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EUROPEAN COMMISSION

Brussels, 26.04.2010

Draft

COMMISSION REGULATION (EU) No …/..

of […]

implementing Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002

(Text with EEA relevance)

(Memorandum from Mr Dalli)

Draft

COMMISSION REGULATION (EU) No …/..

of […]

implementing Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)[1], and in particular Articles 11(b) and (c), 15(1)(b), (c) and (h), 17(1), (3)(b), 19(4)(a) and (b), 20(10), 21(5), (6)(a), (b), (c) and (d), 22(3), points (a), (b), (c), (e), (f) and (g) of the first subparagraph of Article 27, and Articles 31(2), 32(3), 34(2), 40, 41(3), 42, 43 (3), 45(4) and 48(7)(a) thereof,

Whereas:

(1) The Animal By-products Regulation lays down animal and public health rules for animal by-products and products derived thereof. That Regulation determines the circumstances when animal by-products should be disposed of, in order to prevent the spreading of risks for public and animal health. Furthermore, that Regulation specifies under which conditions animal by-products may be used for applications in animal feed and for various purposes, such as in cosmetics, medicinal products and technical applications. That Regulation also obliges operators to handle animal by-products within establishments and plants which are subject to official controls.

(2) Under the Animal By-products Regulation, the detailed rules for the handling of animal by-products and derived products, such as processing standards, hygiene conditions and the format for documentary evidence which has to accompany consignments of animal by-products for the purposes of traceability should be adopted by means of implementing measures.

(3) The Animal By-products Regulation does not apply to entire bodies of wild animals, which are not suspected of being infected or affected with a disease communicable to humans or animals, except for aquatic animals landed for commercial purposes.

[1] OJ L 300, 14.11.2009, p.1.

Furthermore, it does not apply to entire bodies or parts of wild game which are not collected after killing, in accordance with good hunting practice. Regarding those animal by-products from hunting, disposal should be carried out in a way which prevents the transmission of risks, as appropriate for specific hunting practices which have been described by the hunting profession.

(4) The Animal By-products Regulation applies to catering waste if it originates from means of transport operating internationally, such as materials derived from foodstuffs served on board an airplane or a ship arriving in the European Union from a third country destination. Catering waste is furthermore within the scope of that Regulation, if it is destined for feeding purposes, for processing in accordance with one of the authorised processing methods under this Regulation or for transformation into biogas or for composting. The Animal By-products Regulation prohibits the feeding of catering waste to farmed animals, other than fur animals. Therefore, catering waste may be processed and subsequently used, provided that the derived product is not fed to such animals.

(5) Products of animal origin or foodstuffs containing such products, and petfood and feedingstuffs containing animal by-products or derived products, should only be disposed of in a landfill, in accordance with environmental legislation, provided that they have been processed as defined in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[2], in order to mitigate potential health risks.

(6) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[3] obliges Member States to carry out monitoring programmes for transmissible spongiform encephalopathies (TSE). Animals which are used for feeding to certain species, for the purposes of promotion of bio-diversity, should be included in those monitoring programmes to the extent necessary to ensure that those programmes provide sufficient information regarding the prevalence of TSE in a particular Member States.

(7) The Animal By-products Regulation allows the feeding of certain Category 1 material to certain animal species in Member States, for the promotion of biodiversity. Such feeding should be authorised for certain carnivore species referred to in Council Directive 92/43/EC on the conservation of natural habitats and of wild fauna and flora[4] and for certain species of birds of prey referred to in Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds[5].

(8) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[6] specifies certain parameters for the treatment of rendered fats and egg products which provide an adequate control of possible health risks, when such products are used for purposes

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2 OJ L 139, 30.4.2004, p.1.
3 OJ L 147, 31.5.2001, p.1.
4 OJ L 206, 22.7.1992, p.7.
5 OJ L 20, 26.1.2010, p.7.
6 OJ L 226, 25.6.2004, p.22.

other than human consumption. Those parameters should therefore be authorised as alternatives to the treatments for animal by-products which are set out in this Regulation.

(9) The reference to Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs[7] should be updated.

(10) Certain imported materials for the production of petfood should be handled and used under conditions which are appropriate to the risk which such materials may pose. In particular, provision should be made for their safe channelling to establishments of destination where such materials, as well as Category 3 material, are incorporated into petfood. With respect to the plants of destination, the competent authority should be authorised to allow the storage of imported materials together with Category 3 material, provided the imported materials can be traced.

(11) Under the Animal By-products Regulation, certain derived products may be placed on the market in accordance with certain other Union legislation. That legislation also determines the import, collection and movement of animal by-products and derived products for the manufacture of such derived products. However, the Animal By-products Regulation shall apply where that other Union legislation does not provide for conditions providing potential health risks which may arise from such raw materials. Since such conditions have not been laid down regarding materials which have undergone certain stages of processing prior to their fulfilling the conditions for placing on the market under that other Union legislation, they should be laid down in this Regulation. In particular, the conditions for the import and handling of such materials inside the Union under strict control and documentation requirements should be laid down, so as to prevent the transmission of potential health risks from such materials.

(12) In particular, adequate health conditions should be laid down for materials which are used for the manufacture of medicinal products, veterinary medicinal products, medical devices, in vitro diagnostics or laboratory reagents ("the finished products"). If risks arising from such materials are mitigated due to the purification, concentration or due to the conditions under which such materials are handled and disposed of, only the requirements of the Animal By-products Regulation and of this Regulation in relation to traceability should apply. In such case, the requirements related to the separation of animal by-products of different categories within the establishment or plant producing the finished products should not apply, since the subsequent use of materials for other purposes, in particular their diversion into food or feed can be excluded by the proper application of the rules by the operator, under the responsibility of the competent authority.

(13) Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements[8] should be referred to in this Regulation, insofar as those third countries

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7 OJ L 343, 22.12.2009, p.74.

8 OJ L 73, 20.3.2010, p.1.

and other territories should be authorised for the importation of certain animal by-products or derived products.

(14) It is therefore necessary to lay down measures for the implementation of the Animal By-products Regulation by way of this Regulation.

(15) The Animal By-products Regulation repeals Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[9] with effect from 4 March 2011.

(16) For the implementation of Regulation (EC) No 1774/2002, the Commission has adopted Regulation (EC) No 811/2003 on the intra-species recycling ban for fish, and the burial and burning of certain animal by-products[10], Decision 2003/322/EC on the feeding of certain necrophagous birds with certain Category 1 materials[11], Decision 2003/324/EC on a derogation from the intra-species recycling ban for fur animals[12], which was adapted due to the accession of Estonia by Decision 2004/434/EC[13], Regulation (EC) No 79/2005 on milk and milk-based products[14], Regulation (EC) No 92/2005 on means of disposal or uses[15], Regulation (EC) No 181/2006 on organic fertilisers and soil improvers other than manure[16], Regulation (EC) No 1192/2006 on lists of approved plants[17] and Regulation (EC) No 2007/2006 on the importation and transit of certain Category 3 intermediate products[18]. The Commission has furthermore adopted certain transitional measures, in particular Regulation (EC) No 878/2004 on the import and handling of certain Category 1 and Category 2 materials[19], Decision 2004/407/EC on the import of certain materials for the production of photogelatine[20] and Regulation (EC) No 197/2006 on handling and disposal of former foodstuffs[21], to lay down risk-proportionate measures for certain specific uses of animal by-products, before the revision of Regulation (EC) No 1774/2002 was initiated.

(17) With the objective to further simplify the Union rules for animal by-products, as requested by the Presidency of the Council at the time of the adoption of the Animal By-products Regulation, the provisions laid down in those Commission measures should therefore be reviewed, as necessary, and they should be incorporated into this Regulation, so as to constitute a coherent legal framework. Furthermore, in order to improve clarity of Union law, the Commission measures for the implementation of Regulation (EC) No 1774/2002 and the transitional measures referred to above should be repealed with effect from entry into application of this Regulation.

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9 OJ L 273, 10.10.2002, p.1.
10 OJ L117, 13.5.2003, p.14.
11 OJ L 117, 13.5.2003, p.32.
12 OJ L 117, 13.5.2003, p.37.
13 OJ L 189, 27.5.2004, p. 43.
14 OJ L 16, 20.1.2005, p.46.
15 OJ L 19, 21.1.2005, p.27.
16 OJ L 29, 2.2.2006, p.31.
17 OJ L 215, 5.8.2006, p.10.
18 OJ L 379, 28.12.2006, p. 98.
19 OJ L 162, 30.4.2004, p.62.
20 OJ L 208, 10.6.2004, p.9.
21 OJ L 32, 4.2.2006, p.13.

(18) A transitional period should be provided for, following the entry into application of this Regulation, in order to allow stakeholders to adjust to the new rules, to place on the market certain products which have been produced in accordance with the Union health rules applicable before the date of entry into application of this Regulation, and to allow for a continuation of imports when the requirements of this Regulation become applicable.

(19) In accordance with the request expressed by the European Parliament at the time of its agreement to the Animal By-products Regulation at first reading, and taking into account the Parliament's more specific suggestions for addressing certain technical issues, a draft of this Regulation has been presented on […] to its Committee for the Environment, Public Health and Food Safety for an exchange of views.

