisible.

(c) It shall be drawn up in at least one of the official languages of the EU Member State in which the inspection at the border post shall be carried out and of the EU Member State of destination. However, these Member States may allow other languages, accompanied, if necessary, by an official translation.

(d) If for reasons of identification of the items of the consignment, additional pages are attached to the certificate, these pages shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying official veterinarian, in each of the pages.

(e) When the certificate, including additional schedules referred to in d), comprises more than one page, each page shall be numbered — (*page number*) of (*total number of pages*) — on its bottom and shall bear the code number of the certificate that has been designated by the competent authority on its top.

(f) The original of the certificate must be completed and signed by an official veterinarian. In doing so, the competent authorities of the exporting country shall ensure that the principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.

(g) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.

(h) The original of the certificate must accompany the consignment at the EU border inspection post.

(i) If health certificates are used for consignments in transit, box No I.5 (Consignee) of the relevant health certificate shall be completed with the name and address of the border inspection post through which the consignment is intended to leave the European Community.

▼M9

CHAPTER 1

Health certificate

For processed animal protein not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments Manufacturing plant	Net weight	Batch number

▼M9

COUNTRY

Processed animal protein not intended for human consumption including mixtures and products other than petfood containing such protein

	II.a. Certificate reference number	II.b.

Part II: Certification

II. **Health attestation**

I, the **undersigned** official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 ([1]) and in particular Article 6 and Annex VII Chapter II thereof and certify that:

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

(a) has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 17 and where appropriate Article 11 of Regulation (EC) No 1774/2002 ([2]) and

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

([2]) *either* [— parts of slaughtered animals, which were fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

([2]) *and/or* [— hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, underwent antemortem inspection and were fit, as a result of such inspection, for slaughter in accordance with Community legislation,]

([2]) *and/or* [— blood obtained from animals other than ruminants that were slaughtered in a slaughterhouse, underwent antemortem inspection and were fit, as a result of such inspection, for slaughter in accordance with Community legislation,]

([2]) *and/or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

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

([2]) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]

([2]) *and/or* [— fresh by-products from fish from plants manufacturing fish products for human consumption,]

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

and

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

([2]) *either* [heating to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars produced by saturated steam, with a particle size prior to processing of not more than 50 millimetres;]

([2]) *or* [in the case of non-mammalian protein other than fishmeal, the processing method …… as set out in Annex V, Chapter III, of Regulation (EC) 1774/2002;]

([2]) *or* [in the case of fishmeal the processing method …… as set out in Annex V, Chapter III, of Regulation (EC) 1774/2002;]

([2]) *or* [in the case of porcine blood, the processing method……as set out in Annex V, Chapter III to Regulation (EC) No 1774/2002, where in case of method 7 a heat treatment of at least 80 °C has been applied throughout its substance;]

II.2. the competent authority examined a random sample immediately prior to dispatch and found it to comply with the following standards ([3]):

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

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

II.3. the end product:

([2]) *either* [was packed in new or sterilised bags;]

([2]) *or* [was transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

which bear labels indicating “NOT FOR HUMAN CONSUMPTION”

II.4. the end product was stored in enclosed storage;

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

▼M9

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.05; 05.06; 05.07 or 23.01

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Where:

n = number of samples to be tested;

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

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

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M17

CHAPTER 2

Health certificate

For milk, milk products, colostrum and colostrum products not intended for human consumption for dispatch to or transit through (*) *the European Union*

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference number I.2.a. I.3. Central competent authority I.4. Local competent authority
I.5. Consignee Name Address Postal code Tel.	I.6. Person responsible for the load in EU Name Address Postal code Tel.
I.7. Country of origin ISO code I.8. Region of origin Code	I.9. Country of destination ISO code I.10. Region of destination Code
I.11. Place of origin Name Approval number Address	I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references	I.16. Entry BIP in EU I.17. No(s) of CITIES
I.18. Description of commodity	I.19. Commodity code (HS code) I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Identification of container/Seal number	I.24. Type of packaging
I.25. Commodities certified for: Animal feedingstuff ☐ Further process ☐ Technical use ☐ Other ☐	
I.26. For transit through the EU to a 3rd country ☐ 3rd country ISO code	I.27. For import or admission into the EU ☐
I.28. Identification of the commodities Species Approval number of establishments Manufacturing plant Net weight Batch number	

(*) Delete as appropriate.

▼M17

COUNTRY:

Milk, milk products, colostrum and colostrum products not for human consumption

II. Health information	II.a. Certificate reference number	II.b.

Part II: Certification

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1), and in particular Article 6 and Chapter V of Annex VII thereto, and certify that the milk (2), the milk products (2) the colostrum (2) or the colostrum products (2) referred to in box I.28 comply with the following conditions:

II.1. they were produced and derived in ..... *(name of exporting country)* (3), ... *(insert name of region)* (3), which is listed in the Annex to Decision 2004/438/EC, and which has been free from foot-and-mouth disease (FMD) and rinderpest for 12 months immediately prior to export and has not practiced vaccination against rinderpest during that period;

II.2. they were produced from raw milk or colostrum derived from animals which at the time of milking did not show clinical signs of any disease transmissible through milk or colostrum to humans or animals, and which had been kept for at least 30 days prior to production on holdings that were not subject to official restrictions due to foot and mouth disease or rinderpest;

II.3. they are milk or milk products that:

(2) *either* [have undergone one of the treatments or combinations thereof described in point II. 4]

(2) *or* [comprise whey to be fed to animals of species susceptible to foot-and-mouth disease, and that whey was collected from milk subjected to one of the treatments described in point II. 4 and

(2) *either* [the whey was collected at least 16 hours after clotting and has a pH below 6;]

(2) (4) *or* [the whey has been produced at least 21 days before the shipping and during that period no cases of FMD have been detected in the exporting country;]

(2) (4) *or* [the whey has been produced on .../.../..., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union;]]

II.4. they have been subject to one of the following treatments:

(2) *either* [High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds, or an equivalent pasteurisation achieving a negative reaction to a phosphatase test in bovine milk, in combination with:

(2) *either* [a subsequent second High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or an equivalent pasteurisation which itself achieves a negative reaction to a phosphatase test in bovine milk;]

(2) *or* [a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72 °C or higher;]

(2) *or* [a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6;]

(2) (4) *or* [the condition that the milk/milk product has been produced at least 21 days before the shipping and during that period no cases of FMD have been detected in the exporting country;]

(2) (4) *or* [the milk/milk product has been produced on .../.../..., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union;]

(2) *or* [sterilisation at a level of at least $F_0$3;]]

(2) *or* [Ultra High Temperature treatment at 132 °C for at least one second in combination with:

(2) *either* [a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72 °C or higher,]

(2) *or* [a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6;]

(2) (4) *or* [the condition that the milk/milk product has been produced at least 21 days before the shipping and during that period no cases of FMD has been detected in the exporting country;]

(2) (4) *or* [the milk/milk product has been produced on .../.../... this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union;]]

II.5. they are colostrum or colostrum products of bovine animals that have been subject to High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds, or an equivalent pasteurisation achieving a negative reaction to a phosphatase test in bovine milk, in combination with:

(2) (4) *either* [the condition that the colostrum or colostrum products have been produced at least 21 days before the shipping and in this period no cases of FMD have been detected in the exporting country;]

(2) (4) *or* [the colostrum or colostrum products have been produced on .../.../..., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union;]

▼M17

COUNTRY: **Milk, milk products, colostrum and colostrum products not for human consumption**

II. Health information	II.a. Certificate reference number	II.b.

and have been obtained from animals subject to regular veterinary inspections to ensure that animals come from holdings on which all bovine herds are:

(2) (4) *either* [recognised as officially tuberculosis and brucellosis free (5),]

(2) (4) *or* [not restricted under the national legislation of the third country of origin regarding eradication of tuberculosis and brucellosis,]

and (2) (4) *either* [recognised as official enzootic-bovine-leukosis free (5);]

(2) (4) *or* [included in an official system for the control of enzootic bovine leukosis and there has been no evidence as result of clinical and laboratory testing of this disease in the herd during the past two years;]

II.6. every precaution was taken to avoid contamination of the milk/milk product/colostrum/colostrum product after processing;

II.7. the milk/milk product/colostrum/colostrum product was packed:

(2) *either* [in new containers,]

(2) *or* [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority,]

and the containers are marked so as to indicate the nature of the milk/milk product/colostrum and bear labels indicating that the product is Category 3 material and not intended for human consumption.

Notes

Part I:

— Box reference I.6: Person responsible for the load in EU: this box is to be filled in only if it is a certificate for transit commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the Border Inspection Post of the European Union.

— Box reference I.19: Use the appropriate Harmonised System (HS) code of the World Customs Organisation: 23.09.10, 23.09.90, 35.01, 35.02 or 35.04.

— Box reference I.23: For bulk containers, the container number and the seal number (if applicable) must be included.

— Box reference I.26 and I.27: Fill in according to whether it is a transit or an import certificate.

— Box reference I.28: "Manufacturing plant": provide the registration number of treatment or processing establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) For completion if the authorisation to import into the European Union is restricted to certain regions of the third country concerned.

(4) This condition applies only to third countries listed in column "A" of Annex I to Decision 2004/438/EC.

▼**M17**

COUNTRY: **Milk, milk products, colostrum and colostrum products not for human consumption**

II. Health information	II.a. Certificate reference No	II.b.

([5]) Officially tuberculosis and brucellosis free herd as laid down in Annex A to Council Directive 64/432/EEC; and officially enzootic-bovine-leukosis free herd as laid down in Chapter I of Annex D to Council Directive 64/432/EEC.

— The signature and the seal must be in a different colour from that of the printing

— Note for the importer: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the Border Inspection Post of the European Union.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp:

▼M9

CHAPTER 3(A)

Health certificate

For canned petfood intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No		I.2. Certificate reference number	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6. Person responsible for the consignment in EU Name Address Postal code Tel. No	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code) **23.09.10**	I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages
I.23. Identification of container/Seal number			I.24. Type of packaging
I.25. Commodities certified for: Animal feedingstuff ☐ Technical use ☐ Other ☐			
I.26. For transit to third country vis-à-vis EU ☐ 3rd country ISO code		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments: Manufacturing plant	Net weight	Batch number

▼M9

COUNTRY **Canned Petfood**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and in particular Article 6 and Annex VIII Chapter II thereof and certify that the petfood described above:

II.1. has been prepared and stored in a plant approved and supervised by the competent authority in accordance with Article 18 and where appropriate Article 11 of Regulation (EC) No 1774/2002;

II.2. has been prepared exclusively with the following animal by-products:

(2) *either* [— parts of slaughtered animals, which were fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

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

(2) *and/or* [— blood obtained from animals other than ruminants that were slaughtered in a slaughterhouse, underwent antemortem inspection and were fit, as a result of such inspection, for slaughter in accordance with Community legislation,]

(2) *and/or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

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

(2) *and/or* [— raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals,]

(2) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]

(2) *and/or* [— fresh by-products from fish from plants manufacturing fish products for human consumption,]

(2) *and/or* [— shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals,]

(2) *and/or* [— material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 28 of Regulation (EC) No 1774/2002];

II.3. has been subjected to heat treatment to a minimum Fc value of 3 in hermetically sealed containers;

II.4. was analysed by a random sampling of at least five containers from each processed batch by laboratory diagnostic methods to ensure adequate heat treatment of the whole consignment as foreseen under point II.3;

II.5. has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

▼M9

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 3(B)

Health certificate

For processed petfood other than canned petfood, intended for dispatch to or for transit through (2) *the European Community*

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code | I.8. Region of origin Code

I.9. Country of destination ISO code | I.10. Region of destination Code

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
23.09.10

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments	Manufacturing plant	Net weight	Batch number

▼M9

COUNTRY **Processed petfood other than canned petfood**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and in particular Article 6 and Annex VIII Chapter II thereof and certify that the petfood described above:

II.1. has been prepared and stored in a plant approved and supervised by the competent authority in accordance with Article 18 and where appropriate Article 11 of Regulation (EC) No 1774/2002;

II.2. has been prepared exclusively with the following animal by-products:

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

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

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

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

(2) and/*or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

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

(2) and/*or* [— raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals,]

(2) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]

(2) *and*/or [— fresh by-products from fish from plants manufacturing fish products for human consumption,]

(2) *and/or* [— shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals,]

(2) *and/or* [— material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 28 of Regulation (EC) No 1774/2002;]

II.3.

(2) *either* [was subjected to a heat treatment of at least 90 °C throughout its substance;]

(2) *or* [was produced as regards ingredients of animal origin using exclusively products which had been

(a) in the case of meat or meat products subjected to a heat treatment of at least 90 °C throughout its substance;

(b) in the case of milk and milk based products,

(i) if they are from third countries or parts of third countries listed in column B of Annex I to Decision 2004/438/EC (3) submitted to a pasteurisation treatment sufficient to produce a negative phosphatase test;

(ii) with a pH reduced to less than 6 from third countries or parts of third countries listed in column C of Annex I to Decision 2004/438/EC, first submitted to a pasteurisation treatment sufficient to produce a negative phosphatase test;

(iii) if they are from third countries or parts of third countries listed in column C of Annex I to Decision 2004/438/EC, submitted to a sterilisation process or a double heat treatment where each treatment was sufficient to produce a negative phosphatase test on its own;

▼M9

(iv) if they are from third countries or parts of third countries listed in column C of Annex I to Decision 2004/438/EC where there has been an outbreak of foot-and-mouth disease in the last 12 months or where vaccination against foot-and-mouth disease has been carried out in the last 12 months submitted to:

either

— a sterilisation process whereby an Fc value equal or greater than 3 is achieved,

or

— 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

either

— 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;

(c) in the case of gelatine, produced using a process that ensures that unprocessed Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses with subsequent adjustment of the pH and subsequent, if necessary repeated, extraction by heat, followed by purification by means of filtration and sterilisation;

(d) in the case of hydrolysed protein produced using a production process involving appropriate measures to minimise contamination of raw Category 3 material, using only material with a molecular weight below 10 000 Dalton and, in the case of hydrolysed protein entirely or partly derived from ruminant hides and skins produced in a processing plant dedicated only to hydrolysed protein production, using a process involving the preparation of raw Category 3 material by brining, liming and intensive washing followed by

(i) exposure of the material to a pH of more than 11 for more than three hours at a temperature of more than 80 °C and subsequently by heat treatment at more than 140 ºC for 30 minutes at more than 3,6 bar; or

(ii) exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140° C for 30 minutes at 3 bar;

(e) in the case of egg products submitted to any of the processing methods 1 to 5 or 7, as referred to in Annex V Chapter III to Regulation (EC) No 1774/2002; or treated in accordance with Chapter II of Section X of Annex III to Regulation (EC) No 853/2004 [4];

(f) in the case of collagen submitted to a process ensuring that unprocessed Category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion, the use of preservatives other than those permitted by Community legislation being prohibited;

(g) in the case of blood products, produced using any of the processing methods 1 to 5 or 7, as referred to in Annex V Chapter III to Regulation (EC) No 1774/2002;

(h) in the case of mammalian processed animal protein submitted to any of the processing methods 1 to 5 or 7 and, in the case of porcine blood, submitted to any of the processing methods 1 to 5 or 7 provided that in the case of method 7 a heat treatment throughout its substance at a minimum temperature of 80 °C has been applied;

(i) in the case of non-mammalian processed protein with the exclusion of fishmeal submitted to any of the processing methods 1 to 5 or 7 as referred to in Annex V Chapter III to Regulation (EC) No 1774/2002;

(k) in the case of fishmeal submitted to any of the processing methods or to a method and parameters which ensure that the products complies with the microbiological standards set in Annex VII Chapter I paragraph 10 to Regulation (EC) No 1774/2002;

(l) in the case of rendered fat, including fish oils, submitted to processing methods 1 to 5 or 7 (and method 6 in the case of fish oil) as referred to in Annex V Chapter III to Regulation (EC) No 1774/2002 or produced in accordance with Chapter II of Section XII of Annex III to Regulation (EC) No 853/2004 [4]; rendered fats from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not excess 0,15 % in weight;

(m) in the case of dicalcium phosphate produced by a process that

(i) ensures that all Category 3 bone-material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;

(ii) following the procedure under (i), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and

(iii) finally, air dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C;

▼M9

(n) in the case of tricalcium phosphate produced by a process that ensures

(i) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);

(ii) continuous cooking with steam at 145 °C during 30 minutes at 4 bar;

(iii) separation of the protein broth from the hydroxyapatite (tricalciuum phosphate) by centrifugation; and

(iv) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200 °C];

II.4. was analysed by a random sampling of at least five samples from each processed batch taken during or after storage at the processing plant and complies with the following standards ([5]):

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

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 gram;

II.5. has undergone all precautions to avoid contamination with pathogenic agents after treatment;

II.6. was packed in new packaging, which, if the petfood is not dispatched in ready-to-sale packages on which it is clearly indicated that the content is destined for feeding to pets only, bear labels indicating “NOT FOR HUMAN CONSUMPTION”.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1]) OJ L 273, 10.10.2002, p. 1.

([2]) Delete as appropriate.

([3]) OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22.

([4]) OJ L 226, 25.6.2004, p. 22.

([5]) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 3(C)

Health certificate

For dogchews intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
42.05.00

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments: Manufacturing plant	Net weight	Batch number

▼M9

COUNTRY **Dogchews**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and in particular Article 6 and Annex VIII Chapter II thereof and certify that the dogchews described above:

II.1. have been prepared and stored in a plant approved and supervised by the competent authority in accordance with Article 18 and where appropriate Article 11 of Regulation (EC) No 1774/2002;

II.2. have been prepared exclusively with the following animal by-products:

(2) *either* [— parts of slaughtered animals, which were fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

(2) *and/or* [— hides and skins originating from animals that were slaughtered in a slaughterhouse, underwent ante-mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with Community legislation,]

(2) *and/or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

(2) *and/or* [— fresh by-products from fish from plants manufacturing fish products for human consumption,]

(2) *and/or* [— material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 28 of Regulation (EC) No 1774/2002];

II.3. have been subjected:

(2) *either* [in the case of dogchews made from hides and skins of ungulates or from fish, to a treatment sufficient to destroy pathogenic organisms (including salmonella); and the dogchews are dry];

(2) *or* [in the case of dogchews made from animal by-products other than hides and skins of ungulates or from fish, to a heat treatment of at least 90 °C throughout their substance;]

II.4. were examined by random sampling of at least five samples from each processed batch taken during or after storage at the processing plant and complies with the following standards (3):

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

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 gram;

II.5. have undergone all precautions to avoid contamination with pathogenic agents after treatment;

II.6. were packed in new packaging.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

▼M9

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 3(D)

Health certificate

For raw petfood for direct sale or animal by-products to be fed to farmed fur animals, intended for dispatch to or for transit through (*) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight	Batch number

▼M9

COUNTRY **Raw petfood for direct sale or animal by products to be fed to farmed fur animals**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 ([1]) and in particular Article 6 and Annex VIII Chapter II thereof and certify that the raw petfood or animal by-product described above:

II.1. consist of animal by-products that satisfy the health requirements below;

II.2. consist of animal by-products:

(a) derived from meat which satisfies the relevant animal and public health requirements laid down in:

— Council Decision 79/542/EEC ([2]) and provided the animals from which the meat is derived come from a territory or part of a territory …… (ISO code) as listed in that Decision which has been free of foot and mouth disease, rinderpest, classical swine fever, African swine fever and swine vesicular disease for the last 12 months and where no vaccination has taken place during that time (only as relevant for the susceptible species),

— and/or Commission Decision 2006/696/EC ([3]), and provided the animals from which the meat is derived come from a territory or part of a territory …… (ISO code) as listed in that Decision which has been free from Newcastle disease and Avian Influenza for the last 12 months,

— and/or Commission Decision 2000/585/EC ([4]), and provided the animals from which the meat is derived come from a territory or part of a territory …… (ISO code) as listed which has been free from foot and mouth disease, rinderpest, classical swine fever, African swine fever, swine vesicular disease, Newcastle disease and Avian Influenza for the last 12 months and where no vaccination has taken place during that time (only as relevant for the susceptible species);

(b) derived from animals that, at the slaughterhouse, have passed the ante-mortem health inspection during the 24 hours before the slaughter and have shown no evidence of the diseases referred in the Decisions above for which the animals are susceptible; and

(c) derived from animals that have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EC ([5]) on animal welfare;

II.3. consist only of the following animal by-products:

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

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

II.4. have been obtained and prepared without contact with other material not complying with the conditions required in the Decisions above, and it has been handled so as to avoid contamination with pathogenic agents;

II.5. have been packed in final packaging which bear labels indicating “RAW PETFOOD — NOT FOR HUMAN CONSUMPTION” or “ANIMAL BY-PRODUCTS FOR FEED FOR FUR ANIMALS — NOT FOR HUMAN CONSUMPTION” and then in leak-proof and officially sealed boxes/containers or in new packaging preventing any leakage and officially sealed boxes/containers which bear labels indicating “RAW PETFOOD — NOT FOR HUMAN CONSUMPTION” or “ANIMAL BY-PRODUCTS FOR FEED FOR FUR ANIMALS — NOT FOR HUMAN CONSUMPTION”, the name and the address of the establishment of destination;

II.6. in the case of raw petfood:

(a) have been prepared and stored in a plant approved and supervised by the competent authority in accordance with Article 18 and where appropriate Article 11 of Regulation (EC) No 1774/2002; and

(b) were examined by random sampling of at least five samples from each batch taken during storage (before dispatch) and complies with the following standards ([6]):

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

Enterobacteriacae: n = 5, c = 2, m = 10, M = 300 in 1 gram.

▼M9

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.91; 05.11.99 or 23.09.90.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: select raw petfood or animal by-product.

Part II:

(*) Delete as appropriate.

([1]) OJ L 273, 10.10.2002, p.1.

([2]) Council Decision 79/542/EEC of 21 December 1976 drawing up a list of third countries or parts of third countries, and laying down animal and public health and veterinary certification conditions, for importation into the Community of certain live animals and their fresh meat.

([3]) OJ L 295, 25.10.2006, p. 1.

([4]) Commission Decision 2000/585/EC of 7 September 2000 laying down animal and public health conditions and veterinary certifications for import of wild and farmed game meat and rabbit meat from third countries and repealing Commission Decisions 97/217/EC, 97/218/EC, 97/219/EC and 97/220/EC. OJ L 251, 6.10.2000, p. 1.

([5]) Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing. OJ L 340, 31.12.1993, p. 21.

([6]) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 3(E)

Health certificate

For flavouring innards for use in the manufacture of petfood, intended for dispatch to or for transit through (2) *the European Community*

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight	Batch number

▼M9

COUNTRY **Flavouring innards for use in the manufacture of petfood**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and in particular Article 6 and Annex VIII Chapter XIV thereof and certify that the flavouring innards products described above:

II.1. consist of animal by-products that satisfy the animal health requirement below;

II.2. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 18 and where appropriate Article 11 of Regulation (EC) No 1774/2002;

II.3. have been prepared including the following animal by-products which are exclusively:

(2) *either* [— parts of slaughtered animals, which were fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

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

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

(2) *and/or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

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

(2) *and/or* [— raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals,]

(2) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]

(2) *and/or* [— fresh by-products from fish from plants manufacturing fish products for human consumption,]

(2) *and/or* [— shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals,]

(2) *and/or* [— material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 28 of Regulation (EC) No 1774/2002;]

II.4. have been subjected to processing in accordance with Annex VIII, Chapter XIV of Regulation (EC) No 1774/2002, in order to kill pathogenic agents;

II.5. have been examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards (3):

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

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 gram;

II.6. the end product was:

(2) *either* [packed in new or sterilised bags;]

(2) *or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use;]

and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”;

II.7. the end product was stored in enclosed storage;

II.8. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.04 or 05.11.91.

▼M9

—	Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.
—	Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
—	Box reference I.28: define the innard product.

Part II:

(1)	OJ L 273, 10.10.2002, p. 1.
(2)	Delete as appropriate.
(3)	Where:
	n = number of samples to be tested;
	m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;
	M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
	c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.
—	The signature and the stamp must be in a different colour to that of the printing.
—	Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals):	Qualification and title:
Date:	Signature:
Stamp:	

▼M9

CHAPTER 3(F)

Health certificate

For animal by-products (*) for the manufacture of petfood, intended for dispatch to or for transit through (3) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Further process ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **Animal by-products for the manufacture of petfood**

Part II: Certification

II.a. Certificate reference number	II.b.

II.1. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the animal by-products described above:

II.1.1. consist of animal by-products that satisfy the animal health requirements below;

II.1.2. have been obtained in the territory of: …… (2) from animals:

(3) *either* [(a) that have remained in this territory since birth or for at least the last three months before slaughter;]

(3) *or* [(b) killed in the wild in this territory (4);]

II.1.3. have been obtained from animals:

(3) *either* [(a) coming from holdings:

(i) where, for the following diseases for which the animals are susceptible, there has been neither case/outbreak of rinderpest, swine vesicular disease, Newcastle disease or highly pathogenic avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days; nor in the holdings situated in their vicinity within 10 km, during the prior 30 days; and

(ii) where there has been neither case/outbreak of foot and mouth disease during the prior 60 days, nor in the holdings situated in their vicinity within 25 km, during the prior 30 days; and

(b) which:

(i) were not killed to eradicate any epizootic disease;

(ii) have remained in their holdings of origin for at least forty days before departure and which have been transported directly to the slaughterhouse without contact with other animals which did not comply with the same health conditions;

(iii) at the slaughterhouse, have passed the ante-mortem health inspection during the 24 hours before the slaughter and have shown no evidence of the diseases referred to above for which the animals are susceptible; and

(iv) have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EC on animal welfare;]

(3) *or* [(a) captured and killed in the wild in an area:

(i) in which within 25 km there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot and mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days; and

(ii) that is situated at a distance that exceeds 20 km from the borders separating another territory of a country or part thereof, which is not authorised at these dates for exporting this material to the European Community; and

(b) which after killing were transported within 12 hours for chilling either to a collection centre and immediately afterwards to a game establishment, or directly to a game establishment;]

II.1.4. have been obtained in an establishment around which, within a radius of 10 km, there has been no case/outbreak of diseases referred to in point II.1.3 for which the animals are susceptible during the prior 30 days or, in the event of a case of disease, the preparation of raw material for exportation to the European Community has been authorised only after removal of all meat, and the total cleaning and disinfection of the establishment under the control of an official veterinarian;

II.1.5. have been obtained and prepared without contact with other material not complying with the conditions required above, and it has been handled so as to avoid contamination with pathogenic agents;

II.1.6. have been packed in new packaging preventing any leakage and in officially sealed containers bearing the label indicating "RAW MATERIAL ONLY FOR THE MANUFACTURE OF PETFOOD" and the name and address of the EU establishment of destination;

II.1.7. consist only of the following animal by-products:

(3) *either* [— parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

(3) *and/or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

▼M9

(3) *and/or*	[—	former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste (5) which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,]
(3) *and/or*	[—	fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]
(3) *and/or*	[—	fresh by-products from fish from plants manufacturing fish products for human consumption,]
(3) *and/or*	[—	shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals,]
(3) *and/or*	[—	raw material derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC for the manufacture of petfood, as referred to in Article 28 of Regulation (EC) No 1774/2002;]
II.1.8.		have been deep-frozen at the plant of origin or have been preserved in accordance with EU legislation in such a way that they will not spoil between dispatch and delivery to the plant of destination;
II.1.9.		in the case of raw material derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC for the manufacture of petfood, as referred to in Article 28 of Regulation (EC) No 1774/2002:
	(a)	it has been marked in the third country before entry into the territory of the Community by a cross of liquefied charcoal or activated carbon on each outer side of each frozen block in a way that the marking covers at least 70 % of the diagonal length of the frozen block and be of at least 10 cm width;
	(b)	in case of material which is not frozen, the raw material has been marked in the third country before entry into the territory of the Community by spraying it with liquefied charcoal or by applying charcoal powder in a way that the charcoal is clearly visible on the material; and
	(c)	in the case the animal by-products are made up of raw material which has been treated as referred to above and other non-treated raw material, all the raw materials have been marked as laid down in point (a) and (b) above.
(3) (6) [II.2.		**Specific requirements**
(3) (7) II.2.1.		The by-products in this consignment come from animals that have been kept in the territory mentioned under (II.1.2), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled in domestic bovine animals.
(3) (8) II.2.2.		The by-products in this consignment consists only of animal by-products derived from trimmed offal of domestic ruminants, which have maturated at an ambient temperature of more than + 2 °C for at least three hours, or in the case of masseter muscles of bovine animals and de-boned meat of domestic animals, for at least 24 hours.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.91 or 05.11.99.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the veterinary control number of the approved establishment.

▼M9

Part II:

(*) Excluding raw blood, raw milk, hides and skins, hooves and horn, pig bristles and feathers (see relevant specific certificates for the import of these products).

(1) OJ L 273, 10.10.2002, p. 1.

(2) The name and ISO code number of the exporting country as laid down in:

— part 1 of Annex II of Council Decision 79/542/EEC,

— the Annex to Commission Decision 94/984/EC, and

— the Annex to Commission Decision 2000/585/EC.

In addition the ISO code of regionalisation in this Annex (where applicable for the susceptible species concerned) should be included.

(3) Delete as appropriate.

(4) Only for countries from where game meat intended for human consumption of the same animal species is authorised for importation into the European Community.

(5) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

(6) Supplementary guarantees to be provided when the material of domestic ruminants originated in the territory of a South American or South African country or part thereof from where only maturated and de-boned fresh meat of domestic ruminants for human consumption is permitted for exportation to the European Community. In the case of offal only trimmed offal of domestic ruminants which must be exclusively offal from which the bones, cartilage, trachea and main bronchi, lymphatic glands, adhering connective tissue, fat and mucus have been completely removed is permitted. The whole masseter muscles of bovine animals, incised in accordance with paragraph 41(a) of Chapter VIII of Annex I to Council Directive 64/433/EEC, are also permitted.

(7) Only for certain South American countries.

(8) Only for certain South American and South African countries.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M16

CHAPTER 4 (A)

Health certificate

For the import of blood and blood products from equidae for technical purposes, intended for dispatch to or for transit through (2) the European Union

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Tel. Nº	I.2. Certificate reference number	I.2.a
	I.3. Central Competent Authority	
	I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. Nº	I.6. Person responsible for the load in EU Name Address Postal code Tel. Nº	
I.7. Country of origin ISO code / I.8. Region of origin Code	I.9. Country of destination ISO code	I.10.
I.11. Place of origin Name Approval number Address	I.12. Place of destination Customs warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading	I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references	I.16. Entry BIP in EU	
	I.17.	
I.18. Description of commodity	I.19. Commodity code (HS code) **30.02**	
	I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages	
I.23. Identification of container/Seal number	I.24. Type of packaging	
I.25. Commodities certified for Technical use ☐		
I.26. For transit to 3rd Country vis-à-vis EU ☐ 3rd country ISO code	I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species (Scientific name) Approval number of establishments Manufacturing plant		

▼**M16**

COUNTRY **Blood and blood products from equidae for technical purposes**

Part II: Certification	II. Health information	II.a. Certificate reference number	II.b.

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 ([1]) and in particular Article 4(1)(c), Article 6 and Chapter V of Annex VIII thereto and certify that the blood or blood products of equidae described above :

II.1. consist of blood or blood products from equidae that satisfy the health requirements below;

II.2. consist exclusively of blood or blood products of equidae not intended for human nor animal consumption;

II.3. come from a third country, territory or part thereof listed in Part XIII of Annex XI to Regulation (EC) No 1774/2002 where the following diseases are compulsorily notifiable: African horse sickness, dourine, glanders (*Burkholderia mallei*), equine encephalomyelitis (all types including VEE), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;

II.4. have been derived from blood which was collected under the supervision of a veterinarian, from equidae, which on inspection at the time of collection were free from clinical signs of infectious disease:

([2]) *either* [in slaughterhouses approved in accordance with Regulation (EC) No 853/2004 ([3]);]

([2]) *or* [in slaughterhouses approved and supervised by the competent authority of the country of export;]

([2]) *or* [in facilities approved and supervised by the competent authority of the country of export for the purpose of collecting blood from equidae for the production of blood products for technical purposes;]

II.5. have been derived from blood which was collected from equidae,

II.5.1. which on inspection on the date of blood collection did not show clinical signs of any of the compulsorily notifiable diseases listed in Annex A to Directive 90/426/EEC ([4]) , and of Equine influenza, Equine piroplasmosis, Equine rhinopneumonitis and Equine viral arteritis listed in point 4 of Article 1.2.3. of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), 2009 Edition;

II.5.2. which have been kept for at least 30 days prior to the date of and during blood collection on holdings under veterinary supervision which were not subject to a prohibition order pursuant to Article 4(5) or restrictions for African horse sickness in accordance with Article 5 of Directive 90/426/EEC;

II.5.3. which had no contact with equidae from a holding which was subject to a prohibition order for animal health reasons pursuant to Article 4(5) of Directive 90/426/EEC.

II.5.4. which was collected from equidae for which the period for the prohibition order referred to in points II.5.2. and II.5.3 has been determined as followed:

([2]) *either* [where not all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected the period of prohibition has been:

— six months in the case of glanders (*Burkholderia mallei*), beginning on the date on which the equidae infected with the disease are slaughtered;

— six months in the case of equine encephalomyelitis of any type, including Venezuelan equine encephalomyelitis, beginning on the date on which the equidae infected with the disease are slaughtered;

— in the case of equine infectious anaemia, until the date on which, the infected animals having been slaughtered, and the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart;

— during six months from the date of the last recorded case of vesicular stomatitis;

— during one month from the date of the last recorded case of rabies;

— during 15 days from the date of the last recorded case of anthrax.]

([2]) *or* [if all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected, the period of prohibition shall be 30 days, beginning on the date on which the animals were slaughtered and the premises disinfected, except in the case of anthrax, where the period of prohibition shall 15 days]

▼M16

COUNTRY **Blood and blood products from equidae for technical purposes**

II. Health information	II.a. Certificate reference number	II.b.

II.6. blood products come from a plant approved by the competent authority of the third country meeting the specific conditions set out in Article 17 or 18 of Regulation (EC) No 1774/2002.

II.7. blood products have been produced from blood which fulfils the conditions referred in II.4. and II.5 and

(2) *either* [has been produced from blood collected from equidae which have been kept for a period of at least three months, or since birth if less than three months old, prior to the date of collection on holdings under veterinary supervision in the country of collection which during that period and the period of blood collection has been free of:

(a) African horse sickness for two years

(b) Venezuelan equine encephalomyelitis for a period of at least two years;

(c) glanders

(2) *either* [for a period of three years;]

(2) *or* [for a period of six months where the animals have passed the post-mortem inspection for glanders in the slaughterhouse referred to in II.4, including a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum;]

(d) vesicular stomatitis for six months;]

(2) *or* [has been subjected to at least one of the following treatments, followed by an effectiveness check, for the inactivation of possible causative pathogens for African horse sickness, equine encephalomyelitis of all types including Venezuelan equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and glanders (*Burkholderia mallei*):

(2) *either* [heat treatment at a temperature of 65 °C for at least three hours,]

(2) *or* [irradiation at 25 kGy by gamma rays,]

(2) *or* [change in pH to pH 5 for two hours,]

(2) *or* [heat treatment of at least 80 °C throughout their substance]]

II.8. all precautions have been taken to avoid contamination of the blood and blood products with pathogenic agents during production, handling and packaging;

II.9. were packed in sealed impermeable containers clearly labelled “NOT FOR HUMAN OR ANIMAL CONSUMPTION” and bearing the approval number of the establishment of collection;

II.10. were stored in enclosed storage.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the veterinary control number of the registered establishment of collection.

▼**M16**

COUNTRY **Blood and blood products from equidae for technical purposes**

II. Health information	II.a. Certificate reference number	II.b.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) OJ L 139, 30.4.2004, p. 55.

(4) OJ L 224, 18.8.1990, p. 42.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 4(B)

Health certificate

For blood products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Batch number

▼M9

COUNTRY **Blood products that could be used as feed material**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the blood products described above:

II.1. consist of blood products that satisfy the health requirements below;

II.2. consist exclusively of blood products not intended for human consumption;

II.3. have been prepared and stored in a plant, approved, validated and supervised by the competent authority in accordance with Article 17 and where appropriate Article 11 of Regulation (EC) No 1774/2002;

II.4. have been prepared (derived) exclusively with the following animal by-products:

(2) *either* [blood of slaughtered animals, which is fit for human consumption in accordance with Community legislation, but is not intended for human consumption for commercial reasons;]

(2) *and/or* [blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to humans or animals, derived from carcasses that are fit for human consumption in accordance with Community legislation;]

II.5. have been submitted

(2) *either* [to processing in accordance with processing method …….. (3) as set out in Annex V, Chapter III of Regulation (EC) No 1774/2002;]

(2) *or* [to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I, paragraph 10 of Annex VII to Regulation (EC) No 1774/2002;]

in order to kill pathogenic agents;

II.6. have been examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards (4):

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

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 gram;

II.7. the end product was:

(2) *either* [packed in new or sterilised bags;]

(2) *or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”;

II.8. the end product was stored in enclosed storage;

II.9. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.91 or 05.11.99.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

▼M9

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Insert method 1 to 5 or 7 as applicable.

(4) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼**M13**

CHAPTER 4(C)

Health certificate

For untreated blood products, excluding of equidae, for the manufacture of technical products, intended for dispatch to or for transit through (2) the European Community

COUNTRY — Veterinary certificate to EU

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No		I.2. Certificate reference number	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6. Person responsible for the consignment in EU Name Address Postal code Tel. No	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10.
I.11. Place of origin Name Approval number Address		I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code) **30.02**	
			I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages
I.23. Identification of container/Seal number			I.24. Type of packaging
I.25. Commodities certified for: Technical use ☐			
I.26. For transit to 3rd Country vis-à-vis EU ☐ third country ISO code		I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species (Scientific name) Nature of commodity Approval number of establishments Manufacturing plant Batch number			

▼**M13**

COUNTRY

Untreated blood products, excluding of equidae, for technical products

Part II: Certification

II. Health information		II.a. Certificate reference number	II.b.

II.	Health attestation
	I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 [1] and in particular Article 4(1)(c), Article 6 and Chapter IV of Annex VIII thereof and certify that:
II.1.	the blood products described above consist of blood products that satisfy the health requirements below;
II.2.	they consist exclusively of blood products not intended for human or animal consumption;
II.3.	they have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 18 or in the establishment of collection and where appropriate Article 11 of Regulation (EC) No 1774/2002 [2], exclusively with the following animal by-products:
[2] *either*	[— blood of slaughtered animals, which is fit for human consumption in accordance with Community legislation, but is not intended for human consumption for commercial reasons;]
[2] *and/or*	[— blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to humans or animals, derived from carcasses that are fit for human consumption in accordance with Community legislation;]
[2] *and/or*	[— blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;]
[2] *and/or*	[— blood and blood products originating from live animals that did not show clinical signs of any disease communicable through these products to humans or animals;]
II.4.	the blood from which such products are manufactured has been collected:
[2] *either*	[in slaughterhouses approved in accordance with Community legislation,]
[2] *or*	[in slaughterhouses approved and supervised by the competent authority of the third country,]
[2] *or*	[from live animals in facilities approved and supervised by the competent authority of the third country.]
[2] II.5.	in the case of blood products derived from animals belonging to the *taxa Artiodactyla, Perissodactyla* and *Proboscidea,* including their crossbreds, the products come:
II.5.1.	from a country where no case of rinderpest, *peste des petits* ruminants and Rift Valley fever has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months,
[2] [II.5.2. *either*	[from the territory of a country or region with code … [3] where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination has not been carried out against this disease for at least 12 months,]]
[2] [II.5.2. *or*	[from the territory of a country or region with code … [3] where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination programmes against foot-and-mouth disease are being officially carried out and controlled in domestic ruminant animals for at least 12 months [4]]]
[2] II.5.3.	In addition, in case of animals other than *Suidae* and *Tayassuidae*:
[2] *either*	[in the country or region of origin no case of vesicular stomatitis and bluetongue [2] (including the presence of seropositive animals) has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months,]
[2] *or*	[in the country or region of origin vesicular stomatitis and bluetongue [2] seropositive animals are present [4]]
[2] [II.5.4.	In addition, in case of *Suidae* and *Tayassuidae*:
II.5.4.1.	[in the country or region of origin no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for at least 12 months and vaccination has not been carried out against those diseases for at least 12 months in the susceptible species,]]
[2] [II.5.4.2. *either*	[in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for 12 months and in which vaccination has not been carried out against this disease for at least 12 months,]]

▼M13

COUNTRY

Untreated blood products, excluding of equidae, for technical products

II. Health information	II.a. Certificate reference number	II.b.

(2) [II.5.4.2. *or* [in the country or region of origin vesicular stomatitis seropositive animals are present (4),]]

(2) [II.6. in the case of blood products derived from poultry or other avian species the animals and the products come from the territory of a country or region with code … (5)]

which has been free from Newcastle disease and highly pathogenic avian influenza as defined in the Terrestrial Animal Health Code of the OIE,

which for at least 12 months has not carried out vaccination against avian influenza,

where the animals from which the products derive have not been vaccinated against Newcastle disease with vaccines prepared from a Newcastle disease master strain showing a higher pathogenicity than lentogenic virus strains.

II.7. the products were:

(2) *either* [packed in new or sterilised bags or bottles,]

(2) *or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

the outer packaging or containers bear labels indicating "NOT FOR HUMAN OR ANIMAL CONSUMPTION";

II.8. the products were stored in enclosed storage;

II.9. the products have undergone all precautions to avoid contamination with pathogenic agents during transport.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in the European Community: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Code of the territory as it appears in Part 1 of Annex II to Decision 79/542/EEC.

(4) In this case following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the technical plant of destination.

(5) Code of the territory as it appears in Part 1 of Annex II to Decision 2006/696/EC.

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

— Note for the person responsible for the consignment in the European Community: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:'

▼M16

CHAPTER 4 (D)

Health certificate

For treated blood products, excluding those of equidae, for the manufacture of technical products, intended for dispatch to or for transit through ([2]) the European Union

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Tel. Nº	I.2. Certificate reference number I.2.a I.3. Central Competent Authority I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. Nº	I.6. Person responsible for the load in EU Name Address Postal code Tel. Nº	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code I.10.
I.11. Place of origin Name Approval number Address	I.12. Place of destination Customs warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading	I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references	I.16. Entry BIP in EU I.17.	
I.18. Description of commodity	I.19. Commodity code (HS code) **30.02** I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages	
I.23. Identification of container/Seal number	I.24. Type of packaging	
I.25. Commodities certified for Technical use ☐		
I.26. For transit to 3rd Country vis-à-vis EU ☐ 3rd country ISO code	I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species (Scientific name) Nature of commodity Approval number of establishments Manufacturing plant Batch number		

▼M16

COUNTRY **Treated blood products, excluding those of equidae, for technical products**

II. Health information	II.a. Certificate reference number	II.b.

Part II: Certification

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No1774/2002 ([1]) and in particular Article 4(1)(c), Article 6 and Chapter IV of Annex VIII thereof and certify that:

II.1. the blood products described above consist of blood products that satisfy the requirements below;

II.2. they consist exclusively of blood products not intended for human or animal consumption;

II.3. they have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 18 or in the establishment of collection and where appropriate Article 11 of Regulation (EC) No 1774/2002 ([2]), exclusively with the following animal by-products:

([2]) *either* [— blood of slaughtered animals, which is fit for human consumption in accordance with Union legislation, but is not intended for human consumption for commercial reasons;]

([2]) *and/or* [— blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to humans or animals, derived from carcasses that are fit for human consumption in accordance with Union legislation;]

([2]) *and/or* [— blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation;]

([2]) *and/or* [— blood and blood products originating from live animals that did not show clinical signs of any disease communicable through these products to humans or animals;]

II.4. the blood from which such products are manufactured has been collected:

([2]) *either* [in slaughterhouses approved in accordance with Union legislation,]

([2]) *or* [in slaughterhouses approved and supervised by the competent authority of the third country,]

([2]) *or* [from live animals in facilities approved and supervised by the competent authority of the third country;]

([2]) [II.5. In case of blood products derived from *taxa Artiodactyla, Perissodactyla* and *Proboscidea* including their crossbreeds, other than *Suidae* and *Tayassuidae*, the products have undergone one of the following treatments, guaranteeing the absence of pathogens of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue:

([2]) *either* [heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,]

([2]) *or* [irradiation at 25 kGy by gamma rays, followed by an effectiveness check,]

([2]) *or* [change in pH to pH 5 for two hours, followed by an effectiveness check,]

([2]) *or* [heat treatment of at least 80 °C throughout their substance, followed by an effectiveness check]]

([2]) [II.6. In the case of blood products derived from *Suidae, Tayassuidae*, poultry and other avian species, the products have undergone one of the following treatments guaranteeing the absence of pathogens of the following diseases: foot-and-mouth disease, vesicular stomatitis, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease and highly pathogenic avian influenza as appropriate to the species;

([2]) *either* [heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check,]

([2]) *or* [irradiation at 25 kGy by gamma rays, followed by an effectiveness check,]

([2]) *or* [heat treatment of at least 80 °C for *Suidae/Tayassuidae* ([2]) and at least 70 °C for poultry and other avian species ([2]) throughout their substance, followed by an effectiveness check]]

([2]) [II.7. In the case of blood products derived from species other than listed under II.5. or II.6. the products have undergone of the following treatment (please specify): .....;]

II.8. the products were:

([2]) *either* [packed in new or sterilised bags or bottles,]

▼**M16**

COUNTRY **Treated blood products, excluding those of equidae, for technical products**

II. Health information	II.a. Certificate reference number	II.b.

(2) *or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

the outer packaging or containers bear labels indicating "NOT FOR HUMAN OR ANIMAL CONSUMPTION";

II.9. the products were stored in enclosed storage;

II.10. the products have undergone all precautions to avoid contamination with pathogenic agents after treatment.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses approved for that purpose.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Keep as appropriate.

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

— Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 5(A)

Health certificate

For fresh or chilled hides and skins of ungulates, intended for dispatch to or for transit through (2) *the European Community*

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments: Manufacturing plant	Net weight

▼M9

COUNTRY **Fresh or chilled hides and skins of Ungulates**

Part II: Certification

II.a. Certificate reference number	II.b.

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and in particular Article 6 and Annex VIII Chapter VI thereof and certify that the hides and skins described above:

II.1. have been obtained from animals that (2):

(a) were slaughtered and their carcasses are fit for human consumption in accordance with Community legislation; or

(b) were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

II.2. originate from a country or, in the case of regionalisation in accordance with Community legislation, from a part of a country from which imports of all categories of fresh meat of the corresponding species are authorised and which:

(a) for at least 12 months before dispatch, has been free from the following diseases (3):

[— classical swine fever, and African swine fever,]

[— rinderpest,]

and

(b) has been free for at least 12 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 (4);

II.3. have been obtained from:

[animals that have remained in the territory of the country of origin for at least three months before being slaughtered or since birth in the case of animals less that three months old;]

[in the case of hides and skins from bi-ungulates, animals that come from holdings in which there has been no outbreak of foot-and-mouth disease in the previous 30 days, and around which within a radius of 10 km there has been no case of foot-and-mouth disease for 30 days;]

[in the case of hides and skins from swine, animals that come from holdings in which there has been no outbreak of swine vesicular disease in the previous 30 days, or of classical or African swine fever in the previous 40 days, and around which within a radius of 10 km there has been no case of these diseases for 30 days;]

[animals that have shown no evidence of [foot-and-mouth disease], [rinderpest], [classical swine fever], [African swine fever] or [swine vesicular disease] (5) during ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter;]

II.4. have undergone all precautions to avoid recontamination with pathogenic agents.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 41.01; 41.02 or 41.03.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

▼M9

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Delete diseases not applicable to the species concerned.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 5(B)

Health certificate

For treated hides and skins of ungulates, intended for dispatch to or for transit through (2) *the European Community*

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments: Manufacturing plant	Net weight

▼M9

COUNTRY **Treated hides and skins of Ungulates**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and in particular Article 6 and Annex VIII Chapter VI thereof and certify that the hides and skins described above:

II.1. have been obtained from animals that (2):

(a) were slaughtered and their carcasses are fit for human consumption in accordance with Community legislation; or

(b) were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation; or

(c) did not show any clinical signs of any disease communicable to humans or animals, and were not killed to eradicate any epizootic disease;

(2) *either* [II.2 come from animals originate from a third country or, in the case of regionalisation in accordance with Community legislation, from a part of a third country listed in part 1 of Annex II to Decision 79/542/EEC (3) from which imports of fresh meat of the corresponding species are authorised and have been:

(2) *either* [dried;]

(2) *or* [dry-salted or wet-salted for at least 14 days prior to dispatch;]

(2) *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 of salting before they reach the EC border inspection post;]

(2) *or* [salted for seven days in sea salt with the addition of 2 % of sodium carbonate;]

(2) *or* [salted in sea salt with the addition of 2 % of sodium carbonate 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 of salting before they reach the EC border inspection post;]

(2) *or* [II.2. come from animals originate from a third country or, in the case of regionalisation in accordance with Community legislation, from a part of a third country listed in part 1 of Annex II to Decision 79/542/EEC from which imports of fresh meat of the corresponding species are **NOT** authorised and have been:

(2) *either* [salted for seven days in sea salt with the addition of 2 % of sodium carbonate;]

(2) *or* [salted in sea salt with the addition of 2 % of sodium carbonate 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 of salting before they reach the EC border inspection post;]

(2) *or* [dried for 42 days at a temperature of at least 20 °C;]

II.3. the consignment has not been in contact with other animal products or with live animals presenting a risk of spreading a serious transmissible disease.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) and information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 41.01; 41.02 or 41.03.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

▼M9

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) OJ L 146, 14.6.1979, p. 15.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 5(C)

Official declaration

For treated hides and skins of ruminants and of equidae that are intended for dispatch to or for transit through (1) the European Community and have been kept separate for 21 daysor will undergo transport for 21 uninterrupted days before importation

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments: Manufacturing plant	Net weight

▼M9

COUNTRY

Treated hides and skins of Ruminants and of Equidae that have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation

Part II: Certification

II.a. Certificate reference number	II.b.

II. Declaration

I, the undersigned declare that the hides and skins described above:

II.1. have been obtained from animals that (1):

(a) were slaughtered and their carcasses are fit for human consumption in accordance with Community legislation; or

(b) were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation; or

(c) did not show any clinical signs of any disease communicable to humans or animals, and were not killed to eradicate any epizootic disease;

II.2. have been:

(1) *either* [dried;]

(1) *or* [dry-salted or wet-salted for at least 14 days prior to dispatch;]

(1) *or* [salted for seven days in sea salt with the addition of 2 % of sodium carbonate;]

II.3. have not been in contact with other animal products or with live animals presenting a risk or spreading a serious transmissible disease;

(1) *either* [II.4. have been kept separate immediately before dispatch for 21 days under official supervision after the treatment described under point (II.2);]

(1) *or* [II.4. following the declaration of the transporter, the duration of the transport period is foreseen to be at least 21 days.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 41.01; 41.02 or 41.03.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: This declaration is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 6(A)

Health certificate

For treated game trophies of birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No.(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21.

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Number of packages

▼M9

COUNTRY

Treated game trophies of birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the game trophies described above:

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

(2) *either* [II.2. in the case of game trophies consisting solely of hides or skin:

(2) *either* [have been dried;]

(2) *or* [have been dry-salted or wet-salted for a minimum of 14 days before dispatch;]

(2) *or* [were dry-salted or wet-salted on …….… (date) and, according to the declaration of the transporter, will be transported by ship and the duration of the transport will be such that they will have undergone a minimum of 14 days salting before they reach the EC border inspection post;]]

(2) *or* [II.2. in the case of game trophies consisting solely of bone, horns, hooves, claws, antlers or teeth:

(a) have been immersed in boiling water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; and

(b) have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be

— Box reference I.19: use the appropriate HS code: 05.05; 05.06; 05.07 or

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import

— Box reference I.28: for nature of commodity, specify choosing one or more possibilities among the following: [bones], [horns], [hooves], [claws], [antlers], [teeth], [hides] or [skins].

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 6(B)

Health certificate

For game trophies of birds and ungulates consisting of entire parts not having been treated, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code | I.8. Region of origin Code | I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21.

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities
Species (Scientific name)
Number of packages

▼M9

COUNTRY **Game trophies of birds and ungulates consisting of entire parts not having been treated**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 [1] and certify that the game trophies described above:

([2]) *either* [II.1. with respect to game trophies of cloven-hoofed animals, excluding swine:

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

(b) the game trophies described above:

(i) were obtained from animals which were killed in the territory of that region, which is authorised for export of fresh meat of the corresponding susceptible domestic species and where, during the last 60 days, there have been no animal health restrictions because of outbreaks of diseases to which the game animals are susceptible; and

(ii) originated from animals that were killed at a distance of at least 20 km 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]) *or* [II.1. with respect to game trophies of wild swine:

(a) …… (region) during the last 12 months was free from classical swine fever, African swine fever, swine vesicular disease, foot-and-mouth disease and porcine enteroviral encephalmiyelitis (Teschen disease) and no vaccinations have been carried out against any of those diseases during the last 12 months; and

(b) the game trophies described above:

(i) were obtained from animals which were killed in that territory, which is authorised for export of fresh meat of the corresponding susceptible domestic species and where, during the last 60 days, there have been no animal health restrictions because of outbreaks of diseases to which the swine are susceptible; and

(ii) originated from animals that were killed at a distance of at least 20 km 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;]

([2]) *or* [II.1. with respect to game trophies of solipeds, the game trophies described above were obtained from wild solipeds that were killed in the territory of the exporting country mentioned above;]

([2]) *or* [II.1. with respect to game trophies of game birds:

(a) …… (region) is free from highly pathogenic avian influenza and Newcastle disease; and

(b) the game trophies described above were obtained from wild game birds that were killed in that region and 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;]

II.2. 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.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.05; 05.06 or 05.07.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

▼M9

Part II:	
(1)	OJ L 273, 10.10.2002, p. 1.
(2)	Delete as appropriate.
—	The signature and the stamp must be in a different colour to that of the printing.
—	Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals):	Qualification and title:
Date:	Signature:
Stamp:	

▼M9

CHAPTER 7(A)

Health certificate

For pig bristles from third countries or regions thereof that are free from African swine fever, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code | I.8. Region of origin Code | I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code) **05.02**

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities
Approval number of establishments
Manufacturing plant Number of packages Net weight

▼M9

COUNTRY **Pig bristles from third countries or regions thereof that are free from African swine fever**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that:

II.1. the pig bristles described above have been obtained from pigs originating, and slaughtered in a slaughterhouse, in the country of origin;

II.2. the pigs from which the pig bristles have been obtained did not show during inspection, carried out at the time of slaughtering, signs of diseases communicable to humans or animals and were not killed to eradicate any epizootic disease;

II.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;

II.4. the pig bristles are dry and securely enclosed in packaging.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the veterinary control number of the registered establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 7(B)

Health certificate

For pig bristles from third countries or regions thereof that are not free from African swine fever, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code | I.8. Region of origin Code | I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
05.02

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities
Approval number of establishments
Manufacturing plant Number of packages Net weight

▼M9

COUNTRY **Pig bristles from third countries or regions thereof that are not free from African swine fever**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that:

II.1. the pig bristles described above have been obtained from pigs originating, and slaughtered in a slaughterhouse, in the country of origin;

II.2. the pigs from which the pig bristles have been obtained did not show during inspection, carried out at the time of slaughtering, signs of diseases communicable to humans or animals and were not killed to eradicate any epizootic disease;

II.3. the pig bristles mentioned above have been:

(2) *either* [boiled;]

(2) *or* [dyed;]

(2) *or* [bleached;]

II.4. the pig bristles are dry and securely enclosed in packaging.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the veterinary control number of the registered establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 8

Health certificate

For animal by-products (*) to be used for technical purposes, intended for dispatch to or for transit through [3] *the European Community*

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code | I.8. Region of origin Code | I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Address
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Technical use ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **Animal by-products for the manufacture of technical products**

Part II: Certification

II.a. Certificate reference number	II.b.

II.1. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the animal by-products described above:

II.1.1. consist of animal by-products that satisfy the animal health requirements below;

II.1.2. have been obtained in the territory of: …… (2) from animals:

(3) *either* [(a) that have remained in this territory since birth or for at least the last three months before slaughter;]

(3) *or* [(b) killed in the wild in this territory (4);]

II.1.3. have been obtained from animals:

(3) *either* [(a) coming from holdings:

(i) where, for the following diseases for which the animals are susceptible, there has been neither case/outbreak of rinderpest, swine vesicular disease, Newcastle disease or highly pathogenic avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days; nor in the holdings situated in their vicinity within 10 km, during the prior 30 days; and

(ii) where there has been neither case/outbreak of foot and mouth disease during the prior 60 days, nor in the holdings situated in their vicinity within 25 km, during the prior 30 days; and

(b) which:

(i) were not killed to eradicate any epizootic disease;

(ii) have remained in their holdings of origin for at least forty days before departure and which have been transported directly to the slaughterhouse without contact with other animals which did not comply with the same health conditions;

(iii) at the slaughterhouse, have passed the ante-mortem health inspection during the 24 hours before the slaughter and have shown no evidence of the diseases referred to above for which the animals are susceptible; and

(iv) have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EC on animal welfare;]

(3) *or* [(a) captured and killed in the wild in an area:

(i) in which within 25 km there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot and mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the prior 30 days nor of classical or African swine fever during the prior 40 days; and

(ii) that is situated at a distance that exceeds 20 km from the borders separating another territory of a country or part thereof, which is not authorised at these dates for exporting this material to the European Community; and

(b) which after killing were transported within 12 hours for chilling either to a collection centre and immediately afterwards to a game establishment, or directly to a game establishment;]

II.1.4. have been obtained in an establishment around which, within a radius of 10 km, there has been no case/outbreak of diseases referred to in point II.1.3 for which the animals are susceptible during the prior 30 days or, in the event of a case of disease, the preparation of raw material for exportation to the European Community has been authorised only after removal of all meat, and the total cleaning and disinfection of the establishment under the control of an official veterinarian;

II.1.5. have been obtained and prepared without contact with other material not complying with the conditions required above, and it has been handled so as to avoid contamination with pathogenic agents;

II.1.6. have been packed in new packaging preventing any leakage and in officially sealed containers bearing the label indicating "RAW MATERIAL ONLY FOR THE MANUFACTURE OF TECHNICAL PRODUCTS" and the name and address of the EU establishment of destination;

II.1.7. consist only of the following animal by-products:

(3) *either* [— parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

(3) *and/or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

(3) *and/or* [— former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste (5) which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,]

(3) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,

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(3) *and/or*	[— fresh by-products from fish from plants manufacturing fish products for human consumption,]
(3) *and/or*	[— shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals,]
(3) *and/or*	[— fur originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals,]
II.1.8.	have been deep-frozen at the plant of origin or have been preserved in accordance with EU legislation in such a way that they will not spoil between dispatch and delivery to the plant of destination.
(3) (6) [II.2.	**Specific requirements**
(3) (7) II.2.1.	the by-products in this consignment come from animals that have been obtained in the territory mentioned under (II.1.2), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled in domestic bovine animals.
(3) (8) II.2.2.	The by-products in this consignment consists of animal by-products derived from offal or de-boned meat.]

Notes

Part I:

—	Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.
—	Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.
—	Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.
—	Box reference I.19: use the appropriate HS code: 05.11.91; 05.11.99 or 30.01.
—	Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.
—	Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
—	Box reference I.28: Manufacturing plant: provide the veterinary control number of the approved establishment.

Part II:

(*)	Excluding raw blood, raw milk, hides and skins of ungulates or ruminants and pig bristles (see relevant specific certificates for the import of these products) as well as wool, hair, feathers or parts of feathers.
(1)	OJ L 273, 10.10.2002, p. 1.
(2)	The name and ISO code number of the exporting country as laid down in: — part 1 of Annex II of Council Decision 79/542/EEC, — the Annex to Commission Decision 94/984/EC, and — the Annex to Commission Decision 2000/585/EC. In addition the ISO code of regionalisation in this Annex (where applicable for the susceptible species concerned) should be included.
(3)	Delete as appropriate.
(4)	Only for countries from where game meat intended for human consumption of the same animal species is authorised for importation into the European Community.
(5)	Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.
(6)	Supplementary guarantees to be provided when the material of domestic ruminants originated in the territory of a South American or South African country or part thereof from where only maturated and de-boned fresh meat of domestic ruminants for human consumption is permitted for exportation to the European Community. In the case of offal only trimmed offal of domestic ruminants which must be exclusively offal from which the bones, cartilage, trachea and main bronchi, lymphatic glands adhering connective tissue, fat and mucus have been completely removed is permitted. The whole masseter muscles of bovine animals, incised in accordance with paragraph 41(a) of Chapter VIII of Annex I to Council Directive 64/433/EEC, are also permitted.
(7)	Only for certain South American countries.
(8)	Only for certain South American and South African countries.
—	The signature and the stamp must be in a different colour to that of the printing.
—	Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals):	Qualification and title:
Date:	Signature:
Stamp:	

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CHAPTER 9

Health certificate

For fish oil not intended for human consumption to be used as feed material or for technical purposes, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No	I.2. Certificate reference number I.2.a. I.3. Central Competent Authority I.4. Local Competent Authority
I.5. Consignee Name Address Postal code Tel. No	I.6. Person responsible for the consignment in EU Name Address Postal code Tel. No
I.7. Country of origin ISO code I.8.	I.9. Country of destination ISO code I.10.
I.11. Place of origin Name Approval number Address	I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:	I.16. Entry BIP in EU I.17.
I.18. Description of commodity	I.19. Commodity code (HS code) I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Identification of container/Seal number	I.24. Type of packaging
I.25. Commodities certified for: Animal feedingstuff ☐ Technical use ☐	
I.26. For transit to third country vis-à-vis EU ☐ 3rd country ISO code	I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **Fish oil to be used as feed material or for technical purposes**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the fish oil described above:

II.1. consists of fish oil that satisfy the health requirements below;

II.2. contains exclusively fish oil not intended for human consumption;

II.3. has been prepared and stored in a dedicated fish plant approved, validated and supervised by the competent authority in accordance with Article 17 and where appropriate Article 11 of Regulation (EC) No 1774/2002;

II.4. has been prepared exclusively with the following animal by-products:

(2) *either* [— former foodstuffs of fish origin, other than catering waste (3), which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,]

(2) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]

(2) *and/or* [— fresh by-products from fish from plants manufacturing fish products for human consumption;]

II.5. the fish oil:

(a) has been subjected to processing in accordance with Annex VII, Chapter IV of Regulation 1774/2002/EC, in order to kill pathogenic agents;

(b) has not been in contact with other types of oils including rendered fats from other animal species; and

(2) *either* [(c) is packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination;]

(2) *or* [(c) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the product from the manufacturing plant either directly on to the ship or into shore tanks or direct to plants have been inspected and found to be clean before use;]

and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 15.04 or 15.18.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 10(A)

Health certificate

For rendered fats not intended for human consumption to be used as feed material or for technical purposes, intended for dispatch to or for transit through ([4]) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code I.8.

I.9. Country of destination ISO code I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY

Rendered fats not intended for human consumption to be used as feed material or for technical purposes

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the rendered fats described above:

II.1. consist of rendered fats that satisfy the health requirements below;

II.2. consist of rendered fats not intended for human consumption;

II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 17 and where appropriate Article 11 of Regulation (EC) No 1774/2002 or in accordance with Chapter II of Annex C to Council Directive 77/99/EEC (2) or Chapter 9 of Annex I to Council Directive 92/118/EEC (3), in order to kill pathogenic agents;

II.4. have been prepared exclusively with the following animal by-products:

(4) *either* [— parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

(4) *and/or* [— hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, after undergoing antemortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,]

(4) *and/or* [— blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,]

(4) *and/or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

(4) *and/or* [— former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste (5), which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,]

(4) *and/or* [— milk originating from animals which do not show any clinical signs of any disease communicable through that product to humans or animals,]

(4) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]

(4) *and/or* [— by-products from fish from plants manufacturing fish products for human consumption,]

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

II.5. if derived from ruminant animals were purified in such way that the maximum levels of remaining total insoluble impurities does not exceed 0,15 % in weight;

II.6. the rendered fats:

(a) have been subjected to processing in accordance with Annex VII, Chapter IV of Regulation 1774/2002/EC, or treatment in accordance with Council Directives 77/99/EEC or 92/118/EEC, in order to kill pathogenic agents; and

(4) *either* [(b) are packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination;]

(4) *or* [(b) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the product from the manufacturing plant either directly on to the ship or into shore tanks or direct to plants have been inspected and found to be clean before use;]

and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”.

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Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 15.02; 15.03; 15.04; 15.05; 15.06; 15.16.10; 15.17 or 15.18.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) OJ L 26, 31.1.1977, p. 85.

(3) OJ L 62, 15.3.1993, p. 49.

(4) Delete as appropriate.

(5) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

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CHAPTER 10(B)

Health certificate

For rendered fats not intended for human consumption to be used for technical purposes, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code I.8.

I.9. Country of destination ISO code I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Technical use ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **Rendered fats to be used for technical purposes**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the rendered fats described above:

II.1. consist of rendered fats that satisfy the health requirements below;

II.2. consist of rendered fats not intended for human or animal consumption;

II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 13 and where appropriate Article 11 of Regulation (EC) No 1774/2002, in order to kill pathogenic agents;

II.4. have been prepared exclusively with the following animal by-products:

(2) *either* [Category 2 materials (3);]

(2) *or* [a mixture of Category 2 materials with Category 3 materials (4);]

II.5. if derived from ruminant animals were purified in such way that the maximum levels of remaining total insoluble impurities does not exceed 0,15 % in weight;

II.6. the rendered fats:

(a) have been subjected to processing in accordance with Annex VII, Chapter XII of Regulation (EC) No 1774/2002/EC, in order to kill pathogenic agents; and

(2) *either* [(b) are packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination;]

(2) *or* [(b) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the product from the manufacturing plant either directly on to the ship or into shore tanks or direct to plants have been inspected and found to be clean before use;]

and which bear labels indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION'.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 15.01; 15.02; 15.03; 15.04; 15.05; 15.06; 15.16.10; 15.17 or 15.18.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) List of Category 2 materials:

(a) all animal materials collected when treating waste water from slaughterhouses other than slaughterhouses covered by Article 4(1)(d) or from Category 2 processing plants, including screenings, materials from de-sanding, grease and oil mixtures, sludge and materials removed from drains from those premises;

(b) 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;

(c) products of animal origin, other than Category 1 material, that are imported from third countries and, in the course of the inspections provided for in Community legislation, fail to comply with the veterinary requirements for their importation into the Community, unless they are returned or their importation is accepted under restrictions laid down under Community legislation;

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(d) animals and parts of animals, other than those referred to in Article 4, that die other than by being slaughtered for human consumption, including animals killed to eradicate an epizootic disease;

(e) mixtures of Category 2 material with Category 3 material, including any material destined for processing in a Category 2 processing plant; and

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

([4]) List of Category 3 materials:

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

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

(c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, after undergoing antemortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

(d) blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing antemortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;

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

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

(g) milk originating from animals which do not show any clinical signs of any disease communicable through that product to humans or animals;

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

(i) by-products from fish from plants manufacturing fish products for human consumption;

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

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 11

Health certificate

For gelatine and collagen not intended for human consumption to be used as feed material or for technical purposes, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code I.8.

I.9. Country of destination ISO code I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **Gelatine and collagen not intended for human consumption to be used as feed material or for technical purposes**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the gelatine/collagen (2) described above:

II.1. consists of gelatine/collagen (2) that satisfy the health requirements below;

II.2. consist exclusively of gelatine/collagen (2) not intended for human consumption;

II.3. has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 17 and where appropriate Article 11 of Regulation (EC) No 1774/2002, in order to kill pathogenic agents;

II.4. has been prepared exclusively with the following animal by-products:

(2) *either* [— parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

(2) *and/or* [— hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, after undergoing antemortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,]

(2) *and/or* [— animal by-products derived from the production of products intended for human consumption,]

(2) *and/or* [— former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste (3), which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,]

(2) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]

(2) *and/or* [— fresh by-products from fish from plants manufacturing fish products for human consumption;]

II.5. the gelatine/collagen (2):

(a) was wrapped, packaged, stored and transported under satisfactory hygiene conditions, and in particular wrapping and packaging took place in a dedicated room, and only preservatives permitted under Community legislation were used.

Wrappings and packages containing gelatine/collagen (2) carry the words “GELATINE/COLLAGEN (2) SUITABLE FOR ANIMAL CONSUMPTION”, and

(2) *either* [(b) in the case of gelatine, has been produced by a process that ensuring that unprocessed Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses, involving pH adjustment, extraction by heating one or several times in succession, followed by purification by means of filtration and sterilisation, in order to kill pathogenic agents;]

(2) *or* [(b) in the case of collagen, has been produced by a process that ensuring that unprocessed Category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion, in order to kill pathogenic agents.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 35.03 or 35.04.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: select gelatine or collagen.

Manufacturing plant: provide the registration number of treatment/processing establishment.

▼M9

Part II:	
(1)	OJ L 273, 10.10.2002, p. 1.
(2)	Delete as appropriate.
(3)	Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.
—	The signature and the stamp must be in a different colour to that of the printing.
—	Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals):	Qualification and title:
Date:	Signature:
Stamp:	

▼M9

CHAPTER 12

Health certificate

For hydrolysed protein, dicalcium phosphate and tricalcium phosphate not intended for human consumption to be used as feed material or for technical purposes, intended for dispatch to or for transit through (2) *the European Community*

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No	I.2. Certificate reference number I.2.a. I.3. Central Competent Authority I.4. Local Competent Authority
I.5. Consignee Name Address Postal code Tel. No	I.6. Person responsible for the consignment in EU Name Address Postal code Tel. No
I.7. Country of origin ISO code I.8.	I.9. Country of destination ISO code I.10.
I.11. Place of origin Name Approval number Address	I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code
I.13. Place of loading	I.14. Date of departure
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:	I.16. Entry BIP in EU I.17.
I.18. Description of commodity	I.19. Commodity code (HS code) I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages
I.23. Identification of container/Seal number	I.24. Type of packaging
I.25. Commodities certified for: Animal feedingstuff ☐ Technical use ☐	
I.26. For transit to third country vis-à-vis EU ☐ 3rd country ISO code	I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **Hydrolysed protein, dicalcium phosphate and tricalcium phosphate to be used as feed material or for technical purposes**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the hydrolysed protein/dicalcium phosphate/tricalcium phosphate (2) described above:

II.1. consists of hydrolysed protein/dicalcium phosphate/tricalcium phosphate (2) that satisfy the health requirements below;

II.2. consists exclusively of hydrolysed protein/dicalcium phosphate/tricalcium phosphate (2) not intended for human consumption;

II.3. has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 17 and where appropriate Article 11 of Regulation (EC) No 1774/2002, in order to kill pathogenic agents;

II.4. has been prepared exclusively with the following animal by-products:

(2) *either* [— parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;]

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

(2) *and/or* [— hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, after undergoing antemortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;]

(2) *and/or* [— blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing antemortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;]

(2) *and/or* [— animal by-products derived from the production of products intended for human consumption;]

(2) *and/or* [— former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste (3), which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals;]

(2) *and/or* [— raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals;]

(2) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;]

(2) *and/or* [— fresh by-products from fish from plants manufacturing fish products for human consumption;]

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

II.5. the hydrolysed protein/dicalcium phosphate/tricalcium phosphate (2):

(a) was wrapped and packaged in packaging which bear labels indicating “NOT FOR HUMAN CONSUMPTION” and stored and transported under satisfactory hygiene conditions, and in particular wrapping and packaging took place in a dedicated room, and only preservatives permitted under Community legislation were used; and

(2) *either* [(b) in the case of hydrolysed protein, has been produced by a process involving appropriate measures to minimise contamination of raw Category 3 material.

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

(i) exposure of the material to a pH of more than 11 for more than 3 hours at temperature of more than 80 ºC and subsequently by heat treatment at more than 140 °C for 30 minutes at more than 3,6 bar; and

(ii) exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140 °C for 30 minutes at 3 bar;]

▼M9

(2) *or*	[(b)	in the case of dicalcium phosphate, has been produced by a process that:	
		(i)	ensures that all Category 3 bonematerial is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;
		(ii)	followed by treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and
		(iii)	finally air-dries this precipitate for 15 minutes, with inlet temperature of 270 °C to 325 °C and end temperature between 60 °C and 65 °C;]
(2) *or*	[(b)	in the case of tricalcium phosphate, has been produced by a process ensuring:	
		(i)	that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);
		(ii)	continuous cooking with steam at 145 °C during 30 minutes at 4 bars;
		(iii)	separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation; and
		(iv)	granulation of the tricalcium phosphate after drying in a fluid bed with air at 200 °C.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 28.35 or 35.04.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: specify if hydrolysed protein, dicalcium phosphate or tricalcium phosphate.

Manufacturing plant: provide the registration number of treatment/processing establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 13

Health certificate

For apiculture by-products, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐ Other ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight

▼M9

COUNTRY **Apiculture by-products**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and in particular Article 6 and Annex VIII Chapter IX thereof and certify that the apiculture by-products described above:

II.1. come from an area where the diseases mentioned below are officially notifiable and which is not subject to any restrictions associated with:

(a) American foul brood (*Paenibacillus* larvae);

(b) Acariosis (*Acarapis woodi* (*Rennie*));

(c) Small hive beetle (*Aethina tumida*); and

(d) Tropilaelaps mites (*Tropilaelaps spp*);

II.2. have been

(2) *either* [subjected to a temperature of – 12 °C or lower for at least 24 hours;]

(2) *or* [in the case of wax refined or rendered.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.99 and specify the commodity as listed under note Box reference I.28.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: means honey, beeswax, royal jelly, propolis or pollen used in bee-keeping.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 14(A)

Health certificate

For fat derivatives not intended for human consumption to be used for technical purposes, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code | I.8. Region of origin Code | I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code) **15.16.10**

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Technical use ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **For fat derivatives to be used for technical purposes**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the fat derivatives described above:

II.1. consist of fat derivatives that satisfy the health requirements below;

II.2. consist of fat derivatives containing exclusively fat derivatives not intended for human nor animal consumption;

II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 14 and where appropriate Article 11 of Regulation (EC) No 1774/2002, in order to kill pathogenic agents;

II.4. have been prepared from rendered fats exclusively produced from Category 2 and/or Category 3 materials (3);

II.5. the fat derivatives produced from Category 2 materials:

(a) have been produced using the following methods:

(2) *either* [transesterification or hydrolysis at least 200 °C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); and]

(2) *or* [saponification with NaOH 12 M (glycerol and soap):

(2) *either* [in a batch process at 95 °C for three hours; and]

(2) *or* [in a continuous process at 140 °C, 2 bars (2 000 hPa) for eight minutes; and]]

(b) are packaged in new containers or in containers that have been cleaned, and all precautions are taken to prevent its contamination which bear labels indicating “NOT FOR HUMAN OR ANIMAL COSUMPTION”.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of treatment/processing establishment.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) List of Category 2 materials:

(a) all animal materials collected when treating waste water from slaughterhouses other than slaughterhouses covered by Article 4(1)(d) or from Category 2 processing plants, including screenings, materials from de-sanding, grease and oil mixtures, sludge and materials removed from drains from those premises;

(b) 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;

(c) products of animal origin, other than Category 1 material, that are imported from third countries and, in the course of the inspections provided for in Community legislation, fail to comply with the veterinary requirements for their importation into the Community, unless they are returned or their importation is accepted under restrictions laid down under Community legislation;

(d) animals and parts of animals, other than those referred to in Article 4, that die other than by being slaughtered for human consumption, including animals killed to eradicate an epizootic disease;

(e) mixtures of Category 2 material with Category 3 material, including any material destined for processing in a Category 2 processing plant; and

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

▼**M9**

—	The signature and the stamp must be in a different colour to that of the printing.
—	Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals):	Qualification and title:
Date:	Signature:
Stamp:	

▼M9

CHAPTER 14(B)

Health certificate

For fat derivatives not intended for human consumption to be used as feed or for technical purposes, intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code) **15.16.10**

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐ Technical use ☐

I.26. For transit to third country vis-à-vis EU ☐
ISO code | 3rd country

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **Fat derivatives to be used as feed or for technical purposes**

Part II: Certification		II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the fat derivatives described above:

II.1. consist of fat derivatives that satisfy the health requirements below;

II.2. consist of fat derivatives containing exclusively fat derivatives not intended for human consumption;

II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 14 and where appropriate Article 11 of Regulation (EC) No 1774/2002, in order to kill pathogenic agents;

II.4. have been prepared from rendered fats exclusively produced from the following Category 3 materials:

(2) *either* [— parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,]

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

(2) *and/or* [— hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,]

(2) *and/or* [— blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,]

(2) *and/or* [— animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,]

(2) *and/or* [— former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste (3), which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,]

(2) *and/or* [— milk originating from animals which do not show any clinical signs of any disease communicable through that product to humans or animals,]

(2) *and/or* [— fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,]

(2) *and/or* [— by-products from fish from plants manufacturing fish products for human consumption,]

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

II.5. are packaged in new containers or in containers which bear labels indicating “NOT FOR HUMAN CONSUMPTION”, that have been cleaned, and all precautions are taken to prevent its contamination.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of treatment/processing establishment.

▼M9

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 15

Health certificate

For egg products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through (3) *the European Community*

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Tel. No

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel. No

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel. No

I.7. Country of origin ISO code | I.8. Region of origin Code | I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code) **35.02**

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for:
Animal feedingstuff ☐

I.26. For transit to third country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

▼M9

COUNTRY **Egg products not intended for human consumption that could be used as feed material**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and certify that the egg products described above:

II.1. consist of egg products that satisfy the health requirements below;

II.2. consist exclusively of egg products not intended for human consumption;

II.3. have been prepared and stored in a plant, approved, validated and supervised by the competent authority in accordance with Article 17 and where appropriate Article 11 of Regulation (EC) No 1774/2002 or Council Directive 89/437/EEC (2), in order to kill pathogenic agents;

II.4. have been prepared (derived) exclusively with the following animal by-product:

— eggs originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals;

II.5. have been subjected to processing:

(3) *either* [in accordance with processing method …….. (4) as set out in Annex V, Chapter III of Regulation (EC) No 1774/2002;]

(3) *or* [in accordance to a method and parameters which ensure that the products complies with the microbiological standards set in Chapter I, paragraph 10 of Annex VII to Regulation (EC) No 1774/2002]

(3) *or* [treated in accordance with Chapter V of the Annex to Council Directive 89/437/EC]

II.6. have been examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards (5):

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

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 gram;

II.7. meet Community standards on residues of substances that are harmful or might alter the organoleptic characteristics of the product or make its use as feed dangerous or harmful to animal health;

II.8. the end product was:

(3) *either* [packed in new or sterilized bags;]

(3) *or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

and which bear labels indicating 'NOT FOR HUMAN CONSUMPTION';

II.9. the end product was stored in enclosed storage;

II.10. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

▼M9

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) OJ L 212, 22.07.1989, p. 89.

(3) Delete as appropriate.

(4) Insert method 1 to 5 or 7 as applicable.

(5) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:

Stamp:

▼M9

CHAPTER 16

Model Declaration

Declaration by the importer 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 use other than as feed material, organic fertilisers or soil improvers for dispatch to the European Communities

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

I, the undersigned, declare that the following products ([1]):

(a) bones and bone products (excluding bone meal);

(b) horns and horn products (excluding horn meal);

(c) hooves and hoof products (excluding hoof meal);

are intended to be imported by me into the Community, and I declare that these products will not be diverted at any stage for any use in food, feed material, organic fertilizers or soil improvers and will be conveyed directly for the purpose of further processing or treatment to:

Name:..... Address: .....

The importer:

Name:..... Address: .....

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

Signature .....

Reference number as indicated on the common veterinary entry document (CVED) provided for in Annex III to Commission Regulation (EC) No 136/2004:

.....

Official stamp of the border inspection post of entry into the EC ([2])

Signature: .....
(Signature of the official veterinarian of the border inspection post) ([2])

Name: .....
(Name in capital letters)

([1]) Delete as appropriate.
([2]) The signature and the stamp must be in a different colour to that of the printing.

▼M9

CHAPTER 17

Health certificate

For processed manure and processed manure products intended for dispatch to or for transit through (2) the European Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No		I.2. Certificate reference number	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6. Person responsible for the consignment in EU Name Address Postal code Tel. No	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Identification of container/Seal number		I.24. Type of packaging	
I.25. Commodities certified for: Animal feedingstuff ☐ Technical use ☐ Other ☐			
I.26. For transit to third country vis-à-vis EU ☐ 3rd country ISO code		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight

▼M9

COUNTRY **Processed manure and processed manure products**

Part II: Certification

II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) and in particular Article 5 and Annex VIII Chapter VI thereof and certify that the processed manure or processed manure products described above:

II.1. come from a technical plant, a biogas plant or a composting plant approved by the competent authority of the third country meeting the special conditions laid down in Regulation (EC) No 1774/2002;

II.2. (2) have been subjected to:

[a heat treatment process of at least 70 °C for at least 60 minutes]; or

[an equivalent treatment validated and authorized by the importing Member State in accordance with the specific conditions laid down in Regulation (EC) No 1774/2002 as follows:

.....

.....

.....;]

II.3. are:

(a) free from *Salmonella* (no *salmonella* in 25 g treated product);

(b) free from *Escherichia coli* or from *enterobacteriacea* (based on the aerobic count: less than 1 000 cfu per gram of treated product); and

(c) have been subjected to reduction in spore-forming bacteria and toxic formation;

II.4. are securely enclosed in:

(a) well-sealed and insulated containers; or

(b) properly sealed packs (plastic bags or big bags).

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: enter if processed manure or if processed manure products.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capitals): Qualification and title:

Date: Signature:'.

Stamp:

▼M16

CHAPTER 18

Health certificate

For horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers intended for dispatch to or for transit through (2) the European Union

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. Nº		I.2. Certificate reference number	I.2.a
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. Nº		I.6. Person responsible for the load in EU Name Address Postal code Tel. Nº	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination Customs warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references		I.16. Entry BIP in EU I.17. No.(s) of CITES	
I.18. Description of commodity		I.19. Commodity code (HS code) I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Identification of container/Seal number		I.24. Type of packaging	
I.25. Commodities certified for Animal feedingstuff ☐ Further process ☐ Technical use ☐ Other ☐			
I.26. For transit through EU to 3rd Country ☐ 3rd country ISO code		I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species Approval number of establishments Manufacturing plant Net weight Batch number			

▼M16

COUNTRY

Horns and horn products and hooves and hoof products intended to produce organic fertilizers or soil improvers

II. Health information	II.a. Certificate reference number	II.b.

Part II: Certification

II.1. I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1) , and in particular Chapter XV of Annex VIII thereof, and certify that the horns and horn products, excluding horn meal and hooves and hoof products, excluding hoof meal (2) described above:

(2) *either* [originate from animals that were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption]

(2) *or* [originate from animals that did not show clinical signs of any disease communicable through that product to humans or animals]

II.2. horns must have undergone a heat treatment for one hour at a core temperature of at least 80 °C;

II.3. horns must have been removed without opening the cranial cavity;

II.4. at any stage of processing, storage or transport every precaution shall be taken to avoid cross- contamination;

II.5. were packed:

(2) *either* [in new packaging or containers,]

(2) *or* [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority,]

and [the packaging or containers are marked so as to indicate the type of the animal by-product (3) and bear labels indicating "NOT FOR HUMAN AND ANIMAL CONSUMPTION" and the name and address of the EU establishment of destination].

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit must only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity.

Part II:

(1) OJ L 273, 10.10.2002, p. 1.

(2) Delete as appropriate.

(3) Type of product: horns, horn products, hooves, hoof products.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

▼**M16**

ANNEX XI

Lists of third countries from which Member States may authorise imports of animal by-products not intended for human consumption

The inclusion of a third country on one of the following lists is a necessary, but not sufficient, condition for the importation of the relevant products from that third country. Imports must also fulfil the relevant animal health and public health requirements. The following descriptions refer to the territories or parts thereof from which imports of certain animal by-products are permitted, as stated in the relevant animal health certificate or declaration laid down in Annex X.

▼**M17**

PART I

List of third countries from which Member States may authorise imports of milk, milk products, colostrum and colostrum products (health certificate Chapter 2)

A. Milk and milk products:

Third countries listed as authorised in any of the columns of Annex I to Decision 2004/438/EC.

B. Colostrum and colostrum products:

Third countries listed as authorised in column ‘A’ of Annex I to Decision 2004/438/EC.

▼**M16**

PART II

List of third countries from which Member States may authorise imports of processed animal proteins (excluding fishmeal) (health certificate, Chapter 1)

Third countries listed in Part 1 of Annex II to Commission Regulation (EU) No 206/2010 ([1]).

PART III

List of third countries from which Member States may authorise imports of fishmeal and fish oil (health certificate, Chapters 1 and 9)

Third countries listed in Annex II to Commission Decision 2006/766/EC ([2]).

PART IV

List of third countries from which Member States may authorise imports of rendered fats (excluding fish oil) (health certificate, Chapters 10(A) and 10(B))

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.

PART V

List of third countries from which Member States may authorise imports of blood products for feed material (health certificate, Chapter 4(B))

A . *Blood products from ungulates*

Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which imports of all categories of fresh meat of the respective species are authorised.

▼M16

B . *Blood products from other species*

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.

PART VI

List of third countries from which Member States may authorise imports of animal by-products and blood products (with the exception of those of equidae) intended for technical purposes including pharmaceuticals (health certificate, Chapters 4(C) and 8)

A. Blood products:

1. Untreated blood products of ungulates:

Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 from which imports of fresh meat of any domestic ungulate species is authorised and only for the period indicated in columns 7 and 8 of that Part,

— (JP) Japan.

2. Untreated blood products of poultry and other avian species:

Third countries or parts of third countries listed in Part 1 of Annex I to Commission Regulation (EC) No 798/2008 ([3]),

— (JP) Japan.

3. Untreated blood products of other animals:

Third countries listed either in Part 1 of Annex II to Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008, or in Part 1 of Annex I to Commission Regulation (EC) No 119/2009 ([4]),

— (JP) Japan.

4. Treated blood products of any species:

Third countries listed in Part 1 to Annex II of Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008, or in Part 1 of Annex I to Regulation (EC) No 119/2009,

— (JP) Japan.

B. Animal by-products for pharmaceutical use:

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008, or in Part 1 of Annex I to Regulation (EC) No 119/2009 and the following third countries:

— (JP) Japan,

— (PH) Philippines,

— (TW) Taiwan.

▼M16

C. Animal by-products for technical purposes other than pharmaceutical uses: third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 from which imports of that category of fresh meat of the respective species is authorised, in Part 1 of Annex I to Regulation (EC) No 798/2008, or in Part 1 of Annex I to Regulation (EC) No 119/2009.

PART VII(A)

List of third countries from which Member States may authorise imports of animal by-products for the manufacture of petfood (health certificate, Chapter 3(F))

A. Animal by-products from equidae and animals of the bovine, ovine, caprine, and porcine species, including farmed and wild animals:

Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which imports of fresh meat for human consumption of those species of animals is authorised.

B. Raw material from poultry including ratites and wild game-birds:

Third countries or parts of third countries from which Member States authorise imports of fresh poultrymeat, which are listed in Part 1 of Annex I to Regulation (EC) No 798/2008.

C. Raw material from fish:

Third countries listed in Annex II to Decision 2006/766/EC.

D. Raw material from other wild land mammals and Leporidae.

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EC) No 119/2009, from which Member States authorise imports of fresh meat from the same species.

PART VII(B)

List of third countries from which Member States may authorise imports of raw petfood intended for dispatch to the European Union for direct sale or animal by-products to be fed to farmed fur animals (health certificate, Chapter 3(D))

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is authorised.

In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.

PART VII(C)

List of third countries from which Member States may authorise imports of flavouring innards for use in the manufacture of petfood, intended for dispatch to the European Union (health certificate, Chapter 3(E))

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is authorised.

▼M16

In the case of flavouring innards from fish materials, third countries listed in Annex II to Decision 2006/766/EC.

PART VIII

List of third countries from which Member States may authorise imports of pig bristles (health certificate, Chapter 7(A) and 7(B))

A. For untreated pig bristles, third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, which are free of African swine fever for the 12 months prior to the date of importation.

B. For treated pig bristles, third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, which may not be free of African swine fever for the 12 months prior to the date of importation.

PART IX

List of third countries from which Member States may authorise imports of processed manure and processed manure products for the treatment of soil (health certificate, Chapter 17)

For processed manure and processed manure products, third countries listed in:

(a) Part 1 of Annex II to Regulation (EU) No 206/2010;

(b) Annex I to Commission Decision 2004/211/EC ([5]); or

(c) Part 1 of Annex I to Regulation (EC) No 798/2008.

PART X

List of third countries from which Member States may authorise imports of petfood and dogchews (health certificate, Chapters 3(A), 3(B) and 3(C))

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following third countries:

— (JP) Japan

— (EC) Ecuador ([6])

— (LK) Sri Lanka ([7])

— (TW) Taiwan ([8])

PART XI

List of third countries from which Member States may authorise imports of gelatine, hydrolysed protein, collagen, dicalcium phosphate and tricalcium phosphate (health certificate, Chapters 11 and 12)

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following third countries:

— (KR) South Korea ([9])

— (MY) Malaysia ([9])

▼**M16**

— (PK) Pakistan ([9])

— (TW) Taiwan ([9]).

▼**M17**

PART XII

List of third countries from which Member States may authorise imports of apiculture products (health certificate Chapter 13)

Third countries listed in part 1 of Annex II to Regulation (EU) No 206/2010, and the following country:

— '(CM) Cameroon'.

▼**M16**

PART XIII

List of third countries from which Member States may authorise imports of blood and blood products of equidae (health certificate, Chapter 4(A))

A. Untreated blood and blood products: Third countries or parts of third countries listed in Annex I to Decision 2004/211/EC, from which the importation of equidae for breeding and production is allowed.

B. Treated blood products: third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat of domestic equidae.

PART XIV

List of third countries from which Member States may authorise imports of hides and skins of ungulates (health certificate, Chapters 5(A), 5(B) and 5(C))

A. For fresh or chilled hides and skins of ungulates, third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat from the same species.

B. For treated hides and skins of ungulates, third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.

C. For treated hides and skins of ruminants that are intended for dispatch to the Union and which have been kept separate for a period of 21 days or which are to undergo transport for a period of 21 uninterrupted days before importation, any third country.

PART XV

List of third countries from which Member States may authorise imports of game trophies (health certificate, Chapters 6(A) and 6(B))

A. For treated game trophies of birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, any third country.

B. For game trophies of birds consisting of entire parts not having been treated, third countries listed in Part 1 of Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh poultry meat, and the following countries:

— (GL) Greenland

— (TN) Tunisia.

▼**M16**

C. For game trophies of ungulates consisting of entire parts not having been treated, third countries listed in the appropriate columns for fresh meat of ungulates in Part 1 of Annex II to Regulation (EU) No 206/2010, including any restrictions laid down in the column for special remarks for fresh meat.

PART XVI

List of third countries from which Member States may authorise imports of egg products not intended for human consumption that could be used as feed material (health certificate, Chapter 15)

Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and third countries or parts of third countries from which Member States authorise imports of fresh poultry meat, which are listed in Part 1 of Annex I to Regulation (EC) No 798/2008.

PART XVII

List of third countries from which Member States may authorise imports 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 use other than as feed material, organic fertilisers or soil improvers (declaration, Chapter 16)

Any third country.

PART XVIII

List of third countries from which Member States may authorise imports of horns and horn products (excluding horn meal) and hooves and hoof products, (excluding hoof meal) intended for the production of organic fertilizers or soil improvers (health certificate, Chapter 18)

Any third country.

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(1) OJ L 73, 20.3.2010, p. 1.
(2) OJ L 320, 18.11.2006, p. 53.
(3) OJ L 226, 23.8.2008, p. 1.
(4) OJ L 39, 10.2.2009, p. 12.
(5) OJ L 73, 11.3.2004, p. 1.
(6) Petfood of fish origin only.
(7) Dogchews made from hides and skins of ungulates only.
(8) Processed petfood for ornamental fish only.
(9) Gelatine only.