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NOTIFIKAZZJONIJI TAL-GVERN

Nru. 53

ATT TA' L-2001 DWAR IS-SERVIZZI VETERINARJI (ATT NRU. XXIII TA' L-2001)

BIS-SAĦĦA tas-setgħat mogħtija bl-artikolu 3 ta' l-Att ta' l-2002 dwar is-Servizzi Veterinarji, il-Ministru għall-Affarijiet Rurali u ta' l-Ambjent, qiegħed b'din jippubblika l-abbozz ta' regolamenti li ġej biex jippermettu lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti humiex restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

It-18 ta' Jannar, 2005

GOVERNMENT NOTICE

No. 53

VETERINARY SERVICES ACT, 2001 (ACT NO. XXIII OF 2001)

BY VIRTUE of the powers conferred by article 3 of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment, is hereby publishing the following draft regulations to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and ask for the consideration of the revision of such draft:-

18th January, 2005

VETERINARY SERVICES ACT, 2001 (ACT NO. XXIII OF 2001)

IN exercise of the powers conferred by article 3(1) of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has made the following regulations:-

Health Rules Concerning Animal By-Products not intended for Human Consumption Regulations, 2005

CHAPTER I
GENERAL PROVISIONS

Title, scope and applicability

1. (1) The title of these regulations is Health Rules Concerning Animal By-Products not intended for Human Consumption Regulations, 2005.

(2) The scope of these regulations is to implement the rules found under European Union Regulation (EC) No. 1774/2002 laying down health rules concerning animal by-products not intended for human consumption.

(3) These regulations lay 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 there from referred to in Schedules VII and VIII.

(4) These regulations shall not apply to -

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

(e) catering waste, unless -

(i) from means of transport operating internationally,

(ii) destined for animal consumption, or,

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

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

(g) transit by sea or by air.

(5) These regulations shall not affect veterinary legislation having as its objective the eradication and control of certain diseases.

Definitions

2. (1) For the purpose of these regulations, the following definitions shall apply-

(a) "animal" means any vertebrate or invertebrate animal (including fish, reptiles and amphibians);

(b) "animal by-products" means entire bodies or parts of animals or products of animal origin referred to in regulations 4, 5 and 6 not intended for human consumption, including ova, embryos and semen;

(c) "Category 1 material" means animal by-products referred to in regulation 4;

(d) "Category 2 material" means animal by-products referred to in regulation 5;

(e) "Category 3 material" means animal by-products referred to in regulation 6;

(f) "the competent authority" means the Veterinary Services as provided under article 2 of the Veterinary Services Act and which is the central authority in Malta to ensure compliance with the requirements of these regulations.

Provided that this shall also include any authority to which the Veterinary Services has delegated the competence established under these regulations: in particular for the control of feeding stuffs. Moreover, it shall also include, where appropriate, the corresponding authority of a non-member country.

(g) "farmed animal" means 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;

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

(i) "placing on the market" means any operation the purpose of which is to sell animal by-products, or products derived there from covered by these regulations, to a third party in the European 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;

(j) "producer" means any person whose activity produces animal by-products;

(k) "specified risk material" means material referred to in Annex V to European Union Regulation (EC) No. 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

(l) "trade" means trade between Member States in goods within the meaning of Article 23(2) of the Treaty establishing the European Community;

(m) "transit" means a movement through the European Community from one non-member country to another;

(n) "TSEs" means all transmissible spongiform encephalopathies, except those occurring in humans;

(o) "Veterinary Services" means the competent authority as provided in paragraph (e) above, and as established under article 2 of the Veterinary Services Act;

(p) "wild animal" means any animal not kept by humans.

(2) The specific definitions set out in Schedule I shall also apply for the purposes of these regulations.

General obligations

3. (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 these regulations.

(2) However, Malta may regulate under national legislation the importation and placing on the market of products not referred to in Schedules VII and VIII, pending the adoption of a decision in accordance with the procedure referred to in regulation 32(2). Malta shall immediately inform the European Commission of the use made of this possibility.

(3) Malta shall, either individually or cooperatively with other Member States, ensure that adequate arrangements are in place, and that a sufficient infrastructure exists, to ensure compliance with the requirement of sub-regulation (1).

CHAPTER II

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

Category 1 material

4. (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 European Union 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 European Union 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; 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 European Union Council 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 European Union Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing European Union

Council Directives 85/358/EEC and 86/469/EEC and European Union Decisions 89/187/EEC and 91/664/EEC, if such residues exceed the permitted level laid down by European Community legislation or, in the absence thereof, by national legislation;

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

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

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

(2) Category 1 material shall be collected, transported and identified without undue delay in accordance with regulation 7 and, except as otherwise provided in regulations 23 and 24, shall be -

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

(b) processed in a processing plant approved under regulation 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 Schedule 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 regulation 12;

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

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

(e) in the light of developments in scientific knowledge, disposed of by other means that are approved in accordance with the procedure referred to in regulation 32(2), after consultation of the appropriate scientific committee. These means may either supplement or replace those provided for in sub-paragraphs (a) to (d).

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

(4) Category 1 material shall not be imported or exported except in accordance with these regulations or with rules laid down under the procedure referred to in regulation 32(2). However, the import or export of specified risk material shall take place only in accordance with Article 8(1) of European Union Regulation (EC) No. 999/2001.

Category 2 material

5. (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 regulation 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 European Union Council Directive 96/23/EC, if such residues exceed the permitted level laid down by European 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 European Community legislation, fail to comply with the veterinary requirements for their importation into the European Community, unless they are returned or their importation is accepted under restrictions laid down under European Community legislation;

(e) animals and parts of animals, other than those referred to in regulation 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 regulation 7 and, except as otherwise provided in regulations 23 and 24, shall be -

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

(b) processed in a processing plant approved in accordance with regulation 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 Schedule 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 regulation 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 regulation 14;

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

(i) in the case of resulting proteinaceous material, used as an organic fertilizer or soil improver in compliance with requirements, if any, laid down in accordance with the procedure referred to in regulation 32(2), after consultation of the appropriate scientific committee,

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

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

(d) in the case of material of fish origin, ensiled or composted in compliance with rules adopted in accordance with the procedure referred to in regulation 32(2);

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

(i) used without processing as raw material in a biogas plant or in a composting plant approved in accordance with regulation 15 or treated in a technical plant approved for this purpose in accordance with regulation 18,
(ii) applied to land in accordance with these regulations, or

(iii) transformed in a biogas plant or composted in accordance with rules laid down under the procedure referred to in regulation 32(2);

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

(g) disposed of by other means, or used in other ways, in accordance with rules laid down under the procedure referred to in regulation 32(2), after consultation of the appropriate scientific committee.

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

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

(4) Category 2 material shall not be placed on the market or exported except in accordance with this Regulation or with rules laid down under the procedure referred to in regulation 32(2).

Category 3 material

6. (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 European 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 European Community legislation;

(c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with European 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 European 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 regulation 4(1)(e).

(2) Category 3 material shall be collected, transported and identified without undue delay in accordance with regulation 7 and, except as otherwise provided in regulations 23 and 24, shall be -

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

(b) processed in a processing plant approved in accordance with regulation 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 Schedule 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 regulation 12 or in a landfill approved under European Union Council Directive 1999/31/EC;

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

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

(e) used as raw material in a pet food plant approved in accordance with regulation 18;

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

(g) in the case of catering waste referred to in sub-regulation (1)(l), transformed in a biogas plant or composted in accordance with rules laid down under the procedure referred to in regulation 32(2) or, pending the adoption of such rules, in accordance with national law;

(h) in the case of material of fish origin, ensiled or composted in accordance with rules laid down under the procedure referred to in regulation 32(2); or

(i) disposed of by other means, or used in other ways, in accordance with rules laid down under the procedure referred to in regulation 32(2), after consultation of the appropriate scientific committee.

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

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

Collection, transportation and storage

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

(2) During transportation, a commercial document or, when required by these regulations, 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 Schedule II. They shall, in particular, include information concerning the quantity and a description of the material and its marking.

(3) Malta shall ensure that adequate arrangements exist to guarantee the collection and transportation of Category 1 and Category 2 material in accordance with Schedule II.

(4) In accordance with Article 4 of European Union Council Directive 75/442/EEC on waste, Malta 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 regulation 11.

(6) However, Malta may decide not to apply the provisions of this regulation to manure transported between two points located on the same farm or between farms and users located in the same territory.

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

8. (1) Animal by-products and processed products shall be sent to other Member States only subject to the conditions laid down in sub-regulations (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 sub-regulation (2), shall be -

(a) accompanied by a commercial document or, when required by these regulations, a health certificate, and

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

(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 Schedule II, Chapter I, paragraph 2.

(5) When informed of its dispatch in accordance with sub-regulation (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 these regulations.

Records

9. (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 Schedule II.

(2) However, this regulation shall not apply to manure transported between two points located on the same farm or locally between farms and users located in the same territory.

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

Approval of intermediate plants

10. (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 Schedule III, Chapter I;

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

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

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

(3) To be approved, Category 3 intermediate plants must -

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

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

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

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

Approval of storage plants

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

(2) To be approved, storage plants must -

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

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

Approval of incineration and co-incineration plants

12. (1) The incineration and co-incineration of processed products shall take place in accordance with the provisions of European Union Council Directive 2000/76/EC.

The incineration and co-incineration of animal by-products shall take place either in accordance with the provisions of European Union Council Directive 2000/76/EC or, when that Directive does not apply, in accordance with the provisions of Regulation (EC) No. 1774/2002. Incineration and co-incineration plants shall be approved under that Directive or in accordance with sub-regulations (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 European Union Council Directive 2000/76/EC does not apply must fulfil -

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

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

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

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

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

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

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

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

(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 Schedule IV, Chapter I;

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

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

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

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

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

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

(5) The requirements of sub-regulation (2) and (3) may be modified in the light of developments in scientific knowledge in accordance with the procedure referred to in regulation 32(2), after consultation of the appropriate scientific committee.

Approval of Category 1 and Category 2 processing plants

13. (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 Schedule V, Chapter I;

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

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

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

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

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

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

Approval of Category 2 and Category 3 oleochemical plants

14. (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 Schedule 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 regulation 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 sub-regulation (2).

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

Approval of biogas plants and composting plants

15. (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 Schedule VI, Chapter II, Part A;

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

(c) be checked by the competent authority in accordance with regulation 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 Schedule 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

General animal health provisions

16. (1) Malta shall take all necessary measures to guarantee that animal by-products, and products derived therefrom referred to in Schedules 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 these regulations.

(2) The measures referred to in sub-regulation (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 European Community legislation or by virtue of a serious transmissible disease listed in European Union Council Directive 92/119/EEC introducing general European Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease;

(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 paragraph (a) were present at the time of slaughter.

(3) Subject to compliance with the disease control measures referred to in sub-regulation (2)(a), the placing on the market of animal by-products, and products derived therefrom referred to in Schedules 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 these regulations at a plant approved for that purpose by the Member State where the animal health problem occurred;

(c) are properly identified;

(d) comply with the requirements laid down in Schedules VII and VIII, or with detailed rules to be laid down in accordance with the procedure referred to in regulation 32(2).

Conditions alternative to those set out in the sub-regulation (1) may be laid down in specific situations by decisions adopted in accordance with the procedure referred to in regulation 32(2). Such decisions shall take account of any measures concerning the animals or tests to be carried out on them and the specific characteristics of the disease in the species concerned and shall specify any measures needed to ensure the protection of animal health in the European Community.

Approval of Category 3 processing plants

17. (1) Category 3 processing plants shall be subject to approval by the Veterinary Services.

(2) To be approved, Category 3 processing plants must -

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

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

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

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

(e) be checked by the Veterinary Services in accordance with regulation 26; and

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

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

Approval of pet food plants and technical plants

18. (1) Pet food plants and technical plants shall be subject to approval by the Veterinary Services.

(2) To be approved, the pet food plant or the technical plant must -

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

(i) to comply with the specific production requirements set out in these 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 analysis in a laboratory recognised by the Veterinary Services for the purposes of checking compliance with the standards established by these regulations;

(iv) to keep a record of the information obtained pursuant to points (ii) and (iii) for presentation to the Veterinary Services. 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 Veterinary Services in accordance with regulation 26.

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

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

19. Malta 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 regulation 17;

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

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

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

Placing on the market and export of pet food, dog chews and technical products

20. (1) Member States shall ensure that pet food, dog chews, technical products, other than those referred to in sub-regulation (2) and (3), and those animal by-products referred to in Schedule VIII are placed on the market or exported only if they -

(a) meet either -

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

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

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

(2) Malta shall ensure that organic fertilizers and soil improvers produced from processed products, other than those produced from manure and digestive tract content, are placed on the market or exported only if they meet requirements, if any, laid down in accordance with the procedure referred to in regulation 32(2), after consultation of the appropriate scientific committee.

(3) Malta 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 regulation 14 from rendered fats resulting from the processing of Category 2 material in a Category 2 processing plant approved in accordance with regulation 13 following the application of any of processing methods 1 to 5;

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

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

Safeguard measures

21. Article 10 of European Union Council Directive 90/425/EEC shall apply to the products covered by Schedule VII and VIII to these regulations.

Restrictions on use

22. (1) The following uses of animal by-products and processed products are prohibited -

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

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

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

(2) Rules for the implementation of this regulation, including rules concerning control measures, shall be adopted in accordance with the procedure referred to in regulation 32(2). Derogations from sub-regulation (1)(a) may be granted in relation to fish and fur animals by the same procedure, after consultation of the appropriate scientific committee.

CHAPTER V
DEROGATIONS

Derogations regarding the use of animal by-products

23. (1) Malta may authorise, under the supervision of the Veterinary Services -

(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 regulation 18.

(2) (a) Malta may also authorise the use of the animal by-products specified in sub-paragraph (b) for the feeding of the animals specified in sub-paragraph (c), under the supervision of the Veterinary Services and in accordance with the rules laid down in Schedule IX.

(b) The animal by-products referred to in sub-paragraph (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 regulation 6(1)(a) to (j) and, subject to regulation 22, in regulation 6(1)(l).

(c) The animals referred to in sub-paragraph (a) are -

(i) zoo animals,

(ii) circus animals,

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

(iv) fur animals,

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

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

(vii) maggots for fishing bait.

(d) In addition, Malta may authorise the use, under the supervision of the Veterinary Services, of Category 1 material referred to in regulation 4(1)(b)(ii) for the feeding of endangered or protected species of necrophagous birds in accordance with rules laid down under the procedure referred to in regulation 32(2) after consultation of the European Food Safety Authority.

(3) Member States shall inform the European Commission of -

(a) the use made of the derogations referred to in sub-regulation (2); and

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

(4) Malta shall draw up a list of users and collection centres authorised and registered pursuant to sub-regulation (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 Veterinary Services shall supervise the premises of users and collection centres and have free access at all times to all parts of such premises, to ensure compliance with the requirements referred to in sub-regulation (2).

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

(5) Detailed rules concerning verification measures may be adopted in accordance with the procedure referred to in regulation 32(2).

Derogations regarding the disposal of animal by-products

24. (1) The Veterinary Services 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 regulation 4(1)(b)(ii),

(ii) Category 2 material, and

(iii) Category 3 material; and

(c) animal by-products may be disposed of as waste by burning or burial on site in the event of an outbreak of a disease mentioned in List A of the International Office of Epizootic Diseases (OIE), if the Veterinary Services 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 regulation 4(1)(a)(i).

(3) In the case of Category 1 material referred to in regulation 4(1)(b)(ii), burning or burial may take place in accordance with sub-regulation (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) Malta shall inform the European Commission of -

(a) the use they make of the possibilities provided for in sub-regulation (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 sub-regulation (1)(b) and the reasons for that categorisation.

(5) The Veterinary Services 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 regulation may be laid down under the procedure referred to in regulation 32(2).

CHAPTER VI
CONTROLS AND INSPECTIONS

Plants' own-checks

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

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

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

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

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

(ii) with the maximum permitted levels of physicochemical residues laid down in European 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 Veterinary Services;

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

(2) Where the results of a test on samples taken pursuant to sub-regulation (1)(c) do not comply with the provisions of these regulations, the operator of the processing plant must -

(a) notify the Veterinary Services 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 Veterinary Services;

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

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

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

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

(3) Detailed arrangements for implementing this regulation, including rules concerning the frequency of checks and reference methods for microbiological analyses, may be laid down under the procedure referred to in regulations 32(2).

Official controls and lists of approved plants

26. (1) The Veterinary Services shall at regular intervals carry out inspections and supervision at plants approved in accordance with these regulations. Inspections and supervision of processing plants shall take place in accordance with Schedule 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 these regulations are not being met, the Veterinary Services shall take appropriate action.

(4) Malta shall draw up a list of plants approved in accordance with these regulations within its territory. It shall assign an official number to each plant, which identifies the plant with respect to the nature of its activities. Malta shall also send copies of the list and updated versions to the European Commission and other Member States.

(5) Detailed arrangements for implementing this regulation, including rules concerning the frequency of checks and reference methods for microbiological analyses, may be laid down under the procedure referred to in regulation 32(2).

CHAPTER VII

COMMUNITY CONTROLS

Community controls in Member States

27. (1) Experts from the European Commission may make on-the-spot checks, in cooperation with the Veterinary Services of Malta, in so far as is necessary for the uniform application of these

regulations. Malta shall provide the experts with all the assistance necessary for carrying out their duties.
The European Commission shall inform the Veterinary Services of the results of the checks made.

(2) Rules for the implementation of this regulation, in particular those governing the procedure for cooperation with Veterinary Services, shall be laid down under the procedure referred to in regulation 32(2).

CHAPTER VIII

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

General provisions

28. The provisions applicable to the importation of products referred to in Schedules 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 European Community:

Provided that, the importation from third countries of pet-food and raw material for pet-food production, derived from animals which have been treated with certain substances prohibited in accordance with European Union Council Directive 96/22/EC, shall be permitted provided that such raw material is permanently marked and under specific conditions laid down under the procedure referred to in regulation 32(2).

Prohibitions and compliance with European Community rules

29. (1) The importation and transit of animal by-products and processed products shall be prohibited, except in accordance with these regulations.

(2) The importation into, and the transit through, the European Community of the products referred to in Schedules VII and VIII may take place only if such products satisfy the requirements set out in sub-regulations (3) to (6).

(3) Products referred to in Schedules VII and VIII shall, save as otherwise specified in those Schedules, 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 regulation 32(2).

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

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

(a) the legislation of the third country;

(b) the organisation of the competent authority and its inspection services in the third country, the powers of 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 European 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 European 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 European 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 Schedules VII and VIII, except for technical products, must come from plants on a European Community list drawn up under the procedure referred to in regulation 32(2) on the basis of a communication from the competent authorities of the third country to the European Commission declaring that the plant complies with the European 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 European Commission shall inform Malta 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) Malta 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 European Commission;

(c) when at least one Member State makes written comments, the European 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 regulation 32(2);

(d) when the European Commission receives no comments from the Member States within the time limit referred to in sub-paragraph (b), Member States shall be considered to have accepted the modifications to the list. The European 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 Schedule VIII must come from plants that the competent authorities of the third countries have approved and registered.

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

(7) Pending the compilation of the list provided for in sub-regulation (4) and the adoption of model certificates as referred to in sub-regulation (6), Malta may maintain the controls provided for in European Union Council Directive 97/78/EC and certificates provided for under existing national rules.

Equivalence

30. (1) In accordance with the procedure referred to in regulation 32(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 Schedules VII and VIII offer guarantees equivalent to those applied in the European 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 sub-regulation (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 European Community; and

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

(3) Detailed rules for the application of this regulation shall be laid down under the procedure referred to in regulation 32(2).

CHAPTER IX
FINAL PROVISIONS

Amendments to Schedules and transitional measures

31. (1) After consultation of the appropriate scientific committee on any question that could have an impact on animal or public health, the Schedules may be amended or supplemented and any appropriate transitional measures may be adopted in accordance with the procedure referred to in regulation 32(2).

(2) With regard to the ban on the feeding of catering waste referred to in regulation 22, where appropriate control systems are in place in Malta prior to the application of these regulations, transitional measures shall be adopted, in accordance with sub-regulation (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.

European Commission regulatory procedure

32. (1) The European 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 sub-regulation, Articles 5 and 7 of European Union Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

(3) The Committee shall adopt its rules of procedure.

Consultation of scientific committees

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

National provisions

34. (1) Malta shall communicate to the European Commission the text of the provisions of any national law that it adopts in the field covered by these regulations.

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

(3) Malta may adopt or maintain national rules restricting the use of organic fertilizers and soil improvers further than envisaged in these regulations pending the adoption of European Community rules for their use in accordance with regulation 20(2). Malta may adopt or maintain national rules restricting the use of fat derivatives produced from Category 2 material further than envisaged in these regulations pending the addition to Schedule VIII of European Community rules for their use in accordance with regulation 31.

Financial arrangements

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

SCHEDULE I

SPECIFIC DEFINITIONS

For the purpose of this Schedule -

1. 'apiculture products' means honey, beeswax, royal jelly, propolis or pollen used in bee-keeping;

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

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

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

5. 'blood' means fresh whole blood;

6. 'bloodmeal' means products derived from the heat-treatment of blood in accordance with Schedule VII, Chapter II, and intended for animal consumption or organic fertilizers;

7. 'canned pet food' means heat-processed pet food 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 Schedule 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;

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

16. 'co-incineration plant' means a disposal site as defined in Article 3(5) of European Union 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 regulation 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. 'dog chews' 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 European Union Directive 96/25/EC, 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 European Union Directive 2000/76/EC;

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

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

35. 'landfill' means a disposal site as defined by European Union 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;

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 Schedule VIII or otherwise transformed in biogas or composting plants;

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

39. 'pasture land' means land covered with grass or other herbage and grazed by farmed animals;

40. 'pet food plant' means a plant producing pet food or dog chews or flavouring innards and in which certain animal by-products are used in the preparation of such pet food, dog chews or flavouring innards;

41. 'pet food' means food for pet animals containing Category 3 material;

42. 'processed animal protein' means animal proteins derived entirely from Category 3 material, which have been treated in accordance with Chapter II of Schedule V so as to render them suitable for direct use as feed material or other use in feeding stuffs, including pet food, or use in organic fertiliser 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;

43. 'processed pet food' means pet food, other than raw pet food, that has undergone treatment in accordance with the requirements of Schedule VIII;

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

45. 'processing methods' means the methods listed in Schedule V, Chapter III;

46. 'processing plant' means an animal by-products processing plant;

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

48. 'raw pet food' means pet food 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 European Union Directive 95/69/EC, 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;
55. 'unprocessed feathers and parts of feathers' means feathers and parts of feathers that have not been treated with a steam current or by some other method that ensures that no pathogens remain;

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

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

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

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

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

64. 'flavouring innard' means a liquid or dehydrated processed product of animal origin used to enhance the palatability values of pet food.

SCHEDULE II

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

CHAPTER I

Identification

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

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

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

2. During transport, a label attached to the vehicle, container, carton or other packaging material must clearly indicate -

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

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

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

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

(iv) in the case of manure and digestive tract content, the word 'manure'.

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.

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

CHAPTER III

Commercial documents and health certificates

1. During transportation, a commercial document or, when required by these regulations, 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.

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;

(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 regulation 32(2).

5. Health certificates must be issued and signed by the Veterinary Services.

CHAPTER IV

Records

The records referred to in regulation 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 Veterinary Services.

CHAPTER VI

Temperature conditions

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

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

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

CHAPTER VII

Specific rules for transit

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

CHAPTER VIII

Control measures

The Veterinary Services 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 these regulations require it or the Veterinary Services consider it necessary, by sealing.

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

CHAPTER IX

Collection of animal material when treating waste water

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

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

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

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 European Community legislation.

SCHEDULE III

HYGIENE REQUIREMENTS FOR INTERMEDIATE AND STORAGE PLANTS

CHAPTER I

Requirements for the approval of intermediate plants

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

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

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

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

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

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

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

(g) Where it is necessary for the purpose of achieving the objectives of these regulations, 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 regulation 22.

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

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.

B.

11. Waste water must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from Category 1 and Category 2 intermediate plants may be laid down in accordance with the procedure referred to in regulation 32(2).

CHAPTER III

Requirements for the approval of storage plants

Premises and facilities must meet at least the following requirements.

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

2. The plant must -

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

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

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

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

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

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

SCHEDULE IV

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

CHAPTER I

General conditions

1. Incineration or co-incineration plants must be designed, equipped and operated in such a manner as to fulfil the requirements of these regulations. 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.

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 ºC, as measured near the inner wall or at another representative point of the combustion chamber as authorised by the Veterinary Services, 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 ºC. It must also be used during plant start-up and shutdown operations to ensure that the temperature of 850 ºC 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 ºC has been reached; and

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

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

CHAPTER III

Water discharges

7. Incineration or co-incineration plant sites, including associated storage areas for animal by-products, must be designed in such a way as to prevent unauthorised and accidental release of any polluting substances into soil, surface water and groundwater in accordance with the provisions provided for in relevant European 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 European 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 these regulations in accordance with procedures to be decided upon by that authority.

CHAPTER VI

Abnormal operating

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

CHAPTER VII

Incineration of Category 1 material referred to in regulation 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 European Union 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 these regulations.

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 Veterinary Services must inspect the low-capacity incineration plant before approval, and at least once a year to monitor compliance with these regulations.

SCHEDULE 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 -

(a) premises for the processing of animal by-products must not be at the same site as slaughterhouses, unless located in a completely separate building. However, a conveyer system may link an individual processing plant to a slaughterhouse on the same site provided the following conditions are met -

(i) there are separate entrances, reception bays, equipment, exits and personnel for the processing plant and the slaughterhouse; and

(ii) the animal by-products to be processed originate on the same premises.

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAPTER II

General hygiene requirements

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

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

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

4. Waste water originating in the unclean sector must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from processing plants may be laid down under the procedure referred to in regulation 32(2).

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

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

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

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

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

CHAPTER III

Processing methods

Method 1

Reduction

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

Time, temperature and pressure

2. After reduction the animal by-products must be heated to a core temperature of more than 133 ºC 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

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

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 ºC for at least 125 minutes, a core temperature greater than 110 ºC for at least 120 minutes and a core temperature greater that 120 ºC for at least 50 minutes.

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

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

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.

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.

Method 6
(for animal by-products of fish origin only)

Reduction

1. The animal by-products must be reduced to … millimetres. They must then be mixed with formic acid to reduce the pH to …. The mixture must be stored for … hours pending further treatment.

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

Method 7

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

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

Clostridium perfringens absent in 1 g of the products

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

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

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

Where -

n = number of samples to be tested;

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

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

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

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

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

CHAPTER IV
Supervision of production

1. The competent authority must supervise processing plants to ensure compliance with the requirements of these regulations. 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 regulation 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 European 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 these regulations.

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

CHAPTER V
Validation procedures

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

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

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

(c) compliance with the specific process requirements laid down by these regulations; 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).

5. Validation procedures based on testing methods may be laid down under the procedure referred to in regulation 32(2).

SCHEDULE VI

SPECIFIC REQUIREMENTS FOR THE PROCESSING OF CATEGORY 1 AND 2 MATERIAL AND FOR BIOGAS AND COMPOSTING PLANTS

CHAPTER I

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

The following requirements apply in addition to the general requirements laid down in Schedule 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 regulation 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 Schedule V, Chapter III. The critical control points may include -

(a) raw material particle size;

(b) temperature achieved in the heat treatment process;

(c) pressure applied to the raw material; and

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

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

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

5. Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions.

Records must be kept to show the date of calibration of gauges/recorders.

6. Material that may not have received the specified heat treatment (e.g. material discharged at start up, or leakage from cookers) must be re-circulated 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 -

(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

(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 coincineration.

C. *Processed products*

8. Processed products derived from Category 1 or 2 materials, with the exception of liquid products destined for biogas or composting plants, must be permanently marked, where technically possible with smell, using a system approved by the competent authority. Detailed rules for such marking may be laid down under the procedure referred to in regulation 32(2).

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

CHAPTER II

Specific requirements for the approval of biogas and composting plants

A. *Premises*

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

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

(i) installations for monitoring temperature against time;

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

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

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

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

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

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

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

(i) installations for monitoring temperature against time;

(ii) recording devices to record, where appropriate continuously, the results of those measurements; and

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

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

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

(i) ensure that there is no access by vermin;

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

(iii) comply with all other requirements of these regulations.

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;

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

(c) Category 3 material.

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

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

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

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

9. Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented.

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

11. Digestion residues must be handled and stored at the plant in such a way as to preclude recontamination.

C. *Processing standards*

12. Category 3 material used as raw material in a biogas plant equipped with a pasteurisation/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 ºC; and

(c) minimum time in the unit without interruption: 60 minutes.

13. Category 3 material used as raw material in a composting plant must be submitted to the following minimum requirements -

(a) maximum particle size before entering the composting reactor: 12 mm,

(b) minimum temperature in all material in the reactor: 70 ºC; and

(c) minimum time in the reactor at 70 ºC (all material): 60 minutes.

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

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

(a) does not consider that those material present a risk of spreading any serious transmissible disease;

(b) considers that the residues or compost are untreated material.

D. *Digestion residues and compost*

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

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

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

Where -

n = number of samples to be tested;

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

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

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

CHAPTER III

Treatment standards for the further processing of rendered fats

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

1. transesterification or hydrolysis at least 200 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

(b) in a continuous process at 140 ºC 2 bars (2 000 hPa) for eight minutes, or under equivalent conditions laid down in accordance with the procedure referred to in regulation 32(2).

SCHEDULE 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 Schedule 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 regulation 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*

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

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 Schedule V, Chapter III. The critical control points must at least include -

— raw material particle size,

— temperature achieved in the heat treatment process,

— pressure applied to the raw material, if applicable, and

— duration of the heat treatment process or feed rate to a continuous system.

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

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

8. Accurately calibrated gauges/recorders must be used to monitor continuously the processing conditions. Records must be kept for at least two years to show the date of calibration of gauges/recorders.

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

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.

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 regulation 12;

(b) be disposed of in a landfill approved under European Council Directive 1999/31/EC; or

(c) be transformed in a biogas plant or in a composting plant approved in accordance with regulation 15.

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*

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

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

In addition, while the feed ban provided for in Council Decision 2000/766/EC remains in force, processed animal protein of mammalian origin exclusively destined for use in pet food, 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 pet food plants, may have been submitted to any of the processing Methods 1 to 5 or 7.

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.

C. *Importation*

9. Malta must authorise the importation of processed animal protein -

(a) if it comes from third countries that appear on the list in Part II of Schedule XI or, in the case of fishmeal, that appear on the list in Part III of Schedule XI;

(b) if it comes from a processing plant that appears on the list referred to in regulation 29(4);

(c) if it has been produced in accordance with these regulations; and

(d) if it is accompanied by a health certificate that conforms to the model set out in Chapter 1 of Schedule X.

10. Before consignments are released for free circulation within the European 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 European Union Directive 97/78/EC[2] ; or

(b) reprocessed in a processing plant approved pursuant to these regulations or decontaminated by a treatment authorised by the competent authority. A list of permitted treatments may be established in accordance with the procedure referred to in regulation 32(2). The consignment must not be released until it has been treated, tested for *salmonella* by the competent authority in accordance with Chapter I, paragraph 10, and a negative result obtained.

CHAPTER III

Specific requirements for blood products

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

A. *Raw material*

1. Only blood coming under paragraph 1(a) and (b) of regulation 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 -

(a) come from third countries that appear on the list of part V and part VI of Schedule XI as appropriate;

(b) come from a processing plant that appears on the list referred to in regulation 29(4);

[2] Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the European Union Community from third countries.

(c) have been produced in accordance with these regulations; and

(d) if it is accompanied by a health certificate that conforms to the model set out in Chapter 4(B) of Schedule X.

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*

1. Unless the rendered fats have been produced in accordance with Chapter II of Schedule C to European Union Council Directive 77/99/EEC, or Chapter 9 of Schedule I to Council Directive 92/118/EEC, 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 Schedule V, Chapter III.

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

B. *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 Schedule XI;

(b) come from a processing plant that appears on the list referred to in regulation 29(4);

(c) have been produced in accordance with these regulations;

(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

(e) are accompanied by a health certificate that conforms to the model set out in Chapter 10(A) of Schedule X.

C. *Importation of fish oil*

3. Malta must authorise the importation of fish oil if it -

(a) comes from third countries appearing on the list in Part III of Schedule XI;

(b) comes from a processing plant that appears on the list referred to in regulation 29(4);

(c) has been produced in accordance with these regulations; and

(d) is accompanied by a health certificate that conforms to the model set out in Chapter 9 of Schedule X.

D. *Hygiene requirements*

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

CHAPTER V

Specific requirements for milk, milk-based products and colostrum

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

A. *Processing standards*

1. Raw milk and colostrum must be produced under conditions offering adequate guarantees as regards animal health. Such conditions may be established in accordance with the procedure referred to in regulation 32(2).

2. Milk or treated or processed milk products must be subjected to a heat treatment of at least 2 ºC for at least 15 seconds or any combination of temperature and time having at least an equivalent heat effect and producing a negative reaction to the phosphatase test, followed by -

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

(b) in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6.

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

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

(b) the final product must be -

(i) packed in new containers, or

(ii) in the case of bulk transport, transported in vehicles or containers that have been disinfected using a product approved by the competent authority before loading with the milk, milk-based product or colostrum.

B. *Importation*

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

(a) they come from third countries appearing on the list in Part I of Schedule XI;

(b) in the case of milk and milk-based products from third countries or parts of third countries listed in column B of the Annex to European Union Decision 95/340/ EC[3], they have undergone a pasteurisation treatment sufficient to produce a negative phosphatase test and a health certificate conforming to the model laid down in Chapter 2(A) of Schedule X accompanies them;
(c) in the case of milk-based products with a pH reduced to less than 6 from third countries or parts of third countries listed in column C of the Annex to European Union Decision 95/340/EC, they have first undergone a pasteurisation treatment sufficient to produce a negative phosphatase test and a health certificate conforming to the model laid down in Chapter 2(B) of Schedule X accompanies them;

(d) in the case of milk and milk-based products from third countries or parts of third countries listed in column C of the Annex to European Union Decision 95/340/ EC, they have first undergone a sterilisation process or a double heat treatment where each treatment was sufficient to produce a negative phosphatase test on its own and a health certificate conforming to the model laid down in Chapter 2(C) of Annex X accompanies them; and

(e) they come from a processing plant which appears on the list referred to in regulation 29(4).

5. Milk and milk-based products from third countries or parts of third countries listed in column C of the Annex to European Union Decision 95/340/EC where there has been an outbreak of foot-and-mouth disease in the last 12 months or where vaccination against foot-and-mouth disease has been carried out in the last 12 months must, before introduction on to Community territory, have undergone either -

(a) a sterilisation process whereby an Fc value equal to or greater than 3 is achieved; or

(b) an initial heat treatment with a heating effect at least equal to that achieved by a pasteurisation process of at least 72 ºC for at least 15 seconds and sufficient to produce a negative reaction to a phosphatase test, followed by -

(i) a second heat treatment with a heating effect at least equal to that achieved by the initial heat treatment, and which would be sufficient to produce a negative reaction to a phosphatase test, followed, in the case of dried milk, or dried milk-based products, by a drying process, or

(ii) an acidification process such that the pH has been maintained at less than 6 for at least one hour.

6. Where a risk of introduction of an exotic disease or any other risk to animal health is identified, additional conditions for the protection of animal health may be established in accordance with the procedure referred to in regulation 32(2).

[3] Commission Decision 95/340/EC of 27 July 1995 drawing up a provisional list of third countries from which Member States authorise imports of milk and milk-based products and revoking Decision 94/70/EC Decision as last amended by Decision 96/584/EC.

CHAPTER VI

Specific requirements for gelatin and hydrolysed protein

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

A. *Processing standards for gelatin*

1. (a) Gelatin must be produced by a process that ensures that unprocessed Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently.

Gelatin must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

(b) After having been subjected to the processes referred to in subparagraph (a), gelatin may undergo a drying process and, where appropriate, a process of pulverisation or lamination.

(c) The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.

2. Gelatin must be wrapped, packaged, stored and transported under satisfactory hygiene conditions. In particular -

(a) a room must be provided for storing materials for wrapping and packaging;

(b) wrapping and packaging must take place in a room or in a place intended for that purpose; and

(c) wrappings and packages containing gelatin must carry the words 'gelatin suitable for animal consumption'.

B. *Processing standards for hydrolysed protein*

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

(c) an equivalent production process approved in accordance with the procedure referred to in regulation 32(2).

C. *Importation*

4. Malta 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 Schedule XI;

(b) come from a processing plant that appears on the list referred to in regulation 29(4);

(c) have been produced in accordance with this Regulation; and

(d) are accompanied by a health certificate that conforms to the models set out in Chapter 11 and Chapter 12 of Schedule X as appropriate.

CHAPTER VII

Specific requirements for dicalcium phosphate

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

A. *Processing standards*

1. Dicalcium phosphate must be produced by a process that -

(a) ensures that all Category 3 bone-material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;

(b) following the procedure at (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and

(c) finally, air dries the precipitate of dicalcium phosphate with inlet temperature of 65 ºC to 325 ºC and end temperature between 30 ºC and 65 ºC, or by an equivalent process approved in accordance with the procedure referred to in regulation 32(2).

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

B. *Importation*

3. Member States must authorise the importation of dicalcium phosphate if it -

(a) comes from third countries that appear on the list in Part XI of Schedule XI;

(b) comes from a processing plant that appears on the list referred to in regulation 29(4);

(c) has been produced in accordance with these regulations; and

(d) is accompanied by a health certificate that conforms to the model set out in Chapter 12 of Schedule X.

CHAPTER VIII

Specific requirements for tricalcium phosphate

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

A. *Processing standards*

1. Tricalcium phosphate must be produced by a process hat 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 ºC 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 ºC; or by an equivalent production process approved in accordance with the procedure referred to in regulation 32(2).

B. *Importation*

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

(a) comes from third countries that appear on the list in Part XI of Schedule XI;

(b) comes from a processing plant that appears on the list referred to in regulation 29(4);

(c) has been produced in accordance with these regulations; and
(d) is accompanied by a health certificate that conforms to the model set out in Chapter 12 of Schedule 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 European 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 European Community list set out in Part XI of Schedule XI;

(b) comes from a plant that appears on the list referred to in regulation 29(4);

(c) has been produced in accordance with these regulations; and

(d) is accompanied by a health certificate that conforms to the model set out in Chapter 11 of Schedule 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

(c) treated in accordance with Chapter V of the Annex to European Union Council Directive 89/437/EC 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 European Community list set out in Part XVI of Schedule XI;

(b) come from a plant that appears on the list referred to in regulation 29(4);

(c) have been produced in accordance with these regulation; and

(d) are accompanied by a health certificate that conforms to the model set out in Chapter 15 of Schedule X.

SCHEDULE VIII

REQUIREMENTS FOR THE PLACING ON THE MARKET OF PET FOOD, DOG CHEWS AND TECHNICAL PRODUCTS

CHAPTER I

Requirements for the approval of pet food and technical plants

Plants producing pet food, dog chews 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 these regulations, or this material must be sent to a processing plant or to an incineration or co-incineration plant in accordance with these regulations.

CHAPTER II

Requirements for pet food and dog chews

A. *Raw material*

1. The only animal by-products that may be used to produce pet food and dog chews are those referred to in regulation 6(1)(a) to (j). However, raw pet food may be manufactured only from animal by-products referred to in regulation 6(1)(a).

B. *Processing standards*

2. Canned pet food must be subjected to heat treatment to a minimum Fc value of 3.

3. Processed pet food other than canned pet food must be subjected to a heat treatment of at least 90 ºC throughout its substance. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination. The product must be packed in new packaging.

4. Dog chews must be subjected to a heat treatment during processing sufficient to destroy pathogenic organisms (including *salmonella*). After treatment, every precaution must be taken to ensure that the product is not exposed to contamination. The product must be packed in new packaging.

5. Raw pet food 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 'pet food only' must be visibly and legibly displayed on the packaging.

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

C. *Importation*

7. Malta must authorise importation of pet food and dog chews if they -

(a) come from third countries that appear on the list in Part X of Schedule XI;

(b) come from pet food plants approved by the competent authority of the third country meeting the specific conditions laid down in these regulations;

(c) have been produced in accordance with these regulations;

(d) are accompanied -

(i) in the case of canned pet food, by a certificate that conforms to the model laid down in Chapter 3(A) of Schedule X,

(ii) in the case of processed pet food other than canned pet food, by a certificate that conforms to the model laid down in Chapter 3(B) of Schedule X,

(iii) in the case of dog chews, by a certificate that conforms to the model laid down in Chapter 3(C) of Schedule X, or

(iv) in the case of raw pet food, by a certificate that conforms to the model laid down in Chapter 3(D) of Schedule 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 these regulations 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 regulation 32(2) must accompany the manure in such cases.

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

(a) the manure must originate in an area which is not subject to restrictions by virtue of Newcastle disease or avian influenza;

(b) in addition, unprocessed manure from poultry flocks vaccinated against Newcastle disease must not be dispatched to a region which has obtained Newcastle disease non-vaccinating status pursuant to Article 15(2) of European Union Directive 90/539/EEC; and

(c) a health certificate conforming to a model laid down under the procedure referred to in regulation 32(2) must accompany the manure.

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

B. Importation

4. Member States must authorise the importation of unprocessed manure if it -

(a) comes from third countries that appear on the list in Part IX of Schedule XI;

(b) satisfies, according to the species concerned, the requirements of paragraph 1(a);

(c) is accompanied by a health certificate as provided for in regulation 29(6).

II. *Processed manure and processed manure products*

A. Placing on the market

5. The placing on the market of processed manure and processed manure products is subject to the following conditions -

(a) they must come from a technical plant, a biogas plant or a composting plant approved by the competent authority in accordance with these regulations;

(b) they must have been subjected to a heat treatment process of at least 70 ºC for at least 60 minutes or to an equivalent treatment in accordance with rules laid down under the procedure referred to in regulation 32(2);

(c) they must -

(i) be free from *salmonella* (no *salmonella* in 25 g treated product),

(ii) be free from *enterobacteriaceae* (based on the aerobic bacteria count: < 1 000 cfu per gram of treated products), and

(iii) have been subjected to reduction in spore-forming bacteria and toxic formation; and

(d) they must be stored in such a way that, once processed, contamination or secondary infection and dampness is impossible. They must therefore be stored in -

(i) well-sealed and insulated silos, or

(ii) properly sealed packs (plastic bags or 'big bags').

B. Importation

6. Member States must authorise importation of processed manure and processed manure products if they -

(a) come from third countries that appear on the list in Part IX of Schedule XI;

(b) come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in these rgeulations;

(c) satisfy the requirements of paragraph 5 above; and

(d) are accompanied by a health certificate as provided for in regulation 29(6).

III. *Guano*

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

CHAPTER IV

Requirements for blood and blood products used for technical purposes, including pharmaceuticals, *in vitro* diagnosis and laboratory reagents, but excluding serum of equidae

A. *Importation*

1. Imports of blood are subject to the requirements laid down in Chapter XI.

2. Malta must authorise importation of blood products if they -

(a) come from third countries that appear on the list in part VI of Schedule XI;

(b) come from a plant approved by the competent authority of the third country meeting the specific conditions laid down in these regulations; and

(c) are accompanied by a health certificate that conforms to the model set out in Chapter 4 C of Schedule X; and

3. Member States must authorise importation of blood products if they originate in a third country or regions thereof where -

either -

(a) in the case of blood products derived from ruminant animals -

(i) the animals and the products come from a region where no case of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever, African horse sickness and bluetongue[4] has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months in the susceptible species and from which imports of ruminant animals of the specified species are authorised pursuant to European Community legislation. The blood from which such products are manufactured must have been collected -

— in slaughterhouses approved in accordance with Community legislation,

— from live animals in facilities approved in accordance with Community legislation; or

[4] This includes countries with sero-positive ruminant animals.

— in slaughterhouses approved and supervised by the competent authority of the third country. In this case, the Commission and Member States must be notified of the address and approval number of such slaughterhouse or the certificate shall indicate this information;

or

(ii) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the ruminant diseases referred to in subparagraph (i):

— heat treatment at a temperature of 65 ºC for at least three hours, followed by an effectiveness check,

— irradiation at 2,5 megarads or by gamma rays, followed by an effectiveness check,

— change in pH to pH 5 for two hours, followed by an effectiveness check,

— heat treatment of at least 90 ºC throughout their substance, followed by an effectiveness check, or

— any other treatment provided for in accordance with the procedure referred to in regulation 32(2);

(iii) by way of derogation from point (ii) above, a Member State may allow import from countries where sero-positive bluetongue animals are present, of blood and blood products intended for technical purposes including pharmaceuticals, *in vitro* diagnosis and laboratory reagents, provided that the approved technical plant of final destination is situated in the same Member State; the consignment must go directly to that plant 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;

or

(b) in the case of blood products derived from animals belonging to the taxa Proboscidae and Artiodactyla, and their crossbreeds, other than ruminants -

(i) the animals and the products come from a region where no case of foot-and-mouth disease, swine vesicular disease, African horse sickness, classical swine fever, African swine fever, rinderpest, peste des petits ruminants, Newcastle disease or avian influenza has been recorded for 12 months in the susceptible species and in which vaccination has not been carried out against those diseases for at least 12 months;

or

(ii) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in subparagraph (i) :

— heat treatment at a temperature of 65 ºC for at least three hours, followed by an effectiveness check,

— irradiation at 2,5 megarads or by gamma rays, followed by an effectiveness check,

— heat treatment of at least 90 ºC throughout their substance, followed by an effectiveness check,

or

— any other treatment provided for in accordance with the procedure referred to in regulation 32(2).

4. The specific conditions relating to imports of products for use *in vitro* diagnosis and laboratory reagents may be laid down, where necessary, under the procedure referred to in regulation 32(2).

CHAPTER V

Requirements for serum of equidae

A. *Raw material*

1. Serum must -

(a) come from equidae which show no signs of the serious transmissible diseases referred to in European Union Directive 90/426/EEC or of any other serious transmissible disease to which equidae are susceptible; and

(b) have been obtained in bodies or centres not subject to health restrictions pursuant to that Directive.

B. *Importation*

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

(a) it comes from equidae born and raised in a third country that appears on the list of part XIII of Schedule XI;

(b) it was obtained, processed and dispatched in conformity with the following conditions -

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

(ii) it was obtained, under the supervision of a veterinarian, from equidae which, at the time of collection, were free from clinical signs of infectious disease;

(iii) it was obtained from equidae that have remained since birth in the territory or, in case of official regionalisation according to European Community legislation, in parts of the territory of a third country in which -

— Venezuelan equine encephalomyelitis had not occurred during the last two years,

— dourine had not occurred during the last six months, and

— glanders had not occurred during the last six months;

(iv) it was obtained from equidae that had never been present on a holding that had been subject to prohibition for animal health reasons or where -

— in the case of equine encephalomyelitis, the date on which all the equidae suffering from the disease were slaughtered was at least six months before the date of collection,

— in the case of infectious anaemia, all the infected animals had been slaughtered and the remaining animals showed a negative reaction to two Coggins tests carried out three months apart,

— in the case of vesicular stomatitis, the prohibition was lifted at least six months before the date of collection,

— in the case of rabies, the last recorded case was at least a month before the date of collection,

— in the case of anthrax, the last recorded case was at least 15 days before the date of collection, or

— all the animals of species susceptible to the disease located on the holding were slaughtered and the premises disinfected, at least 30 days before the date of collection (or, in the case of anthrax, at least 15 days before);

(v) it has undergone all precautions to avoid contamination with pathogenic agents during production, handling and packaging;

(vi) it was packed in sealed impermeable containers clearly labelled 'serum from equidae' and bearing the registration number of the establishment of collection;

(c) it comes from a plant approved by the competent authority of the third country meeting the specific conditions laid down in these regulations; and

(d) it is accompanied by a health certificate that conforms to the model set out in Chapter 4(A) of Schedule X

CHAPTER VI

Requirements for hides and skins of ungulates

A. *Scope*

1. The provisions of this Chapter do not apply -

(a) to hides and skins of ungulates fulfilling the requirements of European Union Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat;

(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 ºC; or

(e) preserved by a process other than tanning specified in accordance with the procedure referred to in regulation 32(2).

B. *Trade*

3. Trade in fresh or chilled hides and skins is subject to the same health conditions as those applicable to fresh meat pursuant to Council Directive 72/461/ EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat.

4. Trade in treated hides and skins is authorised on condition that the commercial document provided for in Schedule 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 regulation 6(1)(b) or (c);

(b) they come from a third country or, in the case of regionalisation in accordance with European Community legislation, from a part of a third country, appearing on the list set out in part XIV(A) of Schedule XI and which -

(i) for at least 12 months before dispatch, has been free from the following diseases -

— classical swine fever,

— African swine fever, and

— rinderpest, and

(ii) has been free for at least 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;

(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

(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 Schedule 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 regulation 6(1)(b), (c) or (k);

(b) a certificate conforming to the model laid down in Chapter 5(B) of Schedule X accompanies them;

(c) they come either -

(i) 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(B) of Annex XI and they have been treated in accordance with paragraph 2; or

(ii) from animals originating from other regions of a third country or other third countries and they have been treated in accordance with paragraph 2(c) or (d); or

(iii) from ruminant animals and have been treated in accordance with paragraph 2 and 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 (C) of Schedule XI. In this case, the certificate referred to in subparagraph (b) is replaced by a declaration conforming to the model laid down in Chapter 5(C) of Schedule X, to the effect that or proving that those requirements have been met;

(d) in the case of salted hides and skins transported by ship, the hides have been salted before importation for the duration stated in the certificate accompanying the consignment; and

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

7. Fresh, chilled or treated hides and skins of ungulates must be imported in containers, road vehicles, railway wagons or bales sealed by the competent authority of the third country of dispatch.

CHAPTER VII

Requirements for game trophies

A. *Raw material*

1. Without prejudice to the measures adopted pursuant to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (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 European Union Regulation (EC) No. 338/97, game trophies of ungulates and birds not having undergone the treatment mentioned in paragraph 1(a) are subject to the following conditions.

They must -

(a) come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible; or

(b) comply with the conditions laid down in paragraphs 3 or 4 if they come from animals originating in an area subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible.

3. In respect of game trophies consisting solely of bone, horns, hooves, claws, antlers or teeth, the trophies must -

(a) have been immersed in boiling water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

(b) have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned;

(c) be packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination;

and

(d) be accompanied by a document or certificate certifying that the above conditions have been met.

4. In respect of game trophies consisting solely of hides or skin, the trophies must -

(a) have been either -

(i) dried, or

(ii) dry- or wet-salted for a minimum of 14 days before dispatch, or

(iii) preserved by a treatment other that tanning approved in accordance with the procedure referred to in regulation 32(2);

(b) be packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination;

and

(c) be accompanied by a document or certificate certifying that the above conditions have been met.

B. *Importation*

5. Member States must authorise the importation of treated game trophies from birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, from third countries if -

(a) a certificate that conforms to the model laid down in Chapter 6(A) of Schedule 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;

(c) they come from a third country appearing on the list set out in part XV (A) of Schedule XI.

6. Malta must, in accordance with the requirements of paragraph 7, authorise the importation of game trophies from birds and ungulates consisting of entire anatomical parts, not having been treated in any way, from third countries -

(a) that appear on the lists set out in part XV(B) and (C) of Schedule XI as appropriate; and

(b) from which the importation of all categories of fresh meat of the corresponding species is authorised.

7. Malta 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 Schedule X accompanies them.

CHAPTER VIII

Requirements for wool, hair, pig bristles, feathers and parts of feathers

A. *Raw material*

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 regulation 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) Malta notifies the European 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.

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. Malta must authorise the importation of pig bristles from third countries or, in case of regionalisation according to European 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 Schedule 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 Schedule X accompanies the consignment;

(c) they come from a third country that appears on the list of part VIII of Schedule XI as appropriate.

4. Member States must authorise the importation of unprocessed wool, hair, feathers and parts of feathers if they are -

(a) securely enclosed in packaging and dry; and

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

CHAPTER IX

Requirements for apiculture products

A. *Raw material*

1. Apiculture products intended exclusively for use in apiculture must -

(a) not come from an area which is subject of a prohibition order associated with an occurrence of -

(i) American foulbrood (*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 European Union Directive 92/65/EEC;

(iii) small hive beetle (*Aethina tumida*); or

(iv) Tropilaelaps spp. (*Tropilaelaps* spp); and

(b) meet the requirements provided for in Article 8(a) of European Union Directive 92/65/EEC.

B. *Importation*

2. As the small hive beetle and *Tropilaelaps* spp. are not present in the European Community, the following additional safeguards concerning importation of apiculture products have to be laid down.

3. Member States must authorise the importation of apiculture products intended for use in apiculture if they -

(a) come from third countries that appear on the list in part XII of Schedule XI;

(b) (i) are new and have not been in use before and if they have not come into contact with bees or used apiculture products; or

(ii) have been subjected to a temperature of - 12 ºC or lower for at least 24 hours; or

(iii) in the case of wax, the material has been refined or rendered before exportation;

(c) are accompanied by a health certificate that conforms to the model set out in Chapter 13 of Schedule X.

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 European Union Directive 97/78/EC, the products are conveyed directly to the technical plant;

(d) they come from a third country appearing on the list set out in part XVII of Schedule XI.

2. Each consignment must be accompanied by -

(a) a commercial document stamped by the competent authority supervising the establishment of origin, including the following information -

(i) the country of origin,

(ii) the name of the establishment of production,

(iii) the nature of the product (dried bone/dried bone product/dried horns/dried horn products/dried hooves/dried hoof products), and

(iv) the fact that the product was -

— derived from healthy animals slaughtered in a slaughterhouse, or

— dried for 42 days at an average temperature of at least 20 ºC, or

— heated for one hour to at least 80 ºC to the core before drying,
or

— ashed for one hour to at least 800 ºC to the core before drying,

or

— underwent an acidification process such that the pH was maintained at less than 6 to the core for at least one hour before drying, and is not intended at any stage to be diverted for any use in food, feed material, organic fertilizers or soil improvers; and

(b) a declaration of the importer that conforms to the model laid down in Chapter 16 of Schedule X and that must be in at least one official language of the Member State through which the consignment first enters the European Community and in at least one official language of the Member State of destination.

3. On dispatch to the European Community territory, the material must be enclosed in sealed containers or vehicles or carried in bulk in a ship. If transported in containers, the containers, and in all cases all the accompanying documents, must bear the name and the address of the technical plant.

4. Following the border check provided for in European Union 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.

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

CHAPTER XI

Animal by-products for the manufacture of feed including pet food, and for pharmaceuticals and other technical products

Malta must authorise the importation of animal by-products intended for the manufacture of feed including pet food, 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 Schedule XI as appropriate;

2. consist only of animal by-products referred to in regulation 6(1)(a) to (j) and, or, when intended to be used for pet food, material derived from animals treated as referred to in the second paragraph of regulation 28;

However, animal by-products for use in feed for farmed fur animals must consist of by-products referred to in regulation 6(1)(a) and (b) and animal by-products for use in raw pet food must consist of by-products referred to in regulation 6(1)(a) only;

3. have been deep-frozen at the plant of origin or have been preserved in accordance with European 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;

6. are accompanied by a certificate that conforms to the models set out in Chapter 8(A), Chapter 8(B) or Chapter 3(D) of Schedule X;

7. following the border checks provided for in European Union 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 pet food or technical plant, which has given the guarantee that the animal by-products shall be used only for the purpose of producing pet food 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 pet food production derived from animals which have been treated with certain substances prohibited in accordance with European Union Directive 96/22/EC, as referred to in the second paragraph of regulation 28 of these regulations, it shall -

(a) be marked in the third country before entry into the territory of the European 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 European 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 pet food 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 pet food plant referred to under (i), provided that the intermediate plant -

— only handles material covered by this point 8.1, or

— only handles material destined for a pet food plant as referred to under (i);

and

(d) be manipulated to remove the marking provided for in (a) and (b) only in the pet food plant of destination and only immediately prior to use of the material for the manufacture of pet food;

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 pet food 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. Malta 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 Schedule VI, Chapter III, if it:

(a) comes from a third country that appears on a European Community list set out in part IV of Schedule XI;

(b) has been produced in accordance with these regulations; and

(c) is accompanied by a health certificate that conforms to the model set out in Chapter 10(B) of Schedule 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 European Community.

5. Following the checks provided for in European Union 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 Schedule 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.

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 European Community, and thereafter a copy must accompany the consignment until their arrival at the plant of destination.

8. Following the checks provided for in European Union 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 Schedule 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 Schedule 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 Schedule 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 European Community, and thereafter a copy must accompany the consignment until its arrival at the plant of destination.

5. Following the checks provided for in European Union 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 regulation 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.

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 Schedule 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 Schedule XI;

(b) come from pet food plants approved by the competent authority of the third country meeting the specific conditions laid down in regulation 18;

(c) have been produced in accordance with these regulations; and

(d) are accompanied by a health certificate that conforms to the model set out in Chapter 3(E) of Schedule X.

SCHEDULE IX

RULES APPLICABLE TO THE USE OF CERTAIN CATEGORY 2 AND CATEGORY 3 MATERIAL FOR THE FEEDING OF CERTAIN ANIMALS IN ACCORDANCE WITH REGULATION 23(2)

1. This Schedule applies only to users and collection centres authorised and registered pursuant to regulation 23(2)(c)(iv), (vi) and (vii). For the purposes of this Schedule, 'relevant material' means the animal by-products specified in regulation 23(2)(b) and products derived therefrom.

2. Relevant material must be transported to the users or to collection centres in accordance with Schedule II.

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 regulation 23.

3. Collection centres must -

(a) comply at least with the following requirements of Schedule 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 coincineration plant in accordance with these regulations.

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 Schedule II, the following records must be kept in relation to relevant material -

(a) in the case of final users, the quantity used and the date of use; and

(b) in the case of collection centres -

(i) the quantity treated in accordance with paragraph 5;

(ii) the name and address of each final user buying the material;

(iii) the premises to which the material is taken for use;

(iv) the quantity dispatched; and

(v) the date on which the material was dispatched.

5. Operators of collection centres supplying relevant material other than fish offal to final users, must ensure that -

(a) it undergoes one of the following treatments (either in the collection centre or in a slaughterhouse approved by the competent authority in accordance with European 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'.

SCHEDULE X

MODEL HEALTH CERTIFICATES FOR THE IMPORTATION FROM THIRD COUNTRIES 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 Schedule 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, if necessary, accompanied 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 European Union Council Directive 96/93/EC are followed (OJ L 13, 16.1.1997, p. 28).

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.

CHAPTER 1

Health Certificate

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

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

<table>
<tr><td colspan="2">ORIGINAL

VETERINARY CERTIFICATE
For processed animal protein not intended for human consumption, including mixtures and products other than pet food containing such protein, intended for dispatch to the European Community

Reference number[5]:</td></tr>
<tr><td>1. Consignor (name and address in full)

……
……
……
……
……
……
……
……</td><td>2. Consignee (name and address in full)

……
……
……
……
……
……
……
……</td></tr>
<tr><td>3. Origin of the processed animal protein or product

3.1.Country: ……..
……
3.2. Code of territory: ……
……</td><td>4. Competent Authority

4.1. Responsible Ministry: …….
……
4.2. Certifying department: ……
……</td></tr>
<tr><td>5. Intended destination of the processed animal protein or product:

5.1. EU Member State:……...</td><td>6. Place of loading for exportation

……</td></tr>
</table>

[5] Issued by the Competent Authority.

……	……...
5.2. Name and Address of destination:	……...
……	……
……	……

7. Means of transport and consignment identification

7.1. (Lorry, rail wagon, ship or aircraft)[6]

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

7.3. Registration number(s), ship name or flight number:

……..

……..

……..

7.4. Nature of packaging: …….

……..

7.5. Number of packages: …….....

7.6. Net weight: ……...

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

……

……

7.8. Nature of packaging: ……..

……

8. Identification of the processed animal protein or product

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

……...

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

……..

[6] Delete as appropriate.

8.3. Address and approval number of the approved establishments of origin: ……

……..

……..

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that –

9.1. the processed animal protein or product described above contains exclusively processed animal protein intended for human consumption that:

(a) has been prepared and stored in a approved, validated and supervised by the competent authority in accordance with regulation 17 and where appropriate Article 11 of European Union Regulation (EC) No. 1774/2002, and

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

either: [- parts of slaughtered animals, which were fit for human consumption in accordance with European Community legislation, but are not intended for human consumption for commercial reasons.]

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 carcases that were fit for human consumption in accordance with EC legislation.]

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 slaughtered in accordance with EC legislation.]

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 EC legislation.]

And/or: [- animal by-products derived from the production of products intended for human consumption including degreased bones and greaves.]

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 a risk to humans or animals.]

And/or: [- fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production.]

And/or: [- fresh by-products from fish from plants manufacturing fish products for human consumption.]

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:

either: [heating to a core temperature of more tan 133 degrees Celsius 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;]

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;]

or: [in the case of fishmeal:

either: [the processing method …… as set out in Annex V, Chapter III, of Regulation (EC) 1774/2002;]

or: [heating to at least 80 degrees Celsius throughout its substance.]

9.2. The Competent Authority examined a random sample immediately prior to dispatch and found it to comply with the following standards[7]:

Salmonella: Absence in 25g: n=5, c=0, m=0, M=0
Enterobacteriaceae: n=5, c=2, m=10, M=300 in 1g

9.3. the end product:

either: [was packed in new sterilised bags,]

or: [was transposed 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"**

9.4. The end product was stored in enclosed storage;

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

Official stamp and signature

Done at ……on ……
(place) *(date)*

……. STAMP[8]
(signature of official veterinarian)[9]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[7] 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.

[8] The stamp must be in a different colour to that of the printing.

[9] The signature must be in a different colour to that of the printing.

CHAPTER 2(A)

Health Certificate

CHAPTER I

Health Certificate

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[10]

1. Consignor (name and address in full) …… …… …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… …… …… ……
3. Origin of milk/milk based product 3.1. Country: …… 3.2. Code of territory: …… ……	**4. Competent Authority** 4.1. Responsible Ministry: …… 4.2. Certifying department: …… ……

[10] Issued by the competent authority.

5. Intended destination of milk/milk-based products	**6. Place of loading for exportation**
5.1. EU Member State:	……
……	……
5.2. Name and Address of destination:	……
……	……
……	……
……	……

7. Means of transport and consignment identification[11]

7.1. (Lorry, rail wagon, ship or aircraft)[12]

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

7.3. Registration number(s), ship name or flight number:

……..

……..

7.4. Nature of packaging: …….

7.5. Number of packages: …….

7.6. Net weight: …….

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

8. Identification of the milk/milk-based product

8.1. Description of milk and milk-based product: …….

……..

……..

8.2. Milk of: …… (animal species).

8.3. Address and registration number of treatment or processing establishment

……...

……

[11] For goods vehicles the registration number should be given, For bulk containers, the container number and the seal number (if applicable) should be included.

[12] Delete as appropriate.

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that –

9.1…… (exporting country) ……(region)[13], has been free from foot-and-mouth disease and rinderpest for 12 months immediately prior to export and has not practised vaccination against foot-and-mouth or rinderpest in the 12 months immediately prior to export;

9.2. the milk and milk-based product referred to in this certificate:

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

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

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

9.3. every precaution was taken to avoid contamination of the milk/milk-based product after processing;

9.4. the milk/milk-based product was packed:

either (in new containers)

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-based product and bear labels indicating "NOT FOR HUMAN CONSUMPTION".

Official stamp and signature

Done at ……on ……..
(place) *(date)*

……
(signature of official veterinarian)[14] STAMP[15]

…….

…….
(name, qualifications and title IN CAPITAL LETTERS)

[13] For completion if the authorisation to import into the European Community is restricted to certain regions of the third country concerned.

[14] The stamp must be in a different colour to that of the printing.

[15] The signature must be in a different colour to that of the printing.

CHAPTER 2(B)

Health Certificate

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[16]

1. Consignor (name and address in full) …… …… …… …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… …… …… …… ……
3. Origin of the milk-based product 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry: …… 4.2. Certifying department: ……
5. Intended destination of the milk-based product 5.1. EU Member State:	**6. Place of loading for exportation** ……

[16] Issued by the competent authority.

……	……
5.2. Name and Address of destination:	……
……	……
……	……
……	……
……	

7. Means of transport and consignment identification[17]

7.1. (Lorry, rail wagon, ship or aircraft)[18]

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

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging: ……..

……

7.5. Number of packages: ……..

……

7.6. Net weight: ……

……..

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

……

8. Identification of milk based product

8.1. Description of milk and milk-based product: …….

……..

8.2. Milk of: ……(animal species)

8.3. Address and registration number of treatment or processing establishments[19]

……...

……

[17] For good, vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[18] Delete as appropriate.

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that –

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

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

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

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

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

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

9.2. every precaution was taken to avoid contamination of the milk-based product after processing;

9.3. the milk-based product was packed:

either (in new containers)

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-based product and bear labels indicating "NOT FOR HUMAN CONSUMPTION".

Official stamp and signature

Done at ……on ……
(place) *(date)*

…….
(signature of official veterinarian)[20]

STAMP[21]

……

……

(name, qualifications and title IN CAPITAL LETTERS)

[19] Delete as appropriate.
[20] The signature must be in different colour to the printing.
[21] The stamp must be in different colour to the printing.

CHAPTER 2(C)

Health Certificate

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

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

<table>
<tr><td colspan="2">ORIGINAL
VETERINARY CERTIFICATE

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

Reference number[22]</td></tr>
<tr><td>1. Consignor (name and address in full)

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……</td><td>2. Consignee (name and address in full)

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……
……
……
……
……
……</td></tr>
<tr><td>3. Origin of milk/milk based product

3.1. Country:

……

3.2. Code of territory:

……

……</td><td>4. Competent Authority

4.1. Responsible Ministry:

……

4.2. Certifying department:

……

……</td></tr>
<tr><td>5. Intended destination of milk/milk-based products

5.1. EU Member State:</td><td>6. Place of loading for exportation

……</td></tr>
</table>

[22] Issued by the competent authority.

……	……
5.2. Name and Address of destination:	……
……	……
……	……
……	……

7. Means of transport and consignment identification[23]

7.1. (Lorry, rail wagon, ship or aircraft)[24]

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

7.3. Registration number(s), ship name or flight number:

……..

……..

7.4. Nature of packaging: …….

7.5. Number of packages: …….

7.6. Net weight: …….

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

8. Identification of the milk/milk-based product

8.1. Description of milk and milk-based product: …….

……..

……..

8.2. Milk of: …… (animal species).

8.3. Address and registration number of treatment or processing establishment

……...

……

[23] For goods vehicles the registration number should be given, For bulk containers, the container number and the seal number (if applicable) should be included.

[24] Delete as appropriate.

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that –

9.1. the milk/milk based product referred to in this certificate:

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

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

(b) has undergone:

either (i) a sterilisation process whereby an Fc value equal to or greater than 3 is achieved;

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

9.3. every precaution was taken to avoid contamination of the milk/milk-based product after processing;

9.4. the milk/milk-based product was packed:

either (in new containers)

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-based product and bear labels indicating "NOT FOR HUMAN CONSUMPTION".

Official stamp and signature

Done at ……on ……..
(place) *(date)*

……
(signature of official veterinarian)[25]

STAMP[26]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[25] The stamp must be in a different colour to that of the printing.

[26] The signature must be in a different colour to that of the printing.

CHAPTER 3(A)

Health Certificate

For canned pet food intended for dispatch to the European Community.

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

<table>
<tr><td colspan="2">ORIGINAL

VETERINARY CERTIFICATE

For canned pet food intended for dispatch to the European Community

Reference number[27]</td></tr>
<tr><td>1. Consignor (name and address in full)

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……
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……</td><td>2. Consignee (name and address in full)

……
……
……
……
……
……</td></tr>
<tr><td>3. Origin of pet food

3.1. Country:

……

3.2. Code of territory:

……</td><td>4. Competent Authority

4.1. Responsible Ministry

……

4.2. Certifying department

……

……</td></tr>
<tr><td>5. Destination of pet food

5.1. EU Member State:

……

5.2. Name and Address of destination:</td><td>6. Place of loading for exportation

……

……

……</td></tr>
</table>

[27] Issued by the competent authority.

……	……
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……	

7. Means of transport and consignment identification[28]

7.1. (Lorry, rail wagon, ship or aircraft)[29]

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

7.3. Registration number(s), ship name or flight number:

……

……

7.4. Nature of packaging: ……..

……..

……..

7.5. Number of packages: …….

……

7.6. Net weight: …….

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

8. Identification of pet food

8.1. The pet food was produced from raw material of the following species:

…….

……(animal species)

8.3. Address and registration number of the approved establishment:

……...

……

[28] For goods vehicles the registration number should be given. For bulk container number, the container number and the seal number (if applicable) should be included.

[29] Delete where appropriate.

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the pet food described above –

9.1. has been prepared and stored in a plant approved and supervised by the competent authority in accordance with regulation 18 and where appropriate Article 11 of Regulation (EC) No. 1774/2002;

9.2. Has been prepared exclusively with the following animal by-products:

either [– parts of slaughtered animals, which were fit for human consumption in accordance with EC legislation, but are not intended for human consumption for commercial reasons;]

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 unfit for human consumption in accordance with EC legislation;]

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 EC legislation;]

and/or [- blood obtained from animals other than ruminants that were slaughtered in a slaughter house, underwent ante-mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with EC legislation;]

and/or [– animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;]

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;]

and/or [– raw milk originating from animals that do not show clinical signs of any disease communicable through that products to humans or animals;]

and/or [– fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;]

and/or [– fresh by-products fish from plants manufacturing fish products for human consumption;]
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;]

9.3. has been subjected to heat treatment to a minimum Fc value of 3 in hermetically sealed containers;

9.4. 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 9.1.;

9.5. has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Official stamp and signature

Done at …… on ……
(place) *(date)*

……..
(signature of official veterinarian)[30]

STAMP[31]

……..……

…….
(name, qualifications and title IN CAPITAL LETTERS)

[30] The signature must be in a different colour to that of the printing.
[31] The stamp must be in a different colour to that of the printing.

CHAPTER 3(B)

Health Certificate

For processed pet food other than canned pet food, intended for dispatch to the European Community.

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

ORIGINAL

VETERINARY CERTIFICATE
For processed pet food other than canned pet food, intended for dispatch to the European Community

Reference number[32]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of pet food 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry: …… 4.2. Certifying department: …… ……
5. Destination of pet food 5.1. EU Member State …… 5.2. Name and Address of destination …… …… ……	**6. Place of loading for exportation** …… …… …… …… …… ……

[32] Issued by the competent authority.

7. Means of transport and consignment identification[33]

7.1. (Lorry, rail wagon, ship or aircraft)[34]

7.2. Number of seal (if applicable):

…….

7.3. Registration number(s), ship name or flight number:

…….

7.4. Nature of packaging:

…….

7.5. Number of packages:

…….

7.6. Net weight:

…….

7.7. Lot/batch production reference number:

…….

8. Identification of pet food

8.1. The pet food was produced from raw material of the following species:
…….

…… (animal species)

8.2. Address and registration number of the approved establishment:

……...

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the pet food described above –

9.1. has been prepared and stored in a plant approved and supervised by the competent authority in accordance with regulation 18 and where appropriate Article 11 of Regulation (EC) No. 1774/2002;

9.2. Has been prepared exclusively with the following animal by-products:

either [– parts of slaughtered animals, which were fit for human consumption in accordance with EC legislation, but are not intended for human consumption for commercial reasons;]

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

[33] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.
[34] Delete as appropriate.

unfit for human consumption in accordance with EC legislation;]

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 EC legislation;]

and/or [- blood obtained from animals other than ruminants that were slaughtered in a slaughter house, underwent ante-mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with EC legislation;]

and/or [– animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;]

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;]

and/or [– raw milk originating from animals that do not show clinical signs of any disease communicable through that products to humans or animals;]

and/or [– fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;]

and/or [– fresh by-products fish from plants manufacturing fish products for human consumption;]

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;]

9.3. has been subjected to heat treatment to a minimum Fc value of 3 in hermetically sealed containers;

9.4. 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:

Salmonella:	absence in 25g:	n=5, c=0, m=0,M=0,
Enterobacteriaceae		n=5, c=2, m=10, M=300 in 1 gram

9.5. has undergone all precautions to avoid contamination with pathogenic agents after treatment.

9.6. was packed in new packaging, which bear labels indicating "NOT FOR HUMAN CONSUMPTION".

Official stamp and signature

Done at ……on ……
(place) *(date)*

…….
(signature of official veterinarian)[35]

STAMP[36]

…….

…….
(name, qualifications and title IN CAPITAL LETTERS)

[35] The signature must be in a different colour to the printing.
[36] The stamp must be in a different colour to the printing.

CHAPTER 3 (C)

Health Certificate

For dog chews intended for dispatch to the European Community

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

<table>
<tr><td colspan="2">ORIGINAL

VETERINARY CERTIFICATE
For dog chews intended for dispatch to the European Community

Reference number[37]</td></tr>
<tr><td>1. Consignor (name and address in full)
……
……
……
……
……
……</td><td>2. Consignee (name and address in full)
……
……
……
……
……
……</td></tr>
<tr><td>3. Origin of dog chews
3.1. Country:
……

3.2. Code of territory:
……</td><td>4. Competent Authority
4.1. Responsible Ministry
……

4.2. Certifying department
……
……</td></tr>
<tr><td>5. Destination of dog chews
5.1. EU Member State

……

5.2. Name and Address of destination
……
……</td><td>6. Place of loading for exportation
……

……

……
……
……
……</td></tr>
</table>

[37] Issued by the competent authority.

7. Means of transport and consignment identification[38]

7.1. (Lorry, rail wagon, ship or aircraft)[39]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging:

……

7.5. Number of packages:

……

7.6. Net weight:

……

8. Identification of dog chews

8.1. The dog chews were produced from raw material of the following species:
…….

…… (animal species)

8.2. Address and registration number of the approved establishment:

……...

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the dog chews described above –

9.1. have been prepared and stored in a plant approved and supervised by the competent authority in accordance with regulation 18 and where appropriate Article 11 of Regulation (EC) No. 1774/2002;

9.2. Have been prepared exclusively with the following animal by-products:

either – parts of slaughtered animals, which were fit for human consumption in accordance with EC legislation, but are not intended for human consumption for commercial reasons;

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 unfit for human consumption in accordance with EC legislation.

And/or - hides and skins originating from animals that were slaughtered in a slaughterhouse, under went ante

[38] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[39] Delete as appropriate.

mortem inspection and were fit as a result of such inspection, for slaughter in accordance with EC legislation;

And/or – animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;

And/or – fresh by-products from fish from plants manufacturing fish products for human consumption;

9.3. has been subjected:

either (in the case of dog chews made from hides and skins of ungulates, to a heat treatment sufficient to destroy pathogenic organism (including salmonella))

or (in the case of dog chews made from animal by-products other than hides and skins of ungulates, to a heat treatment of at least 90 degrees Celsius throughout their substance)

9.4. 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[40]:

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

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

9.5. have undergone all precaution to avoid contamination with pathogenic agents after treatment;

9.6. were packed in new packaging.

Official stamp and signature

Done at …… on ……
(place) *(date)*

…….
(signature of official veterinarian)[41]

STAMP[42]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[40] Where:
n = number of samples to be tested;

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.

[41] The signature must be in a different colour to that of the printing.

[42] The stamp must be in a different colour to that of the printing.

CHAPTER 3(D)

Health Certificate

For raw pet food for direct sale or animal by-products to be fed to fur farm animals, intended for dispatch to the European Community

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

ORIGINAL

VETERINARY CERTIFICATE
For raw pet food for direct sale or animal by-products to be fed to farmed fur animals, intended for dispatch to the European Community

Reference number[43]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of raw pet food/animal by-products[44] 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of raw pet food/animal by-products[45] 5.1. EU Member State	**6. Place of loading for exportation** ……

[43] Issued by the competent authority.
[44] Delete as appropriate.
[45] Delete as appropriate.

…… 5.2. Name and Address of destination …… …… ……	…… …… …… …… ……

7. Means of transport and consignment identification[46]

7.1. (Lorry, rail wagon, ship or aircraft)[47]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of packages

……

7.6. Net weight

……

7.7. Lot/batch production reference number:

……

8. Identification of raw pet food/animal by-products[48]

8.1. The raw pet food/animal by-products[49] derive from the following species:

…….

…….. (animal species)

8.2. Address and registration number of the approved establishment:

[46] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be indicated.

[47] Delete as appropriate.

……...

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the raw pet food or animal by-product described above –

9.1. consist of animal by-products that satisfy the health requirements below;

9.2. consist of animal by-products;

(a) derived from meat which satisfies the relevant animal and public health requirements laid down in:

- EU Council Decision 79/542/EEC[50], 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 an 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 EU Commission Decision 94/984/EC[51], 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 EU Commission Decision 2000/585/EC[52], and provided the animal from which the meat is derived come from the 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 non 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 EU Decisions mentioned above for which the animals are susceptible, and

(c) derived from animals that have been treated in the slaughterhouse before and ate the time of slaughter or killing in accordance with the relevant provisions of EU Council Directive 93/119/EC[53] on animal welfare;

9.3. consist only of the following by-products:

(a) in the case of animal by-products for use in feed for farmed fur animals;

[48] Delete as appropriate.

[49] Delete as appropriate.

[50] Council Decision 79/542/EEC on EC health conditions on imports of animals and fresh meat including minced meat from third countries.

[51] Commission Decision 94/984/EC laying down animal health conditions and veterinary certificates for the importation of fresh poultry meat from third countries.

[52] Commission Decision 2000/585/EC laying down animal and public health conditions and veterinary certification for import of wild and farmed game meat and rabbit meat from third countries.

[53] Council Directive 93/119/EC on the protection of animals at the time of slaughter and killing.

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

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

(b) in the case of animal by-products for use in raw pet-food:

parts of slaughtered animals, which were fit for human consumption in accordance with EC legislation but are not intended for human consumption for commercial reasons; and

9.4. have been obtained and prepared without contact with other material not complying with the conditions required in the Decision above, and it has been handled so as to avoid contamination with pathogenic agents;

9.5. have been packed in final packaging which bear labels indicating **"RAW PET FOOD – 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 PET-FOOD – 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;

9.6. in the case of raw pet-food, have been prepared and stored in a plant approved and supervised by the competent authority in accordance with regulation 18 and where appropriate Article 11 of Regulation (EC) No. 1774/2002.

Official stamp and signature

Done at ……... on ……
(place) *(date)*

……..
(signature of official veterinarian)[54]

STAMP[55]

……..

……..
(name, qualifications and title IN CAPITAL LETTERS)

[54] Signature must be in a different colour to that of the printing.

[55] Stamp must be in a different colour to that of the printing.

CHAPTER 3(E)

Health Certificate

For flavouring innards for use in the manufacture of pet-food, intended for dispatch to the European Community.

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

ORIGINAL

VETERINARY CERTIFICATE
For flavouring innards for use in the manufacture of pet-food, intended for dispatch to the European Community.

Reference number[56]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the flavouring innards products 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the flavouring innards products 5.1. EU Member State ……	**6. Place of loading for exportation** …… ……

[56] Issued by the competent authority.

5.2. Name and Address of destination …… …… ……	…… …… …… ……

7. Means of transport and consignment identification[57]

7.1. (Lorry, rail wagon, ship or aircraft)[58]

7.2. Number of seal (if applicable):

…….

7.3. Registration number(s), ship name or flight number:

…….

7.4. Nature of packaging

…….

7.5. Number of packages

…….

7.6. Net weight

…….

7.7. Lot/batch production reference number:

…….

8. Identification of the flavouring innards products

8.1. Nature of flavouring innards products:

…….

…….

8.2. Species of animals from which the flavouring innards products derive:

[57] For goods vehicles, the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be indicated.

[58] Delete as appropriate.

…….

8.3. Address and registration number of the approved establishment:

……...

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the flavouring innards products described above –

9.1. consist of animal by-products that satisfy the animals health requirement below;

9.2. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with regulation 18 and where appropriate Article 11 of Regulation (EC) No. 1774/2002;

9.3. Have been prepared including the following animal by-products which are exclusively:

either [– parts of slaughtered animals, which were fit for human consumption in accordance with EC legislation, but are not intended for human consumption for commercial reasons;]

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 unfit for human consumption in accordance with EC legislation;]

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 EC legislation;]

and/or [- blood obtained from animals other than ruminants that were slaughtered in a slaughter house, underwent ante-mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with EC legislation;]

and/or [– animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;]
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;]

and/or [– raw milk originating from animals that do not show clinical signs of any disease communicable through that products to humans or animals;]

and/or [– fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;]

and/or [– fresh by-products fish from plants manufacturing fish products for human consumption;]

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;]

9.4. has been subjected to processing in accordance with Annex VIII, Chapter XIV of Regulation 1774/2002/EC, in order to kill pathogenic agents;

9.5. have been examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards[59]:

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

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

9.6. the end product was:

either (packed in new or sterilised bags).

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"**;

9.7. The end product was stored in enclosed storage;

9.8. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Official stamp and signature

Done at …… on ……
(place) *(date)*

……..
(signature of official veterinarian)[60]

STAMP[61]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[59] 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.

[60] Signature must be in a different colour to that of the printing.

[61] Stamp must be in a different colour to that of the printing.

CHAPTER 4(A)

Health Certificate

For the import of serum from equidae to be used for technical purposes including pharmaceuticals, in vitro diagnosis and laboratory reagents, intended for dispatch to the European Community.

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

ORIGINAL

VETERINARY CERTIFICATE

For import of serum from equidae to be used for technical purposes including pharmaceuticals, in vitro diagnosis and laboratory reagents, intended for dispatch to the European Community

Reference number[62]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the serum 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry: …… 4.2. Certifying department: …… ……
5. Destination of the serum 5.1. EU Member State …… 5.2. Name and Address of destination …… …… ……	**Place of loading for exportation** …… …… …… …… …… ……

[62] Issued by the competent authority.

7. Means of transport and consignment identification[63]

7.1. (Lorry, rail wagon, ship or aircraft)[64]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging:

……

7.5. Number of packages:

……

7.6. Net weight:

……

8. Identification of serum

8.1. Serum of:

……. (animal species)

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

……...

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the serum of equidae described above –

9.1. consist of serum from equidae that satisfy the health requirements below;

9.2. consist exclusively of serum from equidae not intended for human nor animal consumption:

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

9.4. was obtained under the supervision of a veterinarian, from equidae which, at the time of collection, were free from clinical signs of infectious disease or were obtained from equidae that passed ante-mortem inspection at the time of slaughter;

9.5. was obtained by equidae that have remained since birth in the territory or, in case of official regionalisation according to EC legislation, in parts of the territory of a third country in which:

[63] For goods vehicles the registration number should be given. For bulk containers, the container number and seal number (if applicable) should be included.

[64] Delete as appropriate.

(a) Venezuelan equine encephalomyelitis has not occurred during the last two years;

(b) dourine has not occurred during the last six months; and

(c) glanders has not occurred during the last six months;

9.6. was obtained from equidae that had never been present on a holding that had been subject to prohibition for animal health reasons or where:

either:

(a) in the case of equine encephalomyelitis, the date on which all the equidae suffering from the disease were slaughtered was at least six months before the date of collection;

(b) in the case of infectious anaemia, all the infected animals had been slaughtered and the remaining animals showed a negative reaction to two Coggins tests carried out three months apart;

(c) in case of vesicular stomatitis, the prohibition was lifted at least six months before the date of collection; and

(d) in the case of rabies, the last recorded case was at least a month before the date of collection, and

(e) in the case of anthrax, the last recorded case was at least 15 days before the date of collection.

or:

all the animals of species susceptible to the disease located on the holding were slaughtered and the premises disinfected, at least 30 days before the date of collection (or, in the case of anthrax, at least 15 days before);

9.7. has undergone all precautions to avoid contamination with pathogenic agents during production, handling and packaging;

9.8. was packed in sealed impermeable containers clearly labelled "**SERUM FROM EQUIDAE"** and bearing the registration number of the establishment of collection.

Official stamp and signature

Done at …….. On …….
(place) *(date)*

……
(signature of official veterinarian)[65]

STAMP[66]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[65] Signature must be in a different colour to that of the printing.

[66] Stamp must be in a different colour to that of the printing.

CHAPTER 4(B)

Health Certificate

For blood products not intended for human consumption that could be used as feed material, intended for dispatch to the European Community.

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

ORIGINAL

VETERINARY CERTIFICATE
For blood products not intended for human consumption that could be used as feed material, intended for dispatch to the European Community.

Reference number[67]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the blood products 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the blood products 5.1. EU Member State …… 5.2. Name and Address of destination	**6. Place of loading for exportation** …… …… ……

[67] Issued by the competent authority.

……	……
……	……
	……

7. Means of transport and consignment identification[68]

7.1. (Lorry, rail wagon, ship or aircraft)[69]

7.2. Number of seal (if applicable):

…….

7.3. Registration number(s), ship name or flight number:

…….

7.4. Nature of packaging

…….

7.5. Number of packages

…….

7.6. Net weight

…….

7.7. Lot/batch production reference number:

…….

8. Identification of the blood products

8.1. Nature of the blood products:

…….

…….

8.2. Species of animals from which the blood products derive:

……...

……

[68] For goods' vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[69] Delete as appropriate.

8.3. Address and registration number of the approved establishment:

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the blood products described above –

9.1. consist of blood products that satisfy the health requirements below;

9.2. consist exclusively of blood products not intended for human consumption;

9.3. have been prepared and stored in plant, approved, validated and supervised by te competent authority in accordance with regulation 17 and where appropriate Article 11 of Regulation (EC) No. 1774/2002;

9.4. have been prepared (derived) exclusively with the following animal by-products:

either [blood of slaughtered animals, which is fit fro human consumption in accordance with European Community legislation, but is not intended for human consumption for commercial reasons;]

and/or [blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any sign of diseases communicable to humans or animals, derived from carcases that are fit for human consumption in accordance with European Community legislation;]

9.5. have been submitted:

either [to processing in accordance with processing method …….[70] as set out in Annex V, Chapter III of Regulation (EC) No. 1774/2002/EC,]

or [to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I, paragraph 10 of Regulation (EC) No. 1774/2002/EC,] in order to kill pathogenic agents;

9.6. have been examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards[71]:

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

Enterobacteriaceae: n=5, c=2, =10, M=300 in1 gram;

9.7. the end product was:

[70] Insert method 1 to 5 or 7 as applicable.

[71] 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 of 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.

either [packed in new sterilised bags,]

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";

9.8. the end product was stored in enclosed storage;

9.9. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Official stamp and signature

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

……
(signature of official veterinarian)[72]

STAMP[73]

…….

…….
(name, qualifications and title IN CAPITAL LETTERS)

[72] The signature must be in a different colour to that of the printing;

[73] The stamp must be in a different colour to that of the printing.

CHAPTER 4(C)

Health Certificate

For blood products to be used for technical purposes, including pharmaceuticals, in vitro diagnosis and laboratory reagents, but excluding serum of equidae, intended for dispatch to the European Community

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

ORIGINAL

VETERINARY CERTIFICATE

For blood products to be used for technical purposes, including pharmaceuticals, in vitro diagnosis and laboratory reagents, but excluding serum of equidae, intended for dispatch to the European Community.

Reference number[74]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the blood products 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the blood products 5.1. EU Member State ……	**6. Place of loading for exportation** ……

[74] Issued by the competent authority.

5.2. Name and Address of destination …… …… ……	…… …… …… ……

7. Means of transport and consignment identification[75]

7.1. (Lorry, rail wagon, ship or aircraft)[76]

7.2. Number of seal (if applicable):

…….

7.3. Registration number(s), ship name or flight number:

…….

7.4. Nature of packaging

…….

7.5. Number of packages

…….

7.6. Net weight

…….

7.7. Lot/batch production reference number:

…….

8. Identification of the blood products

8.1. Nature of the blood products:

…….

…….

8.2. Species of animals from which the blood products derive:

……...

[75] For goods' vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[76] Delete as appropriate.

……

8.3. Address and registration number of the approved establishment:

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the blood products described above –

9.1. consist of blood products that satisfy the health requirements below:

9.2. consist exclusively of blood products not intended for human or animal consumption;

9.3. have been prepared exclusively with the following animal by-products:

either [- blood of slaughtered animals, which is fit for human consumption in accordance with EC legislation, but is not intended for human consumption for commercial reasons;]

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 EC legislation;]

and/or [- blood obtained from animals other than ruminants that are slaughtered in a slaughtered, after undergoing ante mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with EC legislation;]

and/or [- blood and blood products derived from production of products intended for human consumption;]

and/or [- blood and blood products originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals;]

either (9.4. in the case of blood products derived from ruminant animals they originate in a third country or regions where:

either [the animals and products come from a region where no case of foot and mouth disease, vesicular stomatitis, rinderpest, peste des petit ruminants, Rift Valley fever and bluetongue has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months and from which imports of ruminant animals are authorised pursuant to EC legislation.

The blood from which such products are manufactured must have been collected:

Either {in slaughterhouses approved in accordance with EC legislation;}

Or {from live animals in facilities approved in accordance with EC legislation;}

Or {in slaughterhouses approved and supervised by the competent authority of the third country. In this case the European Commission and Member States must be notified of the address and approval number of such

slaughterhouse and the certificate shall indicate this information,}]

Or [the products have undergone one of the following treatments, guaranteeing the absence of pathogens of the ruminant diseases foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue[77];

Either {heat treatment at a temperature of 65 degrees Celsius for at least three hours, followed by an effectiveness check,}

Or {irradiation at 2.5 megarads or by gamma rays, followed by an effectiveness check}

Or {change in pH to pH 5 for two hours, followed by an effectiveness check,}

Or {heat treatment of at least 90 degrees Celsius throughout their substance, followed by a effectiveness check,}]

Or {sero-positive bluetongue animals are present, and the blood and blood products are intended for technical purposes including pharmaceutical, in vitro diagnosis and laboratory reagents, to be processed in the approved plants (approval number) in (Member States)[78]});

Or (9.4. in the case of blood products derived from animals excluding ruminants they originate in a third country or regions where:

Either [the animals and the products come from a region where no case of foot-and-mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease or avian influenza has been recorded for 12 months in the susceptible species and in which vaccination has not been carried out against those diseases for at least 12 months. The health certificate shall follow the model according to the species of animal from which the blood products are derived;]

Or [the products have undergone a heath treatment at a temperature of 65 degrees Celsius for at least three hours, followed by an effectiveness check, guaranteeing the absence of pathogens of the following diseases:

Foot-and-mouth disease, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease or avian influenza in the susceptible species;])

9.5. the end product was:

either (packed in new or sterilised bags,)

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 OR ANIMAL CONSUMPTION";

9.6. the end product was stored in enclosed storage;

9.7. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

[77] In the case of countries in which bluetongue sero-positive ruminant animals are present, blood products have been tested sero-negative.

[78] This must be the same Member State of first entry of the products into the European Community.

Official stamp and signature

Done at ……..on ……
(place) *(date)*

……
(signature of official veterinarian)[79]

STAMP[80]

……...

……
(name, qualifications and title IN CAPITAL LETTERS)

[79] The signature must be in a different colour to that of the printing.

[80] The stamp must be in a different colour to that of the printing.

CHAPTER 5 (A)

Health Certificate

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[81]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the hides and skins 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
7. Means of transport and consignment identification[82] 7.1. (Lorry, rail wagon, ship or aircraft)[83] 7.2. Number of seal (if applicable):	

[81] Issued by the competent authority.

[82] For goods' vehicles the registration number should be given. For bulk containers, the container number and seal number (if applicable) should be included.

[83] Delete as appropriate

……...

7.3. Registration number(s), ship name or flight number:

……...

7.4. Nature of packaging

……...

7.5. Number of packages

……...

7.6. Net weight

……...

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

……...

8. Identification of the hides and skins

8.1. Hides and skins of : ……..(animal species)

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

…….

…….

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the hides and skins described above –

9.1. have been obtained from animals that were:

(a) slaughtered in a slaughterhouse, underwent ante mortem inspection and were fit, as a result of such inspection, for slaughter in accordance with EC legislation;

(b) not affected by any signs of diseases communicable to humans or animals, and

(c) not killed to eradicate any epizootic disease;

9.2. originate from a country or, in the case of regionalisation in accordance with EC 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) originate from a country, or in the case of regionalisation in accordance with EC legislation from a

part of a country from which imports of all categories of fresh meat of the corresponding species are authorised and which:

either (classical swine fever, and
- African swine fever,)

and/or (rinderpest,)

and

(b) has been free for at least 24 months before dispatch from foot-and-mouth disease and where for 12 months before dispatch, no vaccination has been carried out against foot-and-mouth disease;

9.3. have been obtained from:

either (animals that have remained in the territory of the country of origin for at least three months before being slaughtered or since birth in the case of animals less than three months old;)

or (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 10kn there has been no case of foot and mouth disease for 30 days;)

or (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 (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)

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

Official stamp and signature

Done at …… on ……
(place) *(date)*

…….
(signature of official veterinarian)[84]

STAMP[85]

……...

……...

(name, qualifications and title IN CAPITAL LETTERS)

[84] The signature must be in a different colour to that of the printing.

[85] The stamp must be in a different colour to that of the printing.

CHAPTER 5(B)

Health Certificate

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[86]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the hides and skins 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the hides and skins 5.1. EU Member State …… 5.2. Name and Address of destination ……	**6. Place of loading for exportation** …… …… ……

[86] Issued by the competent authority.

……	……
……	……

7. Means of transport and consignment identification[87]

7.1. (Lorry, rail wagon, ship or aircraft)[88]

7.2. Number of seal (if applicable):

…….

7.3. Registration number(s), ship name or flight number:

…….

7.4. Nature of packaging

…….

7.5. Number of packages

…….

7.6. Net weight

…….

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

…….

8. Identification of the hides and skins

8.3. Hides and skins of : ……..(animal species)

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

…….

…….

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the hides and skins described above –

9.1. have been obtained from animals that were:

(a) did not show any clinical signs of any disease communicable to humans or animals, and;

[87] For goods' vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[88] Delete as appropriate.

(b) were not killed to eradicate any epizootic disease;

either - (9.2. come from animals originating in a country or a part of a country not subject, pursuant to EC legislation, to restrictions as a result of an outbreak of a serious transmissible disease to which the animals of the species concerned are susceptible and have been:

either [dried]

or [dry-salted or wet-salted for at least 14 days prior to dispatch;]

or [salted for seven days in sea salt with the addition of 2% of sodium carbonate]

or [dried for 42 days at a temperature of at least 20 degrees Celsius]

or [9.2. have been:

either [dry-salted or wet-salted for at least 14 days prior to dispatch]

or [salted for seven days in sea salt with the addition of 2% of sodium carbonate]

or [9.2. were salted on ……. (date) before being transported by a ship;]

9.3. the consignment has not been in contact with other animal products or with live animals presenting a risk of spreading a serious transmissible disease.

Official stamp and signature

Done at ……on ……
(place) *(date)*

……..
(signature of official veterinarian)[89]

STAMP[90]

…….

…….
(name, qualifications and title IN CAPITAL LETTERS)

[89] The signature must be in a different colour to that of the printing.

[90] The stamp must be in a different colour to that of the printing.

CHAPTER 5(C)

Official Declaration

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[91]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the hides and skins 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department ……
5. Destination of the hides and skins 5.1. EU Member State …… 5.2. Name and Address of destination …… ……	**6. Place of loading for exportation** …… …… …… ……

[91] Issued by the competent authority.

7. Means of transport and consignment identification[92]

7.1. (Lorry, rail wagon, ship or aircraft)[93]

7.2. Number of seal (if applicable):

…….

7.3. Registration number(s), ship name or flight number:

…….

7.4. Nature of packaging

…….

7.5. Number of packages

…….

7.6. Net weight

…….

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

…….

8. Identification of the hides and skins

8.5. Hides and skins of : ……..(animal species)

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

…….

…….

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the hides and skins described above –

9.1. have been obtained from animals that:

(a) did not show any clinical signs of any disease communicable to humans or animals, and;

(b) were not killed to eradicate any epizootic disease;

[92] For goods' vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[93] Delete as appropriate.

9.2. have been:

either [dried;]

or [dry-salted or wet-salted for at least 14 days prior to dispatch;]

or [salted for seven days in seas salt with the addition of 2% of sodium carbonate;]

or [dried for 42 days at a temperature of at least 20 degrees Celsius;]

9.3. have not been in contact with other animal product or with live animals presenting a risk or spreading a serious transmissible disease;

either [9.4. have been kept separate immediately before dispatch for 21 days under official supervision after the treatment described under point (9.2)]

or [9.4.following the declaration of the transporter, the duration of the transport period is foreseen to be at least 21 days]

Official stamp and signature

Done at …… on ……
(place) *(date)*

……..
(signature of official veterinarian)[94]

STAMP[95]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[94] The signature must be in a different colour to that of the printing.

[95] The stamp must be in a different colour to that of the printing.

CHAPTER 6(A)

Health Certificate

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[96]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of game trophies 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the game trophies 5.1. EU Member State ……	**6. Place of loading for exportation** …… ……

[96] Issued by the competent authority.

5.2. Name and Address of destination …… …… ……	…… …… …… ……

7. Means of transport and consignment identification[97]

7.1. (Lorry, rail wagon, ship or aircraft)[98]

7.2. Number of seal (if applicable):

…….

7.3. Registration number(s), ship name or flight number:

…….

7.4. Nature of packaging

…….

7.5. Number of parts or packages

…….

7.6. Reference number of Cites certificate:

…….

8. Identification of game trophies

8.1. Game trophies of: …….(animal species)

8.2. Nature of the game trophies:

(a) solely [bones], [horns], [hooves], [claws], [antlers], [teeth]:

…….

(b) solely [hides] or [skins]:

…….

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation

[97] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[98] Delete as appropriate.

(EC) No. 1774/2002 and certify that the hides and skins described above –

9.1. 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;

either (9.2. in the case of game trophies consisting solely of hides and skins;

either [have been dried]

or [have been dry-salted or wet-salted for a minimum of 14 days before dispatch]

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])

or (9.2. 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.)

Official stamp and signature

Done at …….. on ……
(place) *(date)*

…….
(signature of official veterinarian)[99]

STAMP[100]

……..

……..
(name, qualifications and title IN CAPITAL LETTERS)

[99] The signature must be in a different colour to that of the printing.

[100] The stamp must be in a different colour to that of the printing.

CHAPTER 6(B)

Health Certificate

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[101]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of game trophies 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department ……
5. Destination of the game trophies 5.1. EU Member State …… 5.2. Name and Address of destination	**6. Place of loading for exportation** …… …… ……

[101] Issued by the competent authority.

……	……
……	……
……	……

7. Means of transport and consignment identification[102]

7.1. (Lorry, rail wagon, ship or aircraft)[103]

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

7.3. Registration number(s), ship name or flight number:
…….

7.4. Nature of packaging
…….

7.5. Number of parts or packages
…….

7.6. Reference number of Cites certificate:
…….

8. Identification of game trophies

8.1. Game trophies of: …….(animal species)

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the game trophies described above –

Either [9.1. 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 the 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

[102] For goods' vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[103] Delete as appropriate.

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 EC.]

Or [9.1. 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 EC.)

or [9.1. 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.]

or [9.1. with respect to game trophies of game birds:

(a) …….. (region) is free from 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 restriction because of outbreaks of disease to which the wild birds are susceptible;]

9.2. 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.

Official stamp and signature

Done at …… on ……
(place) *(date)*

……
(signature of official veterinarian)[104]

STAMP[105]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[104] The signature must be in a different colour to the printing.

[105] The stamp must be in a different colour to that of the printing.

CHAPTER 7(A)

Health Certificate

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[106]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the pig bristles 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the pig bristles 5.1. EU Member State	**6. Place of loading for exportation**

[106] Issued by the competent authority.

……	……
5.2. Name and Address of destination ……	……
……	……
……	……
	……
	……

7. Means of transport and consignment identification[107]

7.1. (Lorry, rail wagon, ship or aircraft)[108]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

8. Identification of the pig bristles

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

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation

[107] For goods' vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[108] Delete as appropriate.

(EC) No. 1774/2002 and certify that –

9.1. the pig bristles described above have been obtained from pigs originating, and slaughtered in a slaughterhouse, in the country of origin;

9.2. 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;

9.3. the country of origin or, in case of regionalisation according to European Community legislation, the region of origin, has been free from African swine fever for at least 12 months;

9.4. the pig bristles are dry and securely enclosed in packaging.

Official stamp and signature

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

……
(signature of official veterinarian)[109]

STAMP[110]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[109] The signature must be in a different colour to that of the printing.

[110] The stamp must be in a different colour to that of the printing.

CHAPTER 7(B)

Health Certificate

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

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

ORIGINAL

VETERINARY CERTIFICATE

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

Reference number[111]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the pig bristles 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the pig bristles 5.1. EU Member State ……	**6. Place of loading for exportation** …… ……

[111] Issued by the competent authority.

5.2. Name and Address of destination …… …… ……	…… …… …… ……

7. Means of transport and consignment identification[112]

7.1. (Lorry, rail wagon, ship or aircraft)[113]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

8. Identification of the pig bristles

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

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that –

9.1. the pig bristles described above have been obtained from pigs originating, and slaughtered in a slaughterhouse, in the country of origin;

[112] For goods' vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[113] Delete as appropriate.

9.2. 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;

9.3. the country of origin or, in case of regionalisation according to European Community legislation, the region of origin, has been free from African swine fever for at least 12 months;

9.4. the pig bristles mentioned above have been:

either (boiled;)

or (dyed;)

or (bleached)

9.4. the pig bristles are dry and securely enclosed in packaging.

Official stamp and signature

Done at ……on ……
(place) *(date)*

……
(signature of official veterinarian)[114]

STAMP[115]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[114] The signature must be in different colour to that of the printing.

[115] The stamp must be in different colour to that of the printing.

CHAPTER 8 (A)

Health Certificate

For animal by-products[116] for the manufacture of pet food, intended for dispatch to the European Community

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

ORIGINAL

VETERINARY CERTIFICATE
For animal by-products for the manufacture of pet food, intended for dispatch to the European Community.

Reference number[117]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of animal by-products 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department ……
5. Destination of animal by-products 5.1. EU Member State …… 5.2. Name and Address of destination	**6. Place of loading for exportation** ……

[116] 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).

[117] Issued by the competent authority.

……	……
……	……
……	……
	……
	……

7. Means of transport and consignment identification[118]

7.1. (Lorry, rail wagon, ship or aircraft)[119]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of animal by-products

8.1. Nature of animal by-products:

……

8.2. Animal by-products of: …….(animal species)

[118] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[119] Delete as appropriate.

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

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the animal by-products described above –

9.1. consist of animal by-products that satisfy the animal health requirements below:

9.2. have been obtained in the territory of …….[120] from animals:

either [(a) that have remained in this territory since birth or for at least the last months before slaughter]

or [(b) killed in the wild in this territory[121];]

9.3. have been obtained from animals:

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 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 10km, during the prior 30 days, and

(ii) where there has been neither case/outbreak of foot and mouth disease during the prior 60days nor in the holdings situated in their vicinity within 25km, 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 40 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 European Union Council Directive 93/119/EC on animal welfare;]

or [(a) captured and killed in the wild in an area:

[120] The name and ISO code number of the exporting country as laid down in:

- part 1 of Annex II of EU Council Decision 79/542/EEC;
- the Annex to Commission Decision 94/984/EC;
- the Annex to Commission Decision 2000/585/EC

In addition the ISO code of regionalization in this Annex (where applicable for the susceptible species concerned) should be included.

[121] Only for countries from where game meat intended for human consumption of the same animal species is authorised for importation into the European Community.

(i) in which within 25km 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 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 EC; and

(b) which after killing were transposed within 12 hours for chilling either to a collection centre and immediately afterwards to a game establishment;]

9.4. have been obtained in an establishment around which, within a radius of 10km, there has been no case/outbreak of diseases referred to in point 9.3. 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 EC 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;

9.5. 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;

9.6. have been packed in new packaging preventing any leakage and 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;

9.7. consist only of the following animal by-products:

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

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 EC legislation;)

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

and/or (- former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste[122] 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;)

and/or (- fish or other animals, except sea mammals, caught in the open sea for the purpose of fishmeal production;)

and/or (- fresh by-products from fish from plants manufacturing fish products for human consumption;)

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

and/or (- raw material derived from animals which have been treated with certain substances prohibited in accordance with EU Directive 96/22/EC for the manufacture of pet food, as referred to in Article 28 of EC Regulation (EC) No. 1774/2002;)

9.8. 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;

[122] Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

9.9. in the case of raw material derived from animals which have been treated with certain substances prohibited in accordance with EC Directive 96/22/EC for the manufacture of pet food, 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 EC by a cross of liquefied charcoal or activated carbon on each outer side of each frozen block in a way that the marketing covers at least 70% of the diagonal length of the frozen block and be at least 10cm 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 EC 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 of 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.

10. Specific requirements[123]

10.1. The by-products in this consignment come from animals that have been kept in the territory mentioned under (9.2), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled in domestic bovine animals[124].

10.2. The by-products in the consignment consist only of animal by-products derived from trimmed offal of domestic ruminants, which have matured at an ambient temperature of more than +2 degrees Celsius or at least 3 hours, or in the case of masseter muscles of bovine animals of bovine animals and de-boned meat of domestic animals, for at least 24 hours.)[125]

Official stamp and signature

Done at …….. on ……
(place) *(date)*

……...
(signature of official veterinarian)[126]

STAMP[127]

……..

……..
(name, qualifications and title IN CAPITAL LETTERS)

[123] 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 matured and 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 EU Council Directive 64/433/EEC, are also permitted.

[124] Only for certain South American countries.

[125] Only for certain South American and South African countries.

[126] The signature must be in a different colour to that of the printing.

[127] The stamp must be in a different colour to that of the printing.

CHAPTER 8 (B)

Health Certificate

For animal by-products for the manufacture of technical products (including pharmaceutical products[128]), intended for dispatch to the European Community

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

ORIGINAL

VETERINARY CERTIFICATE

For animal by-products for the manufacture of technical products (including pharmaceutical products[129]), intended for dispatch to the European Community

Reference number[130]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of animal by-products 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department ……
5. Destination of animal by-products 5.1. EU Member State	**6. Place of loading for exportation** ……

[128] Excluding raw blood, raw milk, hides and skins, pig bristles and feathers (see relevant specific certificates for the import of these products).

[129] Excluding raw blood, raw milk, hides and skins, pig bristles and feathers (see relevant specific certificates for the import of these products).

[130] Issued by the competent authority.

……	……
5.2. Name and Address of destination	……
……	……
……	……
……	……

7. Means of transport and consignment identification[131]

7.1. (Lorry, rail wagon, ship or aircraft)[132]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of animal by-products

8.1. Nature of animal by-products:

……

8.2. Animal by-products of: …….(animal species)

[131] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[132] Delete as appropriate.

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

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the animal by-products described above –

9.1. consist of animal by-products that satisfy the animal health requirements below;

9.2. have been obtained in the territory of …….[133] from animals:

either [(a) that have remained in this territory since birth or for at least the last months before slaughter]

or [(b) killed in the wild in this territory[134];]

9.3. have been obtained from animals:

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 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 10km, during the prior 30 days, and

(ii) where there has been neither case/outbreak of foot and mouth disease during the prior 60days nor in the holdings situated in their vicinity within 25km, 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 40 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

[133] The name and ISO code number of the exporting country as laid down in:

- part 1 of Annex II of EU Council Decision 79/542/EEC;
- the Annex to Commission Decision 94/984/EC;
- the Annex to Commission Decision 2000/585/EC

In addition the ISO code of regionalization in this Annex (where applicable for the susceptible species concerned) should be included.

[134] Only for countries from where game meat intended for human consumption of the same animal species is authorised for importation into the European Community.

with the relevant provisions of European Union Council Directive 93/119/EC on animal welfare)

or [(a) captured and killed in the wild in an area:

(iii) in which within 25km 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 avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days; and

(iv) 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 EC; and

(b) which after killing were transposed within 12 hours for chilling either to a collection centre and immediately afterwards to a game establishment;]

9.4. have been obtained in an establishment around which, within a radius of 10km, there has been no case/outbreak of diseases referred to in point 9.3. 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 EC 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;

9.5. 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;

9.6. have been packed in new packaging preventing any leakage and officially sealed containers bearing the label indicating **"RAW MATERIAL ONLY FOR THE MANUFACTURE OF TECHNICAL PRODUCTS INCLUDING PHARMACEUTICAL PRODUCTS"** and the name and address of the EU establishment of destination;
9.7. consist only of the following animal by-products:

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

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 EC legislation;)

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

and/or (- former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste[135] 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;)

and/or (- fish or other sea animals, except sea mammals, caught in the open sea for the purpose of fishmeal production;)

and/or (- fresh by-products from fish from plants manufacturing fish products for human consumption;)

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

[135] Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

and/or (- fur originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals;)

9.8. 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;

[**10. Specific requirements**[136]

10.1. The by-products in this consignment come from animals that have been kept in the territory mentioned under (9.2), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled in domestic bovine animals[137].

10.2. The by-products in the consignment consist only of animal by-products derived from trimmed offal or boned meat.][138]

Official stamp and signature

Done at …… on ……
(place) *(date)*

……
(signature of official veterinarian)[139]

STAMP[140]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[136] 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 matured and 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 EU Council Directive 64/433/EEC, are also permitted.

[137] Only for certain South American countries.

[138] Only for certain South American and South African countries.

[139] The signature must be in a different colour to that of the printing.

[140] The stamp must be in a different colour to that of the printing.

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 the European Community.

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

ORIGINAL

VETERINARY CERTIFICATE

For fish oil not intended for human consumption to be used as feed material or for technical purposes, intended for dispatch to the European Community.

Reference number[141]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the fish oil 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Intended destination of the fish oil 5.1. EU Member State …… 5.2. Name and Address of destination ……	**6. Place of loading for exportation** …… ……

[141] Issued by the competent authority.

……	……
……	……
	……
	……

7. Means of transport and consignment identification[142]

7.1. (Lorry, rail wagon, ship or aircraft)[143]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging:

……

7.5. Number of parts or packages:

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of the fish oil

8.1. Description of the fish oil:

……

8.2. Address and registration of treatment/processing establishment:

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the fish oil described above –

[142] For goods' vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[143] Delete as appropriate.

9.1. consist of fish oil that satisfy the health requirements below:

9.2. contains exclusively fish oil not intended for human consumption;

9.3. has been prepared and stored in a dedicated fish plant approved, validated and supervised by the Competent Authority in accordance with regulation 17 and where appropriate Article 11 of Regulation (EC) No. 1774/2002;

9.4. has been prepared exclusively with the following animal by-products:

either (- former foodstuffs of fish origin, other than catering waste[144], 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;)

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

and/or (-fresh by-products from fish from plants manufacturing fish products for human consumption;)

9.5. 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

either [(c) is packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination;]

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".**

Official stamp and signature

Done at …… on ……
(place) *(date)*

……
(signature of official veterinarian)[145]

STAMP[146]

……

……

(name, qualifications and title IN CAPITAL LETTERS)

[144] Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

[145] The signature must be in a different colour to that of the printing.

[146] The stamp must be in a different colour to that of the printing.

Chapter 10 (A)

Health Certificate

For rendered fats not intended for human consumption to be used as food material or for technical purposes, intended for dispatch to the European Community

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

ORIGINAL

VETERINARY CERTIFICATE

For rendered fats not intended for human consumption to be used as food material or for technical purposes, intended for dispatch to the European Community

Reference number[147]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the rendered fat 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Intended destination of the rendered fat 5.1. EU Member State ……	**6. Place of loading for exportation** …… ……

[147] Issued by the competent authority.

5.2. Name and Address of destination …… …… ……	…… …… …… ……

7. Means of transport and consignment identification[148]

7.1. (Lorry, rail wagon, ship or aircraft)[149]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of the rendered fat

8.1. Description of the rendered fat:

……

8.2. Rendered fat of: …… (animal species)

8.3. Address and registration number of treatment/processing establishment[150]:

……

[148] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[149] Delete as appropriate.

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the rendered fats described above –

9.1. consist of the rendered fats that satisfy the health requirements below;

9.2. consist of rendered fats not intended for human consumption;

9.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with regulation 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 or Chapter IX of Annex I to Council Directive 92/118/EEC, in order to kill pathogenic agents;

9.4. have been prepared exclusively with the following animal by-products:

either [- parts of slaughtered animals, which are fit for human consumption in accordance with EC legislation, but are not intended for human consumption for commercial reasons;]

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 EC legislation;]

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 EC legislation;]

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 EC legislation;]

and/or [- animal by-products derived the production of products intended for human consumption, including degreases bones and greaves;]
and/or [- former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste[151], 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;]

and/or [- milk originating from animals which do not show and clinical signs of any disease communicable through that product to humans or animals;]

and/or [- fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;]

and/or [- by-products from fish from plants manufacturing fish products for human consumption;]

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;]

9.5. 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;

[150] Delete as appropriate.

[151] Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

9.6. 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

either [(b) are packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination;]

or [(b) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk containers or bulk road tanker used in transportation of the product from the manufacturing plant either directly on the ship or into shore tanks or direct to plants have been inspected and found to be cleaned before use;]

and which bear labels indicating **"NOT FOR HUMAN CONSUMPTION"**.

Official stamp and signature

Done at …… on ……
(place) *(date)*

……
(signature of official veterinarian)[152]

STAMP[153]

……

……

(name, qualifications and title IN CAPITAL LETTERS)

[152] The signature must be in a different colour to that of the printing.

[153] The stamp must be in a different colour to that of the printing.

Chapter 10 (B)

Health Certificate

For rendered fats not intended for human consumption to be used for technical purposes, intended for dispatch to the European Community.

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

ORIGINAL

VETERINARY CERTIFICATE

For rendered fats not intended for human consumption to be used for technical purposes, intended for dispatch to the European Community.

Reference number[154]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the rendered fat 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department ……
5. Intended destination of the rendered fat 5.1. EU Member State	**6. Place of loading for exportation** ……

[154] Issued by the competent authority.

……	……
5.2. Name and Address of destination	……
……	……
……	……
……	……

7. Means of transport and consignment identification[155]

7.1. (Lorry, rail wagon, ship or aircraft)

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of the rendered fat

8.1. Description of the rendered fat:

……

8.2. Rendered fat of: …… (animal species)

8.3. Address and registration number of treatment/processing establishment[156]:

[155] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the rendered fats described above –

9.1. consist of the rendered fats that satisfy the health requirements below;

9.2. consist of rendered fats not intended for human consumption or animal consumption;

9.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with regulation 13 and where appropriate Article 11 of Regulation (EC) No. 1774/2002, in order to kill pathogenic agents;

9.4. have been prepared exclusively with the following animal by-products:

either (category 2 materials[157];)

or (a mixture of category 2 materials with category 3 materials[158];)

---

[156] Delete as appropriate.

[157] 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 desanding, grease and oil mixtures, sludge and materials removed from drains from those premises.
(b) Products from animal origin containing residues of veterinary drugs and contaminants listed in group B(1) and (2) of Annex I to EU Directive 96/23/EC, if such residues exceed the permitted laid 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 EC 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.

[158] List of category 3 materials:
(a) parts of slaughtered animals, which are fit for human consumption in accordance with EC 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 EC legislation.
(c) 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 EC 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 EC 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 no present risk to humans or animals;

9.5. 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;

9.6. the rendered fats:

(a) have been subjected to processing in accordance with Annex VII, Chapter XII of Regulation 1774/2002/EC, in order to kill pathogenic agents, and

either [(b) are packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination;]

or [(b) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk containers or bulk road tanker used in transportation of the product from the manufacturing plant either directly on 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 OR ANIMAL CONSUMPTION"**.

Official stamp and signature

Done at …….. on ……
(place) *(date)*

…….
(signature of official veterinarian)[159]

STAMP[160]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

(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 purpose 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.

[159] The signature must be in a different colour to that of the printing.

[160] The stamp must be in a different colour to that of the printing.

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 the European Community.

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

ORIGINAL

VETERINARY CERTIFICATE

For gelatine and collagen not intended for human consumption to be used as feed material or for technical purposes, intended for dispatch to the European Community.

Reference number[161]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the gelatine/collagen 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department ……
5. Intended destination of the gelatine/collagen[162] 5.1. EU Member State ……	**6. Place of loading for exportation** ……

[161] Issued by the competent authority.

[162] Delete as appropriate.

5.2. Name and Address of destination …… ……	…… …… …… …… ……

7. Means of transport and consignment identification[163]

7.1. (Lorry, rail wagon, ship or aircraft) [164]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of the gelatine/collagen[165]

8.1. Description of the gelatine/collagen:

……

[163] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[164] Delete as appropriate.

[165] Delete as appropriate.

8.2. Gelatine/collagen of: …… (animal species)

8.3. Address and registration number of treatment/processing establishment:

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the gelatine/collagen described above –

9.1. consist of gelatine/collagen that satisfy the health requirements below;

9.2. consist exclusively of gelatine/collagen not intended for human consumption;

9.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with regulation 17 and where appropriate Article 11 of Regulation (EC) No. 1774/2002, in order to kill pathogenic agents;

9.4. have been prepared exclusively with the following animal by-products:

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

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 EC legislation;)

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 EC legislation;)

and/or (- animal by-products derived from the production of products intended for human consumption;)

and/or (- former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste[166], 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;)

and/or (- fish or other sea animals, except sea mammals, caught in open sea for the purposes of fish meal production;)

and/or (- fresh by-products from fish from plants manufacturing fish products for human consumption;)

9.5. the gelatine/collagen:

(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 EC legislation were used;

[166] Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

Wrappings and packages containing gelatine/collagen must carry the word **"GELATINE/COLLAGEN SUITABLE FOR ANIMAL CONSUMPTION"**, and

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;)

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.]

Official stamp and signature

Done at ……on ……
(place) *(date)*

……..
(signature of official veterinarian)[167]

STAMP[168]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[167] The signature must be in a different colour to that of the printing.

[168] The stamp must be in a different colour to that of the printing.

CHAPTER 12

Health Certificate

For hydrolysed protein, dicalcium phosphate and tricalcium phosphate not intended for human consumption to be used as food material or for technical purposes, intended for dispatch to the European Community.

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

ORIGINAL

VETERINARY CERTIFICATE

For hydrolysed protein, dicalcium phosphate and tricalcium phosphate not intended for human consumption to be used as food material or for technical purposes, intended for dispatch to the European Community.

Reference number[169]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the hydrolysed protein/dicalcium phosphate/tricalcium phosphate[170] 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Intended destination of the hydrolysed protein/dicalcium phosphate tricalcium phosphate 5.1. EU Member State	**6. Place of loading for exportation** ……

[169] Issued by the competent authority.

[170] Delete as appropriate.

……	……
5.2. Name and Address of destination	……
……	……
	……
	……

7. Means of transport and consignment identification[171]

7.1. (Lorry, rail wagon, ship or aircraft)[172]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of the hydrolysed protein/dicalcium phosphate/tricalcium phosphate

8.1. Description of the [hydrolysed protein]/[dicalcium phosphate]/[tricalcium phosphate]:

……

8.2. [hydrolysed protein]/[dicalcium phosphate]/[tricalcium phosphate] of:

…..……(animal species)

8.3. Address and registration number of treatment/processing establishment:

……

……

[171] For goods' vehicles the registration number, should be given. For bulk containers, the container number and the seal number (if applicable) should be included

[172] Delete as appropriate.

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the hydrolysed protein/dicalcium phosphate/tricalcium phosphate described above –

9.1. consist of hydrolysed protein/dicalcium phosphate/tricalcium phosphate that satisfy the health requirements below;

9.2. consist exclusively of hydrolysed protein/dicalcium phosphate/tricalcium phosphate not intended for human consumption;

9.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with regulation 17 and where appropriate Article 11 of Regulation (EC) No. 1774/2002, in order to kill pathogenic agents;

9.4. have been prepared exclusively with the following animal by-products[173]:

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

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 EC legislation;)

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 EC legislation;)

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 EC legislation;]

and/or (- animal by-products derived from the production of products intended for human consumption;)

and/or (- former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste[174], 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;)

and/or [- raw milk originating from animals that do not show clinical signs of any disease communicable through the product to humans or animals;]

and/or (- fish or other sea animals, except sea mammals, caught in open sea for the purposes of fish meal production;)

and/or (- fresh by-products from fish from plants manufacturing fish products for human consumption;)

and/or [- shells, hatchery by-products and cracked egg by-products originating from animal which do not show clinical signs of any disease communicable through that product to humans or animals;]

9.5. the hydrolysed protein/dicalcium phosphate/tricalcium phosphate:

(a) was wrapped, 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 EC legislation were used; and

[173] Delete as appropriate.
[174] Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens and household kitchens.

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 products, 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 three hours at temperature of more than 80 degrees Celsius and subsequently by heat treatment at more than 140 degrees Celsius 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 degrees Celsius for 30 minutes at 3 bar;]

or [(b) in the case of dicalcium phosphate, has been 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 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 to 325 degrees Celsius and end temperature between 60 and 65 degrees Celsius;]

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 mins};

(ii) continuous cooking with steam at 145 degrees Celsius 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 degrees Celsius.]

Official stamp and signature

Done at ……on …….
(place) *(date)*

…….
(signature of official veterinarian)[175]

STAMP[176]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[175] The signature must be in a different colour to that of the printing.

[176] The stamp must be in a different colour to that of the printing.

CHAPTER 13

Health Certificate

For apiculture products, intended for dispatch to the European Community

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

ORIGINAL

VETERINARY CERTIFICATE

For apiculture products, intended for dispatch to the European Community

Reference number[177]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the apiculture products 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the apiculture products 5.1. EU Member State …… 5.2. Name and Address of destination ……	**6. Place of loading for exportation** …… …… …… ……

[177] Issued by the competent authority.

……	……
……	……

7. Means of transport and consignment identification[178]

7.1. (Lorry, rail wagon, ship or aircraft)[179]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of the apiculture products

8.1. Description of the apiculture products: …….

……

8.2. Address and registration number of the establishment of production:

…..……(animal species)

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the apiculture products described above –

9.1. consist of apiculture products that satisfy the health requirements below;

9.2.

[178] For goods' vehicles the registration number, should be given. For bulk containers, the container number and the seal number (if applicable) should be included

[179] Delete as appropriate.

either [are new and have not been in use before and have not come into contact with bees or used apiculture products;]

or [have been subjected to a temperature of -12 degrees Celsius or lower for at least 24 hours;]

or [in the case of wax, has been refined or rendered;]

9.3. come from an area which is not subject to any restriction associated with:

(a) American foul brood (Paenibacillus larvae larvae);

(b) Acariosis (Acarapis woodi (Rennie);

(c) Small hive beetle (Aethina tumida); and

(d) Tropilaclaps mites (Tropilaelaps spp);

And where the diseases meantioned above are officially notifiable.

Official stamp and signature

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

……..
(signature of official veterinarian)[180]

STAMP[181]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[180] The signature must be in a different colour to that of the printing.

[181] The stamp must be in a different colour to that of the printing.

CHAPTER 14(A)

Health Certificate

For fat derivatives not intended from human consumption to be used for technical purposes, intended for dispatch to the European Community

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

ORIGINAL

VETERINARY CERTIFICATE

For fat derivatives not intended fro human consumption to be used for technical purposes, intended for dispatch to the European Community

Reference number[182]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the fat derivatives 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department ……
5. Intended destination of the fat derivatives 5.1. EU Member State …… 5.2. Name and Address of destination …… …… ……	**6. Place of loading for exportation** …… …… …… …… …… ……

[182] Issued by the competent authority.

7. Means of transport and consignment identification[183]

7.1. (Lorry, rail wagon, ship or aircraft)[184]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of the fat derivatives

8.1. Description of the fat derivatives:
……

8.2.Fat derivatives of:
…..……(animal species)

8.3. Address and registration number of treatment/processing establishment:

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the fat derivates described above –

9.1. consist of fat derivatives that satisfy the health requirements below;

9.2. consist of fat derivatives containing exclusively fat derivatives not intended for human or animal consumption;

9.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with regulation 14 and where appropriate Article 11 of Regulation (EC) No. 1774/2002, in order to kill pathogenic agents;

9.4. have been prepared from rendered fats exclusively produced from category 2 and/or category 3 materials[185];

[183] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[184] Delete as appropriate.

9.5. the fat derivatives produced from category 2 materials:

(a) have been produced using the following methods:

either [transesterification or hydrolysis at least 200 degrees Celsius, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); and]

or [saponification with NaOH 12M (glycerol and soap]:

either [in a batch process at 95 degrees Celsius for three hours; and]

or [in a continuous process at 140 degrees Celsius, 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 CONSUMPTION"**.

Official stamp and signature

Done at ……on …….
(place) *(date)*

…….
(signature of official veterinarian)[186]

STAMP[187]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[185] 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 desanding, grease and oil mixtures, sludge and materials removed from drains from those premises.

(b) Products from animal origin containing residues of veterinary drugs and contaminants listed in group B(1) and (2) of Annex I to EU Directive 96/23/EC, if such residues exceed the permitted laid 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 EC 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.

[186] The signature must be in a different colour to that of the printing.

[187] The stamp must be in a different colour to that of the printing.

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 the European Community

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

ORIGINAL

VETERINARY CERTIFICATE

For fat derivatives not intended fro human consumption to be used as feed or for technical purposes, intended for dispatch to the European Community

Reference number[188]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the fat derivatives 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Intended destination of the fat derivatives 5.1. EU Member State …… 5.2. Name and Address of destination …… …… ……	**6. Place of loading for exportation** …… …… …… …… ……

[188] Issued by the competent authority.

7. Means of transport and consignment identification[189]

7.1. (Lorry, rail wagon, ship or aircraft)

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

7.3. Registration number(s), ship name or flight number:
……

7.4. Nature of packaging
……

7.5. Number of parts or packages
……

7.6. Net weight:
……

7.7. Lot/batch production reference number:

……

8. Identification of the fat derivatives

8.1. Description of the fat derivatives:

……

8.2.Fat derivatives of:

…..…….(animal species)

8.3. Address and registration number of treatment/processing establishment: …….

……

……

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the fat derivates described above –

9.1. consist of fat derivatives that satisfy the health requirements below;

9.2. consist of fat derivatives containing exclusively fat derivatives not intended for human consumption;

9.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with regulation 14 and where appropriate Article 11 of Regulation (EC) No. 1774/2002, in order to kill pathogenic agents;

9.4. have been prepared from rendered fats exclusively produced from the following category 3 materials:

either [- parts of slaughtered animals, which are fit for human consumption in accordance with EC legislation, but are not intended for human consumption for commercial reasons;]

[189] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

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 EC legislation;]

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 EC legislation;]

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 EC legislation;]

and/or [- animal by-products derived from the production of products intended for human consumption;]

and/or [- former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste[190], 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;]

and/or [- milk originating from animals that do not show clinical signs of any disease communicable through the product to humans or animals;]

and/or [- fish or other sea animals, except sea mammals, caught in open sea for the purposes of fish meal production;]

and/or [-by-products from fish from plants manufacturing fish products for human consumption;]

and/or [- shells, hatchery by-products and cracked egg by-products originating from animal which do not show clinical signs of any disease communicable through that product to humans or animals;]

9.5. are packaged in new containers or in containers which bear labels indicating **"NOT FOR HUMAN OR ANIMAL CONSUMPTION"**, that have been cleaned, and all precautions are taken to prevent its contamination.

Official stamp and signature

Done at ……on ……
(place) *(date)*

…….
(signature of official veterinarian)[191]

STAMP[192]

……

……

(name, qualifications and title IN CAPITAL LETTERS)

[190] Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

[191] The signature must be in a different colour to that of the printing.

[192] The stamp must be in a different colour to that of the printing.

CHAPTER 15

Health Certificate

For egg products not intended for human consumption that could be used as feed material, intended for dispatch to the European Community

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

ORIGINAL

VETERINARY CERTIFICATE

For egg products not intended for human consumption that could be used as feed material, intended for dispatch to the European Community

Reference number[193]

1. Consignor (name and address in full) …… …… …… …… …… ……	**2. Consignee** (name and address in full) …… …… …… …… …… ……
3. Origin of the egg products 3.1. Country: …… 3.2. Code of territory: ……	**4. Competent Authority** 4.1. Responsible Ministry …… 4.2. Certifying department …… ……
5. Destination of the egg products 5.1. EU Member State …… 5.2. Name and Address of destination ……	**6. Place of loading for exportation** …… …… ……

[193] Issued by the competent authority.

……	……
……	……

7. Means of transport and consignment identification[194]

7.1. (Lorry, rail wagon, ship or aircraft)[195]

7.2. Number of seal (if applicable):

……

7.3. Registration number(s), ship name or flight number:

……

7.4. Nature of packaging

……

7.5. Number of parts or packages

……

7.6. Net weight:

……

7.7. Lot/batch production reference number:

……

8. Identification of the egg products

8.1. Nature of the egg products:

……

8.2. Species of animals from which the egg products derive:

…..……(animal species)

8.3. Address and registration number of the approved establishment:

……

……

[194] For goods vehicles the registration number should be given. For bulk containers, the container number and the seal number (if applicable) should be included.

[195] Delete as appropriate.

9. Health attestation

I , the undersigned official veterinarian, declare that I have read and understood European Union Regulation (EC) No. 1774/2002 and certify that the egg products derived above –

9.1. consist of egg products that satisfy the health requirements below;

9.2. consist exclusively of egg products not intended for human consumption;

9.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with regulation 14 and where appropriate Article 11 of Regulation (EC) No. 1774/2002 or EU Council Directive 89/437/EEC, in order to kill pathogenic agents;

9.4. have been prepared (derived) exclusively with the following animal by-products:

- eggs originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals;

9.5. have been subjected to processing:

either [in accordance with processing method ……[196] as set out in Annex V, Chapter III of Regulation (EC) No. 1774/2002/EC;]

or [in accordance to a method and parameters which ensure that the products comply with the microbiological standards set in Chapter1, paragraph 10 of Annex VII to Regulation (EC) No. 1774/2002/EC;]

or [treated in accordance with Chapter V of the Annex to Council Directive 89/437/EC;]

9.6. have been examined by the competent authority taking a random sample immediately prior to dispatch and found to comply with the following standards[197]:

Salmonella:	absence in 25g:	n=5, c=0, m=0, M=0
Enterobacteriaceae:		n=5, c=2, m=10, M=300 in 1 gram;

9.7. meet EC 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;

9.8. the end product was:

either (packed in new or sterilised bags;)

either (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;)

[196] Insert method 1 to 5 or 7 as applicable.

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

and which bear labels indicating **"NOT FOR HUMAN CONSUMPTION"**;

9.9. The end product was stored in enclosed storage;

9.10. The product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Official stamp and signature

Done at ……on ……
(place) *(date)*

……
(signature of official veterinarian)[198]

STAMP[199]

……

……
(name, qualifications and title IN CAPITAL LETTERS)

[198] The signature must be in a different colour to that of the printing.

[199] The stamp must be in different colour to that of the printing.

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 Community

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

I, the undersigned, declare that the following products[200]:

(a) bones and bone products excluding bone meal);

(b) horns and horn products (excluding bone meal);

(c) hooves and hoof products (excluding hoof meal);

are intended to be imported by me into the European Community, and I declare that these products will not be diverted at any stage for any use in food, feed material, organic fertilisers or soil improvers and will be conveyed directly to the following processing establishment:

Name: ……

Address: …….

The importer

Name: …….

Address:

……..

……..

Done at ……
(place)

on …….
(date)

Signature ……

Reference number as indicated on the certificate provided for in Annex B to EU Commission Decision 93/113/EEC:

……

……

Official Stamp of the border inspection post of entry into the EC[201]

Signature ……...
(Signature of the official veterinarian of the border inspection post)[202]

Name: ……
(Name in capital letters)

[200] Delete as appropriate.
[201] The stamp must be in a different colour to that of the printing.

[202] The signature must be in a different colour to that of the printing.

SCHEDULE XI

Lists of third countries from which Member States may authorise imports of animal by-products not intended for human consumption

The inclusion of a country on one of the following lists is a necessary, but not sufficient, condition for the importation of relevant products from that country.

Imports must also fulfill the relevant animal health and public health requirements.

PART I

List of third countries from which Member States may authorise imports of milk and milk-based products (health certificates Chapters 2(A), 2(B) and 2(C))

Third countries listed in column B or column C of the Annex to EU Commission Decision 95/340/EC (1).

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 EU Council Decision 79/542/EEC (2).

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 the Annex to EU Commission Decision 97/296/EC (3).

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 EU Council Decision 79/542/EEC.

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 countries listed in part 1 of Annex II to EU Decision 79/542/EEC, from which imports of all categories of fresh meat of the respective species are authorised.

B. Blood products from other species

Third countries listed in part 1 of Annex II to Council Decision 79/542/EEC.

PART VI

List of third countries from which Member States may authorise imports of raw material including blood products (with the exception of equidae) intended for technical purposes including pharmaceutical products (health certificate Chapters 4(C) and 8(B))

A. Blood products

1. Blood products from ungulates:

third countries or parts of third countries listed in part 1 of Annex II of EU Decision 79/542/EEC, from which imports of all categories of fresh meat of the respective species are authorised.

2. Blood products of other species:

third countries listed in part 1 of Annex II of EU Decision 79/542/EEC.

B. Raw material (except blood products) for pharmaceutical use Third countries listed in part 1 of Annex II of EU Decision 79/542/EEC, in the Annex to EU Commission Decision 94/85/EEC (1) or in Annex I to Commission EU Decision 2000/585/EC (2) and the following countries:

— (JP) Japan,

— (PH) Philippines and

— (TW) Taiwan.

C. Raw material for technical purposes other than pharmaceutical uses Third countries listed in part 1 of Annex II of EU Decision 79/542/EEC from which imports of that category of fresh meat of the respective species is authorised, in the Annex to EU Decision 94/85/EEC, or in the Annex to EU Decision 2000/585/EC.

PART VII (A)

List of third countries from which Member States may authorise imports of animal by-products for the manufacture of processed petfood (health certificate Chapter 3(B) and 8(A))

A. Animal by-products from bovine, ovine, caprine, porcine and equine animals, including farmed and wild animals third countries or parts of third countries listed in part 1 of Annex II to EU Decision 79/542/EEC,

from which imports of that category of fresh meat of the respective species is authorised and the following countries for the byproducts specified:

— animal by-products from Bulgaria (BG), Latvia (LV), Romania (RO), [(Slovenia (SI)], concerning material from pigs;

— southern American and southern African countries or parts thereof where matured and boned meat of the corresponding species is authorised, concerning matured and boned meat (including diaphragm) and/or matured trimmed offal of bovine, caprine, ovine animals and game (wild or farmed).

B. Raw material from poultry including ratites

Third countries or parts of third countries from which Member States authorise imports of fresh poultrymeat, which are listed in Annex I to EU Commission Decision 94/984/EC (3) and/or in Annex I to EU Commission Decision 2000/609/EC (4).
C. Raw material from fish

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

D. Raw material from other species, including feathered game, other wild land mammals and leparopidae

Third countries listed in Part 1 of Annex II to EU Decision 79/542/EEC or in the Annex I to EU Decision 2000/585/EC, from which Member States authorize 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 Community 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 Decision 79/542/EEC, in Annex I to Decision 94/984/EC, or in Annex I to Decision 2000/609/EC, 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 the Annex to Decision 97/296/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 Community (health certificate Chapter 3(E))

Third countries listed in part 1 of Annex II to Decision 79/542/EEC, in Annex I to Decision 94/984/EC, or in Annex I to Decision 2000/609/EC, 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 flavouring innards fish materials, third countries listed in the Annex to Commission Decision 97/296/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 Decision 79/542/EEC, which are free of African swine fever for the last 12 months.

B. For treated pig bristles, third countries listed in part 1 of Annex II to Decision 79/542/EEC, which may not be free of African swine fever for the last 12 months.

PART IX

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

A. Processed manure products

Third countries listed in part 1 of Annex II to EU Decision 79/542/EEC.

B. Processed manure from equidae

Third countries listed in Part 1 of Annex II to EU Decision 79/542/EEC for live equidae.
C. Unprocessed manure from poultry

Third countries listed in Annex I to EU Decision 94/984/EC.

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 Decision 79/542/EEC, and the following countries:

'(LK) Sri Lanka[203]

(JP) Japan[204]

(TW) Taiwan[205].'

[203] Dogchews made from hides and skins of ungulates only.
[204] Processed pet food for ornamental fish only.
[205] Processed pet food for ornamental fish only.

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 Decision 79/542/EEC, and the following countries:

'(KR) The Republic of Korea[206]

(MY) Malaysia[207]

(PK) Pakistan[208]

(TW) Taiwan[209].'

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 EU Decision 79/542/EEC.

PART XIII

List of third countries from which Member States may authorise imports of serum of equidae (health certificate Chapter 4(A))

Third countries or parts of third countries listed in Annex I to EU Commission Decision 2004/211/EC (3) (1), from which the importation of horses for slaughter is allowed.

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 EU Decision 79/542/EEC, from which Member States authorize imports of fresh meat from the same species.

[206] Gelatine only.
[207] Gelatine only.
[208] Gelatine only.
[209] Gelatine only.

B. For treated hides and skins of ungulates, third countries or parts of third countries listed in Part 1 of Annex II to EU Decision 79/542/EEC.

C. For treated hides and skins of ruminants that are intended for dispatch to the European Community and which have been kept separate for 21 days or will undergo transport for 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 the Annex to EU Commission Decision 94/85/EC, from which Member States authorise imports of fresh poultry meat, and the following countries:

'(GL) Greenland

(TN) Tunisia.'

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 Decision 79/542/EEC, 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 EU Decision 79/542/EEC, and third countries or parts of third countries from which Member States authorize imports of fresh poultry meat, which are listed in Annex I to EU Decision 94/984/ EC and/or in Annex I to EU Decision 2000/609/EC.

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.

INDUSTRIAL PROPERTY REGISTRATIONS DIRECTORATE

The patents indicated below have been granted with effect from the filing date in accordance with Article 24(2) of the Patents and Designs Act 2000:

(21) **PAT**/2221 (22) *Filing date:* 24 May 2004	(73) Pfizer Inc. (Incorporated in United States)
(54) 2-AMINO-PYRIDINE DERIVATIVES USEFUL FOR THE TREATMENT OF DISEASES	
(72) *Inventors*: Alan Daniel Brown Charlotte Alice Louise Lane Russell Andrew Lewthwaite	
Priorities: [(33) GB (31) 0312832.9 (32) 4 June 2003]	

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(21) **PAT**/2222 (22) *Filing date:* 24 May 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL COMPOUNDS	
(72) *Inventors*: Antonio Mete Barry Teobald	
Priorities: [(33) SE (31) 0301650.8 (32) 4 June 2003]	

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(21) **PAT**/2223 (22) *Filing date:* 26 May 2004	(73) Pfizer Inc. (Incorporated in United States)
(54) 2-AMINO-PYRIDINE DERIVATIVES USEFUL FOR THE TREATMENT OF DISEASES	
(72) *Inventors*: Alan Daniel Brown Justin Stephen Bryans Charlotte Alice Louise Lane Simon John Mantell	
Priorities: [(33) GB (31) 0312840.2 (32) 4 June2003] [(33) GB (31) 0312842.8 (32) 4 June 2003]	

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(21) **PAT**/2224 (22) *Filing date:* 26 May 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL COMPOUNDS	
(72) *Inventors*: Richard Evans Christine Eyssade Rhonan Ford Barrie Martin Toby Thompson Paul Willis	
Priorities: [(33) SE (31) 0312609.1 (32) 2 June 2003] [(33) GB (31) 0301700-1 (32) 10 June 2003]	

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(21) **PAT**/2226 (22) *Filing date:* 26 May 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL COMPOUNDS	
(72) *Inventors*: David Cheshire Nicholas Kindon Michael Stocks	
Priorities: [(33) SE (31) 0301654-0 (32) 5 June 2003]	

GODWIN WARR
18th January, 2005 Comptroller Of Industrial Property

INDUSTRIAL PROPERTY REGISTRATIONS DIRECTORATE

The patents indicated below have been granted with effect from the filing date in accordance with Article 24(2) of the Patents and Designs Act 2000:

(21) **PAT**/2262 (22) *Filing date:* 17 June 2004	(73) Galderma Research & Development, S.N.C. (Incorporated in France)
(54) NOVEL COMPOUNDS THAT MODULATE PPARY TYPE RECEPTORS, AND USE THEREOF IN COSMETIC OR PHARMACEUTICAL COMPOSITIONS	
(72) *Inventors*: Laurence Clary Etienne Thoreau Michel Rivier Jérôme Aubert Laurent Chantalat	
Priorities: [(33) FR (31) 0307487 (32) 20 June 2003]	

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(21) **PAT**/2263 (22) *Filing date:* 17 June 2004	(73) Janssen Pharmaceutical N.V. (Incorporated in Belgium)
(54) 4-(AMINOMETHYL)-PIPERIDINE BENZAMIDES AS $5HT_4$-ANTAGONISTS	
(72) *Inventors*: Bosmans Jean-Paul René Marie André Gijsen Henricus Jacobus Maria Mevellec Laurence Anne	
Priorities: [(33) EP (31) PCT/EPO3/50236 (32) 19 June 2003]	

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(21) **PAT**/2264 (22) *Filing date:* 21 June 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL IMIDAZOPYRIDINE COMPOUND III WITH THERAPEUTIC EFFECT	
(72) *Inventors*: Peter Nordberg	
Priorities: [(33) SE (31) 0301903-1 (32) 26 June2003]	

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(21) **PAT**/2265 (22) *Filing date:* 21 June 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL IMIDAZOPYRIDINE COMPOUND II WITH THERAPEUTIC EFFECT	
(72) *Inventors*: Peter Nordberg	
Priorities: [(33) SE (31) 0301904-9 (32) 26 June 2003]	

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(21) **PAT**/2266 (22) *Filing date:* 21 June 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL IMIDAZOPYRIDINE COMPOUND I WITH THERAPEUTIC EFFECT	
(72) *Inventors*: Peter Nordberg	
Priorities: [(33) SE (31) 0301905-6 (32) 26 June 2003]	

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(21) **PAT**/2267 (22) *Filing date:* 21 June 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL COMPOUNDS	
(72) *Inventors*: Maurice Raymond Verschoyle Finlay David Waterson	
Priorities: [(33) SE (31) 0301922-1 (32) 27 June 2003]	

GODWIN WARR
18th January, 2005 Comptroller Of Industrial Property

INDUSTRIAL PROPERTY REGISTRATIONS DIRECTORATE

The patents indicated below have been granted with effect from the filing date in accordance with Article 24(2) of the Patents and Designs Act 2000:

(21) **PAT**/2268 (22) *Filing date:* 22 June 2004	(73) Glaxo Group Limited (Incorporated in Great Britain)
(54) NOVEL COMPOSITIONS	
(72) *Inventors*: Liddle John	
Priorities: [(33) GB (31) 0314738.6 (32) 24 June 2003]	

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(21) **PAT**/2269 (22) *Filing date:* 22 June 2004	(73) Galderma Research & Development, S.N.C. (Incorporated in France)
(54) COMPOSITION IN THE FORM OF A SPRAY COMPRISING A PHARMACEUTICAL ACTIVE AGENT, AT LEAST ONE VOLATILE SILICONE AND A NONVOLATILE OILY PHASE	
(72) *Inventors*: Claire Mallard Franck Pitre Laurent Fredon	
Priorities: [(33) FR (31) 0307551 (32) 23 June 2003]	

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(21) **PAT**/2270 (22) *Filing date:* 24 June 2004	(73) Sanofi-Aventis (Incorporated in France)
(54) 4-CYANOPYRAZOLE-3-CARBOAXAMIDE DERIVATIVES, THEIR PREPARATION, THEIR THERAPEUTIC APPLICATION	
(72) *Inventors*: Barth Francis Martinez Serge Rinaldi-Carmona Congy Christian	
Priorities: [(33) FR (31) 0307698 (32) 25 June2003]	

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(21) **PAT**/2271 (22) *Filing date:* 24 June 2004	(73) Sanofi-Aventis (Incorporated in France)
(54) DIPHENYLPYRIDINE DERIVATIVES, PREPARATION THEREOF AND APPLICATION THEREFORE IN THERAPEUTICS	
(72) *Inventors*: Barth Francis Hortala Laurent Rinaldi-Carmona Murielle	
Priorities: [(33) FR (31) 0307757 (32) 26 June 2003]	

GODWIN WARR
18th January, 2005 Comptroller Of Industrial Property

INDUSTRIAL PROPERTY REGISTRATIONS DIRECTORATE

The patents indicated below have been granted with effect from the filing date in accordance with Article 24(2) of the Patents and Designs Act 2000:

(21) **PAT**/2227 (22) *Filing date:* 26 May 2004	(73) Astrazeneca UK Limited (Incorporated in United Kingdom)
(54) CHEMICAL PROCESS	
(72) *Inventors*: Jeffrey Norman Crabb John Horbury Nigel Philip Taylor	
Priorities: [(33) GB (31) 0312896.4 (32) 5 June 2003] [(33) GB (31) 0324793.9 (32) 24 Oct 2004]	

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(21) **PAT**/2228 (22) *Filing date:* 26 May 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL COMPOUNDS	
(72) *Inventors*: Richard Harrison Antonio Mete Barry Teobald Iain Walters	
Priorities: [(33) SE (31) 0301653-2 (32) 5 June 2003]	

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(21) **PAT**/2229 (22) *Filing date:* 26 May 2004	(73) Pfizer Products Inc. (Incorporated in United States)
(54) METHODS AND COMPOSITIONS FOR DIAGNOSING AND TREATING DISORDERS INVOLVING ANGIOGENESIS	
(72) *Inventors*: Jenny Hong Cai Xiao Tong	
Priorities: [(33) US (31) 60/476430 (32) 6 June2003]	

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(21) **PAT**/2232 (22) *Filing date:* 1 June 2004	(73) Pfizer Products Inc. (Incorporated in United States)
(54) BETA-LACTAMASE INHIBITOR PRODRUG	
(72) *Inventors*: Anthony Marfat Dale Gordon Mcleod John Paul O'Donnell	
Priorities: [(33) US (31) 60/476456 (32) 5 June 2003] [(33) US (31) 60/498422 (32) 27 Aug 2003]	

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(21) **PAT**/2233 (22) *Filing date:* 3 June 2004	(73) Bristol-Myers Squibb Company (Incorporated in United States)
(54) 1,1-DISUBSTITUTEDCYCLOALKYL-, GLYCINAMIDYL-, SULFONYL-AMIDINO-, AND TETRAHYDROPYRIMIDINYL-CONTAINING DIAMINOALKYL, ß-AMINOACIDS, α-AMINOACIDS AND DERIVATIVES THEREOF AS FACTOR XA INHIBITORS	
(72) *Inventors*: Donald J. Pinto Jennifer S. Qiao	
Priorities: [(33) US (31) 60/475731 (32) 4 June 2003]	

GODWIN WARR
18th January, 2005 Comptroller Of Industrial Property

INDUSTRIAL PROPERTY REGISTRATIONS DIRECTORATE

The patents indicated below have been granted with effect from the filing date in accordance with Article 24(2) of the Patents and Designs Act 2000:

(21) **PAT**/2234 (22) *Filing date:* 8 June 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) BENZIMIDAZOLE DERIVATIVES, COMPOSITIONS CONTAINING THEM, PREPARATION THEREOF AND USES THEREOF	
(72) *Inventors*: Ziping Liu Daniel Page Christopher Walpole Hua Yang	
Priorities: [(33) SE (31) 0301701-9 (32) 10 June 2003]	

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(21) **PAT**/2235 (22) *Filing date:* 8 June 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) NOVEL AZETIDINE COMPOUNDS	
(72) *Inventors*: Anders Johansson Joachim Persson	
Priorities: [(33) SE (31) 0301744-9 (32) 13 June 2003] [(33) SE (31) 0303493-1 (32) 19 Dec 2003]	

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(21) **PAT**/2236 (22) *Filing date:* 8 June 2004	(73) Astrazeneca AB (Incorporated in Sweden)
(54) BENZIMIDAZOLE DERIVATIVES, COMPOSITIONS CONTAINING THEM, PREPARATION THEREOF AND USES THEREOF	
(72) *Inventors*: Ziping Liu Daniel Page Christopher Walpole Hua Yang	
Priorities: [(33) SE (31) 0301699-5 (32) 10 June2003]	

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(21) **PAT**/2247 (22) *Filing date:* 11 June 2004	(73) Bristol-Myers Squibb Company (Incorporated in United States)
(54) N-UREIDOALKYL-PIPERIDINES AS MODULATORS OF CHEMOKINE RECEPTOR ACTIVITY	
(72) *Inventors*: George V. Delucca Soo S. Ko	
Priorities: [(33) US (31) 60/478022 (32) 12 June 2003]	

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(21) **PAT**/2249 (22) *Filing date:* 11June 2004	(73) Giesecke & Devrient GmbH (Incorporated in Germany)
(54) VALUE DOCUMENT HAVING A MACHINE-READABLE AUTHENTICITY MARK	
(72) *Inventors*: Dr. Gerhard Stenzel Dr. Wittich Kaule Dr. Gerhard Schwenk	
Priorities: [(33) DE (31) 103 26 983.5 (32) 12 June 2003]	

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18th January, 2005 Comptroller Of Industrial Property

INDUSTRIAL PROPERTY REGISTRATIONS DIRECTORATE

A request to a surrender of the trademark indicated below has been filed at this Office in accordance with Article 41 of the Trademarks Act 2000:

(210) **TM**/38768 (220) *Filing date:* 4 Apr 2003	(730) Nibe Beverages Limited (Incorporated in Malta)
(540) REPRODUCTION OF THE MARK 	
(511) *Goods/Services:* Table water, mineral water, sparkling water, fizzy water, non-alcoholic beverage, beer, fruit juice, fruit drink syrup.	

Interested parties may appeal from this decision before the Court of Appeal in terms of Rule 21 of the Trademarks Rules 2000.

(210) **TM**/39083 (220) *Filing date:* 5 May 2003	(730) Taste of Russia Limited (Incorporated in England)
(540) REPRODUCTION OF THE MARK **SPUTNIK**	
(511) *Goods/Services:* Beers; low alcohol beers; non-alcoholic beers	

Interested parties may appeal from this decision before the Court of Appeal in terms of Rule 21 of the Trademarks Rules 2000.

(210) **TM**/37949 (220) *Filing date:* 15 Jan 2003	(730) General Re Corporation (Incorporated in United States)
(540) REPRODUCTION OF THE MARK 	
(511) *Goods/Services:* Reinsurance services, namely, underwriting and brokerage of all types of reinsurance, risk management services, claims services, actuarial science services and consultation services; financial analysis services; investment advice, analysis and management services; securities brokerage services.	

Interested parties may appeal from this decision before the Court of Appeal in terms of Rule 21 of the Trademarks Rules 2000.

GODWIN WARR
Comptroller Of Industrial Property

18th January, 2005

DIPARTIMENT TA' L-INFORMAZZJONI – 3, PJAZZA KASTILJA – VALLETTA – MALTA
DEPARTMENT OF INFORMATION – 3, CASTILLE PLACE – VALLETTA – MALTA

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