(20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1
Requirements regarding feeding of fur animals and feeding of farmed animals with herbage

Requirements regarding the conditions for feeding of fur animals with processed animal protein derived from bodies or parts of animals of the same species and conditions for the feeding of farmed animals with herbage from land to which organic fertilisers or soil improvers have been applied, as referred to in Article 11(b) and (c) of the Animal By-products Regulation, are set out in Annex IV to this Regulation.

Article 2
Requirements regarding incineration and co-incineration

Requirements regarding the conditions for the incineration and the co-incineration of animal by-products, as referred to in Article 15(1)(c) of the Animal By-products Regulation, are set out in Annex V to this Regulation.

Article 3
Requirements regarding processing methods and the obligations of operators processing animal by-products

Requirements regarding processing methods for animal by-products, as referred to in Article 15(1)(b) of the Animal By-products Regulation and requirements regarding certain obligations of operators of establishments or plants that are processing animal by-products, as referred to in points (a), (b), (c), (e) and (f) of the first subparagraph of Article 27 of the same Regulation are set out in Annex VI to this Regulation.

Article 4

Requirements regarding transformation of animal by-products into biogas and composting

Requirements regarding the standard transformation parameters for biogas and composting plants, as referred to in point (g) of the first subparagraph of Article 27 of the Animal By-products Regulation, and requirements regarding the hygiene requirements applicable to the handling of animal by-products in establishments or plants that are composting or transforming animal by-products into biogas, as referred to in point (b) of the same subparagraph, are set out in Annex VII to this Regulation.

Article 5

Requirements regarding the use of animal by-products for research, other specific purposes and special feeding purposes and requirements regarding the collection, transport and disposal

Requirements regarding the health conditions for the use of animal by-products for research and other specific purposes, as referred to in Article 17(1) of the Animal By-products Regulation, requirements regarding the conditions under which the use of Category 1 material for special feeding purposes may be authorised, as referred to in Article 17(3)(b) of the same Regulation, and requirements regarding conditions for the burial and burning of animal by-products on site and concerning the maximum percentage of animals in remote areas in a Member State, as referred to in Article 19(4)(a) and (b) of the same Regulation are set out in Annex VIII to this Regulation.

Article 6

Standard format for applications for alternative methods

A standard format for applications for applications for alternative methods as referred to in Article 20(10) of the Animal By-products Regulation is set out in Annex IX to this Regulation.

Article 7

Requirements regarding commercial documents and health certificates, identification, the collection and transport of animal by-products and traceability

Requirements regarding models for commercial documents and regarding health certificates, as referred to in Article 21(5) and (6)(a) of the Animal By-products Regulation, regarding cases where animal by-products or derived products may be transported without documents or certificates, as referred to in point (6)(b) of the same Article, regarding identification, as referred to in point (6)(c) of the same Article, regarding collection and transport, as referred in point (6)(d) of the same Article, regarding traceability, as referred to in Article 22(3) of the same Regulation, and regarding permanent marking, as referred to in Article 15(1)(h) of the same Regulation, are set out in Annex X to this Regulation.

Article 8

Requirements regarding establishments and plants handling animal by-products

Requirements regarding establishments and plants that are handling animal by-products, as referred to in points (a), (b) and (c) of the first subparagraph of Article 27 of the Animal By-products Regulation, are set out in Annex XI to this Regulation.

Article 9'

Requirements regarding the placing on the market for feeding to farmed animals

Requirements regarding the public and animal health conditions for the placing on the market of animal by-products and derived products for feeding to farmed animals, as referred to in Article 31(2) of the Animal By-products Regulation, are set out in Annex XIII to this Regulation.

Article 10'

Requirements regarding the placing on the market and use of organic fertilisers

Requirements regarding the placing on the market of organic fertilisers and the use, in particular the application of such fertilisers to land, as referred to in Article 32(3) of the Animal By-products Regulation, are set out in Annex XIV to this Regulation.

Article 11

Requirements regarding the manufacture of derived products regulated by certain other legislation

Requirements regarding the manufacture of derived products regulated by certain other legislation, in particular as regards their import and movement inside the European Union, as referred to in Articles 21 points (5)(a), (6)(c) and (6)(d) and 41(3), in conjunction with Article 34(2) of the Animal By-products Regulation, are set out in Annex XV to this Regulation.

Article 12'

Requirements regarding the placing on the market of petfood and of other derived products

Requirements regarding the placing on the market of petfood and of other derived products, as referred to in Article 40 of the Animal By-products Regulation, are set out in Annex XVI to this Regulation.

Article 13'

Requirements regarding the import, export and transit of animal by-products and of derived products

Requirements regarding the import, export and transit of animal by-products and of derived products, as referred to in Articles 41(3), 42 and 43(3) of the Animal By-products Regulation, are set out in Annex XVII to this Regulation.

Article 14'
Requirements regarding models for health certificates, commercial documents and declarations

Requirements regarding models for health certificates, commercial documents and declarations, as referred to in Article 42(2)(d) of the Animal By-products Regulation, are set out in Annex XVIII to this Regulation.

Article 15'
Requirements regarding official controls

Requirements regarding detailed arrangements for official controls, as referred to in Articles 45(4) and 48(7)(a) of the Animal By-products Regulation, are set out in Annex XIX to this Regulation.

Article 16
Negative harmonisation

The placing on the market of the animal by-products and the derived products referred to in Annex XIII, Section I of Annex XIV and Annex XVI and the import of the animal by-products and the derived products referred to in Annex XVII shall not be prohibited or restricted for public health or animal health reasons other than those laid down in the Animal By-products Regulation, in this Regulation or in other Union legislation.

Article 17
Repeal

1. The following legal acts shall be repealed with effect from the entry into application of this Regulation:

   (a) Regulation (EC) No 811/2003;

   (b) Decision 2003/322/EC;

   (c) Decision 2003/324/EC;

   (d) Decision 2004/434/EC;

   (e) Regulation (EC) No 878/2004;

   (f) Decision 2004/407/EC;

   (g) Regulation (EC) No 79/2005;

   (h) Regulation (EC) No 92/2005;

   (i) Regulation (EC) No 181/2006;

   (j) Regulation (EC) No 197/2006;

(k) Regulation (EC) No 1192/2006;

(l) Regulation (EC) No 2007/2006.

2. References to those legal acts shall be construed from that date as references to this Regulation.

Article 18
Transitional measures

1. For a transitional period until 31 August 2011 and by way of derogation from Article 10, operators may place on the market organic fertilisers and soil improvers which have been produced from meat and bone meal derived from Category 2 material or from processed animal protein, and which have not been mixed with a component to exclude the subsequent use of the mixture for feeding purposes, provided that those organic fertilisers and soil improvers have been produced in accordance with Regulations (EC) No 1774/2002 and (EC) No 181/2006 before the date of entry into application of this Regulation.

2. For a transitional period until 31 August 2011, Member States shall accept consignments of animal by-products and of derived products which are accompanied by a health certificate completed and signed in accordance with the appropriate model certificates, as set out in Annex X to Regulation (EC) No 1774/2002 before the date of entry into application of this Regulation.

   Until 30 September 2011, Member States shall accept such consignments if the accompanying health certificates were completed and signed before 31 August 2011.

Article 19

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

This Regulation shall apply from 4 March 2011.

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

Done at Brussels, […]

For the Commission
José Manuel BARROSO
President of the Commission

Content

ANNEX I

DEFINITIONS

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

1. "**apiculture by-products**" means honey, beeswax, royal jelly, propolis or pollen;

2. '**batch**' means a unit of production produced in a single plant using uniform production parameters, *such as the origin of the materials,* or a number of such units, when *produced in continuous order in a single plant and* stored together;

3. '**biogas plant'** means a plant in which materials of animal origin are at least part of the material which is submitted to biological degradation under anaerobic conditions for the production of biogas;

4. '**blood**' means fresh whole blood;

5. "**blood meal"** means *processed animal protein* derived from the heat treatment of blood or fractions of blood in accordance with Chapter I of Section II of Annex XIII;

6. '**blood products'** means derived products 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;

7. '**canned petfood'** means heat-processed petfood contained within a hermetically sealed container;

8. '**catering waste'** means all waste food *of animal origin*, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens;

9. '**co-incineration'** means the recovery or disposal of animal by-products or derived products, if they are waste, in a co-incineration plant;

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

11. '**collection centres'** means premises other than processing plants in which certain animal by-products are collected and treated *with the intention* to be used for feeding as referred to in Article 18(1) of the Animal By-products Regulation;

12. '**colour-coding**' means the systematic use of colours as defined in paragraph 1(c) of Section II of Annex X for displaying information as provided for in this Regulation on the surface or of the part of the surface of a packaging, container or vehicle, or on the a label or symbol applied to them;

13. '**combustion**' means a process involving the oxidisation of fuel in order to use the *energetic value of the animal by-products;*

14. ‘**composting plant’** means a plant in which materials of animal origin are at least part of the material which is submitted to biological degradation under aerobic conditions for the production of compost;

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

16. ‘**digestive tract content’** means the content of the digestive tract of mammals and ratites;

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

18. ‘**feed material’** means those feed materials, as defined in Article 3(2)(g) of Regulation (EC) No 767/2009, that are of animal origin, including processed animal proteins, blood products, rendered fats, fish oil, fat derivatives, gelatine and hydrolysed proteins, dicalcium phosphate, milk, milk-based products and colostrum;

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

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

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

22. ‘**gelatine**’ 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);

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

24. **'guano'** means *a natural product which has been collected from the excrements of bats or wild sea birds;*

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

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

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

28. ‘**intermediate product’** means a derived product which is intended for the manufacture of medicinal products, veterinary medicinal products, medical devices, *active implantable medical device,* in vitro diagnostic *medical device* or laboratory reagents; and whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as derived products and to qualify the material for that purpose, except for the fact that it requires some further handling or transformation such as mixing, coating, assembling, packaging or labelling to make

it suitable for placing on the market as medicinal products, veterinary medicinal products, medical devices or in vitro diagnostics;

29. ‘**laboratory reagent’** means a packaged product, ready for use, containing animal by-products or derived products and intended as such or in combination for specific laboratory use as a reagent or reagent product, calibrator or control material to detect, measure, examine or produce other substances;

30. ‘**petfood**’ means feed for pet animals containing certain Category 1 material and/ or Category 3 material, as referred to in Article 35 point a of the Animal By-products Regulation;

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

32. ‘**processed petfood’** means petfood, other than raw petfood, which has been produced in accordance with this Regulation;

33. ‘**processing methods’** means the methods listed in Sections III and IV of Annex VI;

34. ‘**processing plant’** *means premises or facilities for the processing of animal by-products as referred to in Article 24(1)(a) of the Animal By-products Regulation;*

35. ‘**product used for in vitro diagnosis’** means a packaged product, ready for use by the final user, containing a blood product *or another animal by-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;

36. ‘**raw petfood’** means petfood which has not undergone any preserving process other than chilling, freezing or quick freezing;

37. ‘**rendered fats’** means fats derived from processing of animal by-products *or fats derived from the processing of products for human consumption which have been destined for purposes other than human consumption in accordance with Article 2(1)(a) of the Animal By-products Regulation;*;

38. “**incineration and co-incineration residues**” means any liquid or solid material generated by the incineration or co-incineration process *of animal by-products*, the waste-water treatment or other processes within the incineration or co-incineration plant*., provided that those processes are subject to this Regulation; t*hey include bottom ash and slag, fly ash and boiler dust;

39. ‘**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;

40. '**trade**' means trade in goods between Member States within the meaning of Article 28 of the Treaty on the Functioning of the European Union;

41. ‘**treated hides and skins**’ means hides and skins, *other than dogchews*, that have been:

(a) dried;

(b) dry-salted or wet-salted for at least 14 days prior to dispatch;

(c) salted for seven days in sea salt with the addition of 2 % of sodium carbonate;

(d) dried for 42 days at a temperature of at least 20° C; or

(e) preserved by a process other than tanning;

42. ‘**untreated 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;

43. ‘**untreated wool’** means wool that has not undergone factory washing, been obtained from tanning, or been treated by some other method that ensures that no pathogens remain;

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

45. ‘**untreated 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

46. **'white water"** means a mixture of milk, *milk-based products or products derived from milk with* water which is collected during the rinsing of dairy equipment prior to its cleaning and disinfection.

II. The definitions set out in Article 3 of the Animal By-products Regulation shall also apply.

ANNEX II

END POINT IN THE MANUFACTURING CHAIN

CHAPTER I

End point for the derived products referred to in Article 5(1) of the Animal By-products Regulation

[…]

CHAPTER II

End point for the derived products referred to in Article 5(2) of the Animal By-products Regulation

1. For the derived products referred to in Article 5(2) of the Animal By-products Regulation which are listed in the following table in column 1, an end point in the manufacturing chain is determined, subject to the conditions listed in column 2 of the table:

No.	Derived product	Conditions
1	Biodiesel	Annex VI, Section IV, Chapter III, point 2(b)(i)
2	Processed petfood and dogchews	Annex XVI, Chapter II, point 6
3	Hides and skins of ungulates	Annex XVI, Chapter V, point C
4	Game trophies and other preparations from animals	Annex XVI, Chapter V
5	Wool	Annex XVI, Chapter VII,

		point B
6	Feathers	Annex …
7	Rendered fats for oleochemical purposes	Annex …
8		

ANNEX III

ANIMAL HEALTH RESTRICTIONS

CHAPTER I

Serious transmissible diseases as referred to in Article 6(1)(b)(ii) of the Animal By-products Regulation

[…]

CHAPTER II

Conditions for the dispatch of animal by-products as referred to in Article 6(2) of the Animal By-products Regulation

[…]

ANNEX IV

RESTRICTIONS ON THE USE OF ANIMAL BY-PRODUCTS

CHAPTER I

Checks and controls regarding certain prohibitions as referred to in Article 11(2)(a) of the Animal By-products Regulation

[…]

CHAPTER II

Intra-species recycling of fur animals

1. In Estonia, Finland and Latvia, the following fur animals may be fed with meat-and-bone meal *or other products which have been processed in accordance with Section III of Annex VI and which are* derived from bodies or parts of bodies of animals of the same species:

   (a) foxes (*vulpes vulpes*);

   (b) raccoon dogs (*Nycteroites procynides*).

2. In Estonia and Latvia, fur animals of the species American mink (*Mustela vison*) may be fed with meat and bone meal *or other products which have been processed in accordance with Section III of Annex VI and which are* derived from bodies or parts of bodies of animals of the same species.

3. The feeding referred to in points 1 and 2 shall take place under the following conditions:

   (a) Feeding shall only take place in farms which have been authorised and registered by the competent authority:

      (i) on the basis of an application that is accompanied by documentation proving that there is no reason to suspect the presence of the TSE agent in the population of the species covered by the application;

      (ii) where an appropriate surveillance system for TSEs in fur animals is in place and includes regular laboratory testing of samples for TSE;

      (iii) provided the farm supplies appropriate guarantees that no animal by-product or meat-and-bone meal derived from those animals or their offspring may enter the food or feed chain of other animals than fur animals;

(iv) where the farm has had no known contact with any farm with a suspected or confirmed outbreak of TSE;

(v) where the *operator* of the registered farm ensures that

- the carcases of fur animals intended for feeding to animals of the same species are handled and processed separately from carcases not authorised for that purpose;

- fur animals fed with *meat and bone meal or other products which have been processed in accordance with Section III of Annex VI and which are* derived from animals of the same species are kept separate from animals not being fed with *products* derived from animals of the same species.

- the registered farm complies with the requirements set out in Chapter I of Section II to Annex VIII and point (2)(b)(ix) of Section II of Annex X.

(b) The *operator of the farm* shall ensure that meat-and-bone meal *or other products* derived from one species and intended for the feeding of the same species must:

(i) have been processed in a processing plant approved under Article 24(1)(a) of the Animal By-products Regulation and using only methods 1 to 5 or 7 as set out in Section III of Annex VI to this Regulation;

(ii) have been produced from healthy animals killed for the production of fur.

(c) In the event of any known or suspected contact with any farm with a suspected or confirmed outbreak of TSE, the *operator of the farm* must immediately:

(i) inform the competent authority of such contact; and

(ii) cease the dispatch of fur animals to any destination without a written authorisation of the competent authority.

CHAPTER III

Feeding of farmed animals with herbage

Farmed animals may be fed with herbage from land to which organic fertilisers or soil improvers, other than manure, non-mineralised guano and digestive tract content, *or milk, milk-based products and colostrum which the competent authority does not consider to present a risk for the spread of any serious animal disease,* have been applied, either by direct access of the animals to that land or by using cut herbage as feed, provided that

(a) the waiting period referred to in Article 11(1)(c) of the Animal By-products Regulation has been observed; and

(b) only organic fertilisers and soil improvers have been used which comply with Article 32 of the Animal By-products Regulation and Section II of Annex XIV to this Regulation.

ANNEX V

DISPOSAL *AND RECOVERY*

SECTION I

***GENERAL REQUIREMENTS FOR* INCINERATION AND CO-INCINERATION**

Incineration and co-incineration shall take place in plants which have a permit to operate in accordance with Directive 2000/76/EC or in plants which have been approved in accordance with Article 24(1)(b) *or* (c) of the Animal By-products Regulation, as applicable. Plants *which do not have a permit to operate in accordance with Directive 2000/76/EC* shall be approved in accordance with that Article, if they fulfil the conditions laid down in this Section.

CHAPTER I

General conditions

1. Operators of incineration and co-incineration plants shall ensure that their plants meet the following hygiene conditions:

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

   (b) *Plants shall have appropriate arrangements for the cleaning and disinfection of containers and vehicles in place, in particular in a designated area from which waste water is disposed of in accordance with Union legislation, to avoid risks of contamination.*

   (c) *Plants shall be located on a well-drained hard standing.*

   (d) *Plants shall have appropriate arrangements for protection against pests, such as insects, rodents and* birds. A documented pest control programme shall be used for that purpose.

   (e) *Plants shall have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins for staff, if necessary to prevent risks of contamination.*

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

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

2. The operator of an incineration or co-incineration plant shall 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.

3. *Animals* must not have access to the low-capacity plants, animal by-products that are awaiting incineration or co-incineration or ash resulting from the incineration or co-incineration of animal by-products.

4. If the *incineration or co-incineration* plant is located on a livestock holding:

   (a) there must be total physical separation between the incineration or co-incineration equipment 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 or, *alternatively,* cleaned and disinfected before such use.

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

5. The storage of animal by-products and of ashes must be *in* covered, labelled and leak proof *containers*.

6. 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 *in an authorised* landfill or in accordance with relevant Union legislation.

7. Incompletely incinerated animal by-products must be re-incinerated *or disposed of by other means, other than by disposal in an authorised landfill,* in accordance with the Animal By-products Regulation.

CHAPTER II

Operating conditions

Incineration or co-incineration plants shall 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^{o} C for at least 2 seconds *or to a temperature of 1100°C for 0.2 seconds,* as measured near the inner wall or at another representative point of the combustion chamber as authorised by the competent authority.

CHAPTER III

Incineration and co-incineration residues

1. Incineration and co-incineration residues resulting from the operation of the incineration or co-incineration plant shall be minimised in their amount and

harmfulness. *Such* residues must be *disposed of in an authorised landfill, or* recycled, where appropriate, directly in the plant or outside in accordance with relevant Union legislation.

2. Transport and intermediate storage of dry residues in*cluding* dust shall take place in such a way as to prevent dispersal in the environment, such as in closed containers.

CHAPTER IV

Temperature measurement

1. Techniques shall 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.

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

3. The functioning of any automated monitoring equipment shall be subject to control and to an annual surveillance test. Calibration shall be carried out by means of parallel measurements with the reference methods at *regular intervals*.

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

CHAPTER VI

Abnormal operating

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

SECTION II

HIGH-CAPACITY PLANTS

CHAPTER I

Specific operating conditions

Incineration or co-incineration plants with a throughput of more than 50 kg per hour (high-capacity plants) which do not have a permit to operate in accordance with Directive 2000/76/EC shall comply with the following conditions:

(a) The plants shall be quipped for each line with at least one auxiliary burner. This burner shall be switched on automatically when the temperature of the combustion gases after the last injection of combustion air falls below 850° C. It shall also be used during plant start-up and shut-down operations to ensure that the temperature of 850° C is maintained at all times during these operations and as long as unburned material is in the combustion chamber.

(b) When animal by-products are introduced into the combustion chamber by a continuous process, the plants shall operate an automatic system to prevent the introduction of animal by-products at start-up, until the temperature of 850° C has been reached, and whenever the temperature of 850° C is not maintained.

CHAPTER II

Water discharges

1. Sites of high capacity plants, including associated storage areas for animal by-products, shall 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 Union legislation.

2. Storage capacity shall be provided for contaminated rainwater run-off from the plant site or for contaminated water arising from spillage or fire-fighting operations. The *operator shall, if necessary,* ensure that *such rainwater and such* water can be tested and treated before discharge where necessary.

SECTION III

LOW-CAPACITY PLANTS

Incineration and co-incineration plants with a throughput of less than 50 kg of animal by-products per hour (low-capacity plants) which do not have a permit to operate in accordance with Directive 2000/76/EC shall

(a) only be used for the disposal of animal by-products as referred to in Article 8(b)(i) of the Animal By-products Regulation;

(b) be equipped with an *auxiliary* burner.

SECTION IV

LANDFILLING OF *CERTAIN MATERIALS*

By way of derogation from Article 14 point (c) of the Animal By-products Regulation, the competent authority may authorise the disposal of Category 3 materials referred to in Article 10(f) and (g) of the Animal By-products Regulation in an authorised landfill, in accordance with Article 5 of Directive 1999/31/EC, provided that:

1. such materials have not been in contact with any animal by-product referred to in Articles 8, 9 and 10(a) to (e) and (h) to (p) of the Animal By-products Regulation;

2. at the time when they are destined for purposes other than human consumption, materials

   (a) *referred to in Article 10 (f) of the Animal By-products Regulation* have undergone *processing as defined in Article 2(1)(m) of* Regulation (EC) No *852*/2004; and

   (b) *referred to in Article 10 (g) of the Animal By-products Regulation have been processed in accordance with this Regulation; and*

3. the disposal of such materials does not pose a risk to public or animal health.

ANNEX VI

PROCESSING

SECTION I

REQUIREMENTS FOR PROCESSING PLANTS AND CERTAIN OTHER PLANTS AND ESTABLISHMENTS

CHAPTER I

General conditions

1. Processing plants must meet the following requirements, for processing by pressure sterilisation or in accordance with the methods referred to in Article 15(1)(b) of the Animal By-products Regulation:

   (a) Processing plants shall not be situated on the same site as slaughterhouses or other establishments which have been approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004, unless the risks to public and animal health, resulting from the processing of animal by-products which originate from such slaughterhouses or other establishments, are mitigated by compliance with at least the following conditions:

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

      (ii) the following must be installed and operated:

         — a conveyer system which links the processing plant to the slaughterhouse or other establishment and which may not be by-passed,

         — separate entrances, reception bays, equipment and exits for *both* the processing plant and the slaughterhouse or establishment;

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

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

   By way of derogation from points (i) to (iv), in the case of Category 3 processing plants, the competent authority may authorise other conditions instead of those set out in those points, aimed at mitigating the risks to public and animal health, including the risks arising from the processing of Category

3 material, which originates from off-site establishments approved under Regulation (EC) No 853/2004.

Member States shall inform the Commission and the other Member States in the framework of the Committee referred to in Article 52(1) of the Animal By-products Regulation of the use made of this derogation by their competent authorities;

(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;

(c) The processing plant must have adequate facilities including lavatories, changing rooms and washbasins for staff;

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

(e) 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;

(f) where heat treatment is required, all installations must be equipped with:

(i) measuring equipment to monitor temperature against time and, if applicable for the processing method used, pressure at critical points;

(ii) recording devices to record continuously the results of these measurements in a way so that they remain accessible for the purpose of checks and official controls; and

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

(g) to prevent recontamination of the *derived* product by *the introduction of* 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 derived 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 and the other parts of the vehicle, as appropriate, on leaving the unclean sector of the processing plant.

4. All processing plants must have a waste-water disposal system meeting the requirements set out by the competent authority *in accordance with Union legislation*.

5. The processing plant shall 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, be accredited according to *internationally recognised standards or be subject to regular controls by the competent authority.*

6. If on the basis of a risk assessment, the volume of products treated requires regular or permanent presence of the competent authority, the processing plants shall have an adequately equipped lockable room for the exclusive use of the inspection service.

CHAPTER II

Waste water treatment

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 with a filter pore 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 point 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, maceration *or any other processing shall be carried out* which could facilitate the passage of *soluble* animal material through the pre-treatment process.

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

4. Waste water originating in the unclean sector of processing plants shall be treated *in accordance with conditions laid down by the competent authority, in* order to ensure that risks from pathogens are mitigated.

5. Waste water having passed the pre-treatment process in premises referred to in point 1 and waste water from premises only receiving Category 3 material shall be treated in accordance with Union legislation.

5. Without prejudice to points 1 to 6, the disposal of animal by-products including blood and milk or derived products through the waste water stream shall be prohibited.

CHAPTER III

Re-approval after temporary use

If the competent authority has granted an approval in accordance with Article 24(2)(b)(ii) of Regulation(EC) No 1069/2009 for the temporary use of a processing plant for the processing of a Category of animal by-products with a higher risk, it shall initiate the procedure for approval in accordance with Article 44 of the Animal By-products Regulation before issuing a new approval for the processing of animal by-products of a lower risk after the end of the temporary use.

CHAPTER IV

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

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 derived product, *unless a mixture of Category 1 material and Category 2 material is processed as Category 1 material*.

CHAPTER V

Specific requirements for the processing of Category 3 materials

The following requirements apply in addition to the general requirements laid down in Chapter I:

1. Category 3 processing plants shall not be at the same site as Category 1 or Category 2 processing plants, unless in a completely separate building.

2. However, the competent authority may authorise the processing of Category 3 material on a site where handling or processing of *Category 1 or* Category 2 material takes place, if cross-contamination is prevented by way of:

   (a) the layout of the premises, in particular the arrangements for the reception, and by way of the further handling of raw materials,

   (b) the layout and the management of the equipment used for processing, including the layout and the management of separate processing lines or of cleaning procedures which are excluding the propagation of any possible risks to public and animal health; and

   (c) the layout and the management of the areas for the temporary storage of the end products.

3. Category 3 processing plants shall have an installation to check the presence of extraneous matter, such as packaging material, metallic pieces, etc. in the animal by-

products *or derived products, if they are processing materials which are destined for feeding to farmed animals.*

SECTION II

HYGIENE AND PROCESSING REQUIREMENTS

CHAPTER I

General hygiene requirements

In addition to the general hygiene requirements referred to in Article 25 of the Animal By-products Regulation, processing plants shall have a documented pest control programme in place for the implementation of the arrangements referred to in Article 25(1)(c) of that Regulation.

CHAPTER II

General processing requirements

1. 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.

2. Material that may not have received the specified heat treatment, such as material discharged at start up or leakage from cookers, must be re-circulated through the heat treatment or collected and reprocessed or disposed of in accordance with The Animal By-products Regulation.

CHAPTER III

Processing of Category 1 and Category 2 material

Unless the competent authority requires the application of pressure sterilisation as defined in Article 3 no. 19 of the Animal By-products Regulation (method 1), Category 1 and Category 2 material shall be processed in accordance with methods 1 to 5 as referred to in Section III of this Annex.

CHAPTER IV

Processing of Category 3 material

1. The critical control points that determine the extent of the heat treatments applied in processing shall include for each processing method as specified in Section III of this Annex:

   (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.

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

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

SECTION III

STANDARD PROCESSING METHODS

A. Pressure sterilisation as defined in Article 3 no. 19 of the Animal By-products Regulation (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. The animal by-products with the particle size of no greater than 50 millimetres must be heated to a core temperature of more than 133 °C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars. The pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ("saturated steam"); 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.

B. Method 2

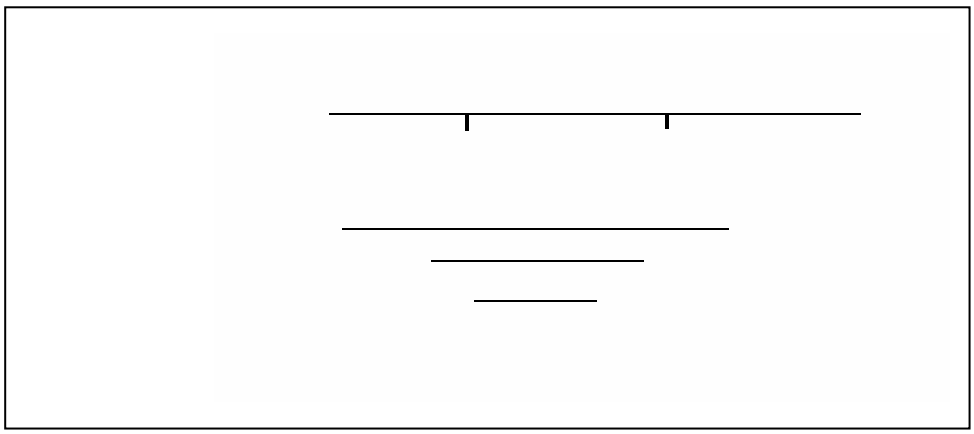
Reduction

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

Time, temperature and pressure

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

The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated, *as illustrated in the following graph:*



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

C. 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 in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 95 minutes, a core temperature greater than 110 °C is achieved for at least 55 minutes and a core temperature greater that 120 °C is achieved for at least 13 minutes.

   The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated, *as illustrated in the graph under point B.2*.

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

D. 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 in a manner which ensures that a core temperature greater than 100 °C is achieved for at least 16 minutes, a core temperature greater than 110 °C is achieved for at least 13 minutes, a core temperature greater than 120 °C is achieved for at least eight minutes and a core temperature greater that 130 °C is achieved for at least three minutes.

   The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated, *as illustrated in the graph under point B.2*.

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

E. 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 in a manner which ensures that a core temperature greater than 80 °C is achieved for at least 120 minutes and a core temperature greater that 100 °C is achieved for at least 60 minutes.

   The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated, *as illustrated in the graph under point B.2*.

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

F. Method 6 (for Category 3 animal by-products origin of aquatic animal origin only)

Reduction

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

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

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

   They must then be mixed with formic acid to reduce and maintain the pH to 4.0 or lower. The mixture must be stored for at least 24 hours pending further treatment.

Time, temperature and pressure

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

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

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

   The core temperatures may be achieved consecutively or through a coincidental combination of the time periods indicated.

   When using a continuous flow system, the progression of the product through the heat converter must be controlled by means of mechanical commands limiting its displacement in such 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. The processing may be carried out in batch or continuous systems.

G. Method 7

1. Any processing method *authorised* by the competent authority where the following have been demonstrated to that authority:

   (a) the identification of relevant hazards in the starting material;

   (b) the capacity of the processing method to reduce those hazards to a level which does not pose any significant risks to public and animal health;

   (c) the sampling of the final product on a daily basis over a period of 30 production days in compliance with the following microbiological standards:

      (i) Samples of material taken directly after the treatment:

         Clostridium perfringens absent in 1 g of the products

(ii) Samples of material taken during or upon withdrawal from storage:

Salmonella: absence in 25g: 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 samples 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 operator 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. By way of derogation from point 1, the competent authority may authorise the use of processing methods which have been approved prior to 4 March 2011, in accordance with Chapter III of Annex V of Regulation (EC) No 1774/2002.

4. *The competent authority shall inform the competent authority of another Member State upon request about the information at its disposal under points 1 and 2 in relation to an authorised method.*

SECTION IV

ALTERNATIVE METHODS

CHAPTER I

General provisions

1. Materials resulting from the processing of Category 1 and 2 materials, except biodiesel produced in accordance with point D of Chapter II, shall be permanently marked in accordance with Section V of Annex X.

2. The competent authority of a Member State shall make the results of official controls available to the competent authority of another Member State upon request, when an alternative method is used for the first time in that Member State, in order to facilitate the introduction of the new alternative method.

CHAPTER II

Processing standards

A. Alkaline hydrolysis process

1. Starting material

For this process, animal by-products of all Categories may be used.

2. Processing method

Alkaline hydrolysis shall be carried out according to the following processing standards:

(a) Either a sodium hydroxide (NaOH) or potassium hydroxide (KOH) solution (or a combination thereof) is used in an amount that assures approximate molar equivalency to the weight, type and composition of the animal by-products to be digested.

In the case of high fat in the animal by-products that neutralises the base, the added base is adjusted *so that the molar equivalency referred to is acheived*.

(b) Animal by-products are placed in a steel alloy container. The measured amount of alkali is added either in solid form or as a solution as referred to in point (a).

(c) The container is closed and the animal by-products and alkali mixture are heated to a core temperature of at least 150 °C and at a pressure (absolute) of at least 4 bars for at least:

(i) three hours without interruption;

(ii) six hours without interruption in case of treatment of animal by-products referred to in Article 8(a)(i) and (ii) of The Animal By-products Regulation.

However, material derived from animals referred to in Article 8(a)(ii) *which are either ruminants not requiring TSE testing or ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001* may be processed in accordance with point 2(c)(i); or

(iii) one hour without interruption in case of animal by-products consisting of fish or of poultry materials.

(d) The process is carried out in a batch system and the material in the vessel is constantly mixed in order to facilitate the digestion process until the tissues are dissolved and bones and teeth are softened; and

(e) The animal by-products are treated in such way that the requirements regarding time, temperature and pressure are achieved at the same time.

B. High pressure high temperature hydrolysis process

1. Starting material

For this process, Category 2 and Category 3 materials may be used.

2. Processing method

High pressure high temperature hydrolysis shall be carried out according to the following processing standards:

(a) The animal by-products are heated to a core temperature of at least 180 °C for at least 40 minutes without interruption at a pressure (absolute) of at least 12 bar, heated by indirect steam application to the biolytic reactor;

(b) The process is carried out in a batch and the material in the vessel is constantly mixed; and

(c) The animal by-products are treated in such a manner that the time-temperature-pressure requirements are achieved at the same time.

C. High pressure hydrolysis biogas process

1. Starting material

For this process, animal by-products of all Categories may be used.

2. Processing method

The high pressure hydrolysis biogas process shall be carried out according to the following processing standards:

(a) The animal by-products are first processed using processing method 1 in an approved processing plant;

(b) Following the above process, the defatted materials are treated at a temperature of at least 220 °C for at least 20 minutes at a pressure (absolute) of at least 25 bar, heated in a two-step procedure, first by direct steam injection, secondly indirect in a coaxial heat exchanger;

(c) The process is carried out in a batch or continuous system and the material is constantly mixed;

(d) The animal by-products are treated in such a manner that the time-temperature-pressure requirements are achieved at the same time; and

(e) The resulting material is then mixed with water and anaerobically fermented (biogas transformation) in a biogas reactor.

(f) In case of starting material of Category 1:the entire process shall take place on the same site and in a closed system and the biogas produced during the process shall be combusted rapidly in the same plant at a minimum of 900 °C followed by rapid chilling ("quenching").'

D. Biodiesel production process

1. Starting material

For this process, a fat fraction of animal by-products of all categories may be used.

2. Processing method

Biodiesel production shall be carried out according to the following processing standards:

(a) Unless *fish oil or* rendered fat is used which have been produced in accordance with Sections *VIII or* XII of Annex III to Regulation (EC) No 853/2004, *respectively*, the fat fraction of animal by-products is first processed using:

(i) in case of Category 1 or 2 materials, processing method 1 as referred to in Section III of this Annex; and

(ii) in the case of Category 3 materials, any of the processing methods 1 to 5 or 7 or, in the case of material derived from fish, methods *1 to 7* as referred to in Section III of this Annex;

(b) The processed fat is then processed further using one of the following methods:

(i) a process whereby the processed fat is separated from the protein and in the case of fat from ruminant origin, insoluble impurities in excess of 0.15 % by weight are removed, and the processed fat is subsequently submitted to esterfication and transesterfication.

However, esterfication is not required for processed fat derived from Category 3 material. For esterfication the pH is reduced to less than 1

by adding sulphuric acid (H_2SO_4) or an equivalent acid and the mixture is heated to 72 °C for at least two hours during which it is intensely mixed.

Transesterfication shall be carried out by increasing the pH to about 14 with potassium hydroxide or with an equivalent base at 35 °C to 50 °C for at least 15 minutes. Transesterfication shall be carried out twice under the conditions described in this point using a new base solution. This process is followed by refinement of the products including vacuum distillation at 150 °C, leading to biodiesel;

(ii) a process using equivalent process parameters authorised by the competent authority.

E. Brookes' gasification process

1. Starting material

For this process, Category 2 and Category 3 material may be used.

2. Processing method

Brookes' gasification shall be carried out according to the following processing standards:

(a) The afterburner chamber is warmed up using natural gas.

(b) The animal by-products are loaded into the primary chamber of the gasificator and the door is closed. The primary chamber has no burners and is heated instead by the transfer of heat by conduction from the afterburner, which is underneath the primary chamber. The only air admitted to the primary chamber is via three inlet valves mounted on the main door to enhance the efficiency of the process.

(c) The animal by-products are volatilised into complex hydrocarbons and the resultant gases pass from the primary chamber via a narrow opening at the top of the back wall to the mixing and cracking zones, where they are broken down into their constituent elements. Finally the gases pass into the afterburner chamber where they are burned in the flame of a natural gas fired burner in the presence of excess air.

(d) Each process unit has two burners and two secondary air fans for back-up in case of burner or fan failure. The secondary chamber is designed to give a minimum residence time of two seconds at a temperature of at least 950^{o} C under all conditions of combustion.

(e) On leaving the secondary chamber the exhaust gases pass through a barometric damper at the base of the stack, which cools and dilutes them with ambient air, maintaining a constant pressure in the primary and secondary chambers.

(f) The process is carried out over a 24-hour cycle, which includes loading, processing, cool down and ash removal. At the end of the cycle the residual ash is removed from the primary chamber by a vacuum extraction system into enclosed bags and sealed before transporting.

(g) The gasification of material other than animal by-products is not permitted.

F. Combustion of animal fat in a thermal boiler process

1. Starting material

For this process, a fat fraction derived from animal by-products of all Categories may be used.

2. Processing method

Combustion of animal fat in a thermal boiler shall be carried out according to the following processing standards:

(a) Unless *fish oil or* rendered fat is used which has been produced in accordance with Sections *VIII or* XII of Annex III to Regulation (EC) No 853/2004, *respectively,* the fat fraction derived from animal by-products is first processed using:

(i) in the case of fat fraction of Category 1 and 2 materials which is intended to be combusted in another plant,

- *for the fat fraction from the processing of animals, other than ruminants which require TSE testing, and of ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001, any of the processing methods 1 to 5 as referred to in Section III of this Annex*;

- *for the fat fraction from the processing of other ruminants, processing method 1 as referred in Section III of this Annex;* and

(ii) in the case of Category 1 and 2 materials intended for combustion within the same plant and in the case of Category 3 material, any of the processing methods 1 to 5 or 7; in the case the materials are derived from fish, processing methods 1 to 7 as referred to in Section III of this Annex;

(b) The fat fraction is separated from the protein and in the case of fat from ruminant origin, insoluble impurities in excess of 0.15 % by weight are removed;

(c) Following the process referred to in (a) and (b), the fat is:

(i) vaporised in a steam-raising boiler and combusted at a temperature of at least 1, 100 °C for at least 0.2 seconds; or

(ii) processed using equivalent process parameters authorised by the competent authority.

(d) The combustion of material of animal origin other than animal fat is not permitted.

(e) The combustion of the fat derived from Category 1 and Category 2 materials shall take place in the same plant where the fat is rendered with the aim of utilising the energy generated for the rendering processes. However, the competent authority may authorise the movement of that fat to other plants for combustion provided that:

(i) the plant of destination is authorised for the combustion;

(ii) approved food or feed processing on the same premises takes place under strict conditions of separation.

(f) The combustion is carried out in accordance with Union legislation for the protection of the environment, in particular, with reference to the standards of that legislation regarding best available techniques for the control and monitoring of emissions.

G. Thermo-mechanical biofuel production process

1. Starting material

For this process, manure and digestive tract content and Category 3 material may be used.

2. Processing method

(a) The animal by-products are loaded into a converter and subsequently treated at a temperature of 80° C for a period of eight hours. During this period, the material is constantly reduced in size using appropriate mechanical abrasion equipment.

(b) The material is subsequently treated *at* a temperature of 100 °C for at least two hours.

(c) The particle size of the resulting material must not be larger than 20 millimetres;

(d) The animal by-products are treated in such a manner that the time-temperature requirements laid down in paragraphs 1 and 2 are achieved at the same time;

(e) During the heat treatment of the material, evaporated water is continually extracted from the air-space above the biofuel and is passed through a stainless steel condenser. The condensate is kept at a temperature of at least 70° C for at least one hour before being discharged as waste water;

(f) After the heat treatment of the material, the resulting biofuel from the converter is then discharged and automatically conveyed by a fully covered and interlocked conveyor to incineration or co-incineration on the same site;

(g) A system of hazard analysis and critical control points is in place and maintained which allows for the control of the requirements laid down in paragraphs (a) to (f);

(h) The process is carried out in a batch mode.

CHAPTER III

Disposal and use of derived products

1. Products derived from the processing of

(a) Category 1 material shall be:

(i) disposed of in accordance with Article 12 point (a) or point (b) of the Animal By-products Regulation;

(ii) disposed of by burial in an authorised landfill as defined in point 21 of Article 3 of the Animal By-products Regulation;

(iii) transformed into biogas, provided the digestion residues are disposed of in accordance with points (i) or (ii).

(b) Category 2 or Category 3 material shall be:

(i) disposed of as provided for in point 1(a)(i) or (ii), with or without prior processing as provided for in Article 12 points (a) and (b);

(ii) further processed into fat derivatives for uses other than feeding;

(iii) used as an organic fertiliser or soil improver;

(iv) composted or transformed into biogas.

2. However, materials resulting from processing in accordance with:

(a) the alkaline hydrolysis process defined in point A of Chapter II may be transformed in a biogas plant and subsequently combusted rapidly at a minimum of 900°C, followed by rapid chilling ("quenching"); in case material referred to in Article 8(a) and (b) of the Animal By-products Regulation has been used as starting material, the transformation into biogas shall take place on the same site as the processing and in a closed system;

(b) the biodiesel production process may be:

(i) in the case of biodiesel and of residues from the distillation of biodiesel, used as a fuel;

(ii) in the case of potassium sulphate, used for the production of derived products for application to land;

(iii) in the case of glycerine

- *derived from Category 1 material which has been processed in accordance with processing method 1 as referred to in Section III of this Annex, transformed into biogas.*

- derived from Category 3 material, used for feeding.

3. Any resulting waste from the processing of animal by-products in accordance with this Section, such as sludge, filter contents, ash and digestion residues shall be disposed of *in accordance with the Animal By-products Regulation and with this Regulation*.

ANNEX VII

TRANSFORMATION INTO BIOGAS, COMPOSTING

SECTION I

REQUIREMENTS APPLICABLE TO PLANTS

CHAPTER I

Biogas plants

1. A biogas plant shall be equipped with a pasteurisation/hygienisation unit, which cannot be by-passed, with:

   (a) installations for monitoring temperature against time;

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

   (c) an adequate system to prevent insufficient heating.

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

   (a) *Category 2 material* that has *been processed in accordance with* processing method 1 *as referred to in Section III of Annex VI*;

   (b) *Category 3 material that has been processed in accordance with processing methods 1 to 5, or in the case of material originating from aquatic animals, methods 1 to 6, as referred to in Section III of Annex VI,*

   (c) Category 3 material that has undergone pasteurisation/hygienisation in another approved plant;

   (d) animal by-products which may be used as raw material without processing; or

   (e) *if authorised by the competent authority, materials which have been processed as defined in Article 2(1)(m) of Regulation (EC) No 852/2004 at the time when they are destined for purposes other than human consumption.*

3. If the biogas plant is located on or next to premises where farmed animals are kept and does not only use manure, milk or colostrums which accrues from those animals, the plant shall be located at an distance from the area where such animals are kept *which ensures that there is no risk for the transmission of a disease communicable to humans or animals through emissions from the biogas plant,* and there must be, in any case, total physical separation between that plant and those animals and their feed and bedding, with fencing where necessary.

4. Each biogas plant must have its own laboratory or make use of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved, be accredited according to *internationally recognised standards or be subject to regular controls by the competent authority.*

CHAPTER II

Composting plants

1. A composting plant shall be equipped with a closed composting reactor, which cannot be by-passed, with:

   (a) installations for monitoring temperature against time;

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

   (c) an adequate safety system to prevent insufficient heating.

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

   (a) 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; *or*

   (b) *transform only materials referred to in points 2(a) to (e) of Chapter I; and*

   (c) comply with all other *relevant* requirements of this Regulation.

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

4. Each composting plant must have its own laboratory or make use of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved, be accredited according to *internationally recognised standards or be subject to regular controls by the competent authority.*

SECTION II

HYGIENE REQUIREMENTS

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

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

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

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

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

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

7. Digestion residues and compost must be handled and stored at the biogas or composting plant in such way as to prevent recontamination.

8. *Plants shall have adequate facilities for the cleaning and disinfecting of vehicles and containers.*

SECTION III

TRANSFORMATION PARAMETERS

CHAPTER I

Standard transformation parameters

1. Category 3 material used as raw material in a biogas plant equipped with a pasteurisation/ hygienisation unit must be submitted to the following minimum requirements:

   (a) maximum particle size before entering the unit: 12 mm;

   (b) minimum temperature in all material in the unit: 70 °C; and

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

   However, Category 3 milk, colostrums and milk products may be used without pasteurization /hygienisation as raw material in a biogas plant, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease.

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

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

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

(c) minimum time *without interruption*: 60 minutes.

CHAPTER II

Alternative transformation parameters for biogas and composting plant

1. The competent authority may authorise the use of other standardised transformation parameters provided an applicant demonstrates that such parameters ensure adequate reduction of biological risks. That demonstration shall include a validation, which shall be carried out in accordance with points (a) to (f):

(a) Identification and analysis of possible hazards, including the impact of input material, based on a full description of the transformation conditions and parameters.

(b) A risk assessment, which evaluates how the specific transformation conditions referred to in (a) are achieved in practice under normal and atypical situations;

(c) Validation of the intended process by measuring the reduction of viability/infectivity of:

(i) endogenous indicator organisms during the process, where the indicator is:

– consistently present in the raw material in high numbers,

– not less heat resistant to the lethal aspects of the transformation process, but also not significantly more resistant than the pathogens for which it is being used to monitor,

– relatively easy to quantify and relatively easy to identify and to confirm; or

(ii) a well-characterised test organism or virus, during exposure, introduced in a suitable test body into the starting material.

(d) The validation of the intended process referred to in (c) must demonstrate that the process achieves the following overall risk reduction:

(i) for thermal and chemical processes by:

– reduction of 5 log10 of Enterococcus faecalis or Salmonella Senftenberg (775W, H2S negative),

– reduction of infectivity titre of thermo resistant viruses such as parvovirus by at least 3 log10, whenever they are identified as a relevant hazard; and

(ii) as regards chemical processes also by:

– reduction of resistant parasites such as eggs of ascaris sp. by at least 99,9 % (3 log10) of viable stages.

(e) Designing a complete control programme including procedures for monitoring the functioning of the process referred to in (c).

(f) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a biogas or composting plant as well as other critical control points must be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant. Records must be made available to the competent authority on request. Information relating to a process authorised under this point must be made available to the Commission on request.

2. However, pending the adoption of rules as referred to in Article 15(2)(a) of the Animal By-products Regulation, 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.

3. The *competent authority may also authorise the use of the* specific requirements *referred to in point 2 for* mixtures of catering waste with manure, digestive tract content, *whether or not separated from the digestive tract*, milk, milk-based products, colostrum, eggs, egg products *and for animal by-products and derived products referred to in Article 10(f) and g) of the Animal By-products Regulation.*

4. Where manure, digestive tract and its content, milk, milk-based products, colostrums, eggs and egg products are the only starting 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) demands that the residues or compost are *further treated in accordance with the Animal By-products Regulation and with this Regulation.*.

5. *Operators may place on the market digestion residues and compost, which have been produced according to parameters authorised in accordance with point 1.*

CHAPTER III

Standards for digestion residues and compost

Representative samples of the digestion residues or compost taken during or immediately after transformation at the biogas plant or composting at the composting plant *or during storage of the compost (before dispatch)* in order to monitor the process must comply with the following standards:

Escherichia coli: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;

or

Enterococaceae: n = 5, c = 1, m = 1 000, M = 5 000 in 1 g;

and

Representative samples of the digestion residues or compost taken during or on withdrawal from storage must comply with the following standards:

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

where:

n = number of samples to be tested;

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

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

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

Digestion residues or compost, which does not comply with the requirements set out in this Chapter, shall be reprocessed, in the case of Salmonella handled or disposed of in accordance with the instructions of the competent authority.

ANNEX VIII

SPECIAL RULES ON RESEARCH, FEEDING AND COLLECTION AND DISPOSAL

SECTION I

SPECIAL RULES ON RESEARCH

[…]

SECTION II

SPECIAL FEEDING RULES

CHAPTER I

General requirements

Animal by-products referred to in Article 18(1)*(d), (f), (g) and (h)* of the Animal By-products Regulation may be used for feeding as set out in this provision under the following conditions:

1. The animal by-products referred to in paragraph 1 shall be transported to the users or to collection centres in accordance with Annex X, Section I, Chapters I and III.

2. Collection centres shall be registered by the competent authority, provided that:

   (a) they comply with the requirements of *Section V of Annex XI* ; and

   (b) they have adequate facilities for destroying unused material, or send it to an approved processing plant or to an approved incineration or co-incineration plant in accordance with this Regulation.

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

4. Operators of collection centres supplying material, other than fish offal, to final users must ensure that it undergoes one of the following treatments:

   (a) 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;

   (b) sterilisation by boiling or steaming under pressure until every piece of material is cooked throughout; or

(c) any other treatment *authorised* by the competent authority *responsible for the operator*.

CHAPTER II

Feeding of certain species in feeding stations

1. The competent authority may authorise the use of Category 1 material referred to in Article 18(2)(b) of the Animal By-products Regulation for the feeding of the following endangered and protected species in feeding stations under the following conditions:

(a) The material is fed to:

(i) one of the following species of necrophagous birds in the following Member States:

Name of the Member State	Animal species
Bulgaria	black vulture (Aegypius monachus) bearded vulture (Gypaetus barbatus) griffon vulture (Gyps fulvus) Egyptian vulture (Neophron pernkopterus) golden eagle (Aquila chrysaetos) imperial eagle (Aquila heliaca) white-tailed eagle (Haliaeetus albicilla) black kite (Milvus migrans) red kite (Milvus milvus)
Cyprus	black vulture (Aegypius monachus) griffon vulture (Gyps fulvus)
France	griffon vulture (Gyps fulvus) black vulture (Aegypius monachus) Egyptian vulture (Neophron pernkopterus) bearded vulture (Gypaetus barbatus) red kite (Milvus milvus)

	black kite (Milvus migrans)
Greece	griffon vulture (Gyps fulvus) bearded vulture (Gypaetus barbatus) Egyptian vulture (Neophron pernkopterus)
Italy	griffon vulture (Gyps fulvus) bearded vulture (Gypaetus barbatus) golden eagle (Aquila chrysaetos)
Portugal	griffon vulture (Gyps fulvus) black vulture (Aegypius monachus) Egyptian vulture (Neophron pernkopterus) golden eagle (Aquila chrysaetos)
Spain	griffon vulture (Gyps fulvus) black vulture (Aegypius monachus) Egyptian vulture (Neophron pernkopterus) bearded vulture (Gypaetus barbatus) Spanish imperial eagle (Aquila adalberti) golden eagle (Aquila chrysaetos) red kite (Milvus milvus) black kite (Milvus migrans)

or

(ii) one of the species of the order carnivora which are listed in Annex II to Directive 92/43/EEC, in special areas of conservation which have been set up under that Directive

(iii) *one of the species of the orders falconiformes or strigiformes, which are listed in Annex I to Directive 2009/147/EC, in special protection areas which have been set up under that Directive*;

(b) The competent authority has granted an authorisation to the person or entity responsible for the feeding station.

The competent authority shall grant such authorisations provided

(i) the feeding is not used as an alternative way of disposal of specified risk materials or fallen ruminant stock containing them posing a TSE risk;

(ii) an appropriate surveillance system for TSEs as laid down in Regulation (EC) No 999/2001 is in place involving regular laboratory testing of samples for TSE;

(c) The competent authority ensures coordination with any other competent authorities responsible for the supervision of the requirements laid down in the authorisation;

(d) The competent authority is satisfied, on the basis of an assessment of the specific situation of the species concerned and their habitat, that the conservation status of the species will be improved;

(e) The authorisation granted by the competent authority:

(i) refers to and names the species actually concerned;

(ii) describes in detail the location of the feeding station in the geographical area where feeding shall take place; and

(iii) is immediately suspended in case of:

- a suspected or confirmed link to the spread of TSE until the risk can be excluded; or

- non-compliance with any of the rules provided for in this Regulation.

(f) The person responsible for the feeding shall:

(i) dedicate an area to the feeding that is enclosed and to which access is limited to animals of the species to be conserved, if appropriate by fences or by other means which correspond to the natural feeding patterns of those species;

(ii) ensure that 10% of *eligible* carcasses of bovine animals and at least 4 % of *eligible* carcasses of ovine and caprine animals intended to be used for feeding are tested prior to that use with a negative result, in the TSE monitoring programme carried out in accordance with Annex III to Regulation (EC) No 999/2001; and

(iii) keep records at least of the number, nature, estimate weight and origin of the carcases of the animals used for feeding, the date of the feeding, the location where feeding took place and if applicable, the results of the TSE tests.

2. Member States that apply to be included into the list under point 1(a) shall submit:

(a) a detailed justification for the extension of the list to certain species of necrophagous birds in this Member State, including an explanation of the reasons why it is necessary to feed such birds with Category 1 material instead of with Category 2 or Category 3 material; and

(b) an explanation of the measures which will be taken in order to ensure compliance with point 1.

CHAPTER III

Feeding of wild animals outside feeding stations

The competent authority may authorise the use of Category 1 material referred to in Article 18(2)(b) of the Animal By-products Regulation outside feeding stations, if appropriate without prior collection of the dead animals, for feeding to wild animals referred to in point 1(a) of Chapter II under the following conditions:

1. The competent authority is satisfied, on the basis of an assessment of the specific situation of the species concerned and their habitat, that the conservation status of the species will be improved;

2. The competent authority has *identified holdings or herds within* a geographically defined feeding zone under the following conditions:

   (a) The feeding zone does not extend to areas where intensive farming of animals takes place;

   (b) Farmed animals in *holdings or herds in* the feeding zone are under the regular surveillance of an official veterinarian regarding the prevalence of TSE and of diseases transmissible to humans or animals;

   (c) Feeding is immediately suspended in case of:

      (i) a suspected or confirmed link to the spread of TSE *in a holding or herd*, until the risk can be excluded; or

      (ii) a suspected or confirmed outbreak of a serious disease transmissible to humans or animals *in a holding or herd*, until the risk can be excluded; or

      (ii) non-compliance with any of the rules provided for in this Regulation;

   (d) The competent authority specifies

      (i) appropriate measures to prevent the transmission of TSE and of transmissible diseases from the dead animals to humans or other animals, such as measures targeted at the feeding patterns of the species to be conserved, seasonal feeding restrictions, movement restrictions for farmed animals *and other measures intended to*

control possible risks of transmission of a disease communicable to humans or animals, such as measures relating to species present in the feeding zone for the feeding of which the animal by-products are not used;

(ii) the responsibilities of persons or entities in the feeding zone who are assisting with the feeding or responsible for farmed animals, in relation to the measures referred to under point (i);

(iii) the conditions for the imposition of penalties as referred to in Article 53 of the Animal By-products Regulation which are applicable to infringements of measures referred to under point (i) by the persons or entities referred to under point (ii);

(e) In case the feeding is carried out without prior collection of the dead animals, an estimation of the likely mortality rate of farmed animals in the feeding zone *and of the likely feeding requirements of the wild animals* has been carried out, as a basis for the assessment of the potential risks of disease transmission.

CHAPTER IV

Feeding of zoo animals with Category 1 material

The competent authority may authorise the use of Category 1 material referred to in Article 18(2)(a) for the feeding of zoo animals under the following conditions:

(a) The competent authority has granted an authorisation to the person responsible for the feeding. The competent authority shall grant such authorisations provided

(i) the feeding is not used as an alternative way of disposal of specified risk materials or fallen ruminant stock containing them posing a TSE risk;

(ii) *when Category 1 material referred to in Article 8(b)(ii) of the Animal By-products Regulation which originates from bovine animals is used,* an appropriate surveillance system for TSEs as laid down in Regulation (EC) No 999/2001 is in place involving regular laboratory testing of samples for TSE;

(b) The authorisation granted by the competent authority is immediately suspended in case of:

(i) a suspected or confirmed link to the spread of TSE until the risk can be excluded; or

(ii) non-compliance with any of the rules provided for in this Regulation;

(c) The person responsible for the feeding shall:

(i) store the material to be used for the feeding and carry out the feeding in an enclosed and fenced area to ensure that no carnivorous animal other than the zoo animals for which the authorisation has been granted have access to the material for the feeding;

(ii) ensure that *ruminant animals* intended to be used for feeding are *included* in the TSE monitoring programme carried out in accordance with Annex III to Regulation (EC) No 999/2001; and

(iii) keep records at least of the number, nature, estimate weight and origin of the carcases of the animals used for feeding, the results of the TSE tests and the date of the feeding.

SECTION III

SPECIAL RULES ON COLLECTION AND DISPOSAL

CHAPTER I

Special disposal rules for animal by-products

1. If the competent authority authorises the disposal of animal by-products on site in accordance with Article 19(1)(a),(b),(c) and (e) of the Animal By-products Regulation, such disposal may take place:

(a) by burning or burial on the premises on which the animal by-products originate;

(b) in an authorised landfill as referred to in Article 3 point 21 of the Animal By-products Regulation; or

(c) by burning or burial at a site which minimises the risk to animal and public health and the environment, provided that the site is located within a range of distance sufficient to enable the competent authority to manage the prevention of the risk to animal and public health and the environment;

2. The burning of animal by-products on the sites referred to in Article 19(1)(b), (c) and (e) of the Animal By-products Regulation must be carried out in such a way to ensure that they are burnt:

(a) on a properly constructed pyre and the animal by-products reduced to ash;

(b) without endangering human health;

(c) without using processes or methods which could harm the environment, in particular through risks to water, air, soil and plants and animals or through noise or odours;

(d) under conditions which ensure that any resulting ash *is disposed of by burial in an approved landfill*.

3. The burial of animal by-products in the sites laid down in Article 19(1)(a), (b), (c) and (e) of the Animal By-products Regulation must be carried out to ensure that they are buried:

(a) in such a way that carnivorous or omnivorous animals cannot gain access to them; and

(b) in an authorised landfill as referred to in Article 3 point 21 of The Animal By-products Regulation; or in another site without endangering human health and using processes or methods which do not harm the environment, in particular through risks to water, air, soil and plants and animals, or through noise or odours.

4. In the case of disposal in accordance with Article 19(1)(e) of the Animal By-products Regulation , movement of the animal by-products from the place of origin to the place of disposal must be carried out in such a way that:

(a) the animal by-products are transported in secure, leak-proof containers or vehicles;

(b) the loading and unloading of the animal by-products is supervised by the competent authority, if appropriate;

(c) the vehicle wheels are disinfected upon leaving the site of origin;

(d) containers and vehicles used for transporting animal by-products are thoroughly cleansed and disinfected after unloading of the animal by-products; and

(e) adequate escorts for the vehicles, leak testing and double covering are provided, if appropriate.

CHAPTER II

Burning and burial of animal by-products in remote areas

The maximum percentage as referred to in Article 19(2) of the Animal By-products Regulation shall not exceed the following:

(a) 10% of the bovine population of the Member State concerned.

(b) 15 % of the ovine and caprine population of the Member State concerned; *and*

(c) 10% of the porcine population of the Member State concerned.

CHAPTER III

Burning and burial of bees and apiculture products

In the case of bees and apiculture by-products referred to in Article 19(1)(f) of the Animal By-products Regulation, the competent authority may authorise disposal by burning or burial on site, provided that all necessary measures are taken to ensure that the burning or burial does not endanger animal or human health or the environment.

SECTION IV

DISPOSAL BY OTHER MEANS

[…]

ANNEX IX

STANDARD FORMAT FOR APPLICATIONS
FOR ALTERNATIVE METHODS

SECTION I

GENERAL PROVISIONS

1. The standard format laid down in Section II shall apply to applications for the authorisation of alternative methods which are submitted by interested parties or by Member States, in accordance with Article 20 of the Animal By-products Regulation.

2. National contact points which are designated by Member States shall provide information on the competent authority responsible as referred to in Article 20(2) of the Animal By-products Regulation to interested parties. The Commission shall publish a list of national contact points on its website.

SECTION II

STANDARD FORMAT

CHAPTER I

Language regime

1. Applications shall be submitted in one of the official languages of the European Union as defined in Article 1 of Regulation 1/1958.

2. Interested parties that submit their applications in a language other than English shall validate the official translation of their application, which EFSA will provide, prior to the assessment. The period referred to in Article 20(5) of the Animal By-products Regulation shall only start once the interested party has validated the official translation.

CHAPTER II

Content of applications

1. Applications shall contain sufficient information on the following points, in order to allow EFSA to assess the safety of their proposed alternative method:

   (a) the categories of animal by-products which are supposed to be submitted to the alternative method, by reference to the categories referred to in Articles 8,9, and 10 of the Animal By-products Regulation;

(b) the identification and characterisation of risk materials according to the following principles:

Significant risk materials should be identified separately. For each material, the likelihood of human and animal exposure under normal and emergency/ abnormal operating conditions should be assessed. In case of significant exposure, the potential risk should be assessed.

(c) the agent risk reduction according to the following principles:

The risk reduction for human and animal health which can be achieved by the process should be estimated on the basis of direct measurements. In case no direct measurement is available, modelling or extrapolation from other processes may also be used. In order to demonstrate effective risk reduction, the identified hazard (e.g. Salmonella) should be quantified both in the input (raw) material and in the resulting output material. For the purpose of this document output material comprises any end-products and by-products deriving from the process. Estimates should be accompanied by evidence. This includes – for measurements – information on the methodology used (sensitivity and reliability of the methods used, nature of samples which have been analysed and evidence that samples are representative (relevant real samples, number of tests performed). If surrogates for prion measurement are used, an explanation should be given of their relevance. In any case it is necessary to provide an evaluation of the validity with the uncertainties involved.

(d) the risk containment according to the following principles:

The likely effectiveness of the technical measures used to ensure that the risks are contained should be analysed. This analysis should reflect normal and abnormal/ emergency operating conditions including a breakdown of the process. Monitoring and surveillance procedures to demonstrate containment should be specified. If full containment is not achievable, an assessment is required of any potential risk.

(e) the identification of interdependent processes according to the following principles:

Possible indirect impacts which may influence the risk reduction capacity of a particular process should be evaluated. Indirect impacts may arise from transport, storage and safe disposal of end-products and by-products of a process.

(f) the intended end use of the products according to the following principles:

The intended end use of products and by-products of a process should be specified. The likely risks involved should be calculated from the risk reduction estimated in accordance with (c), which may arise to human and animal health.

2. Applications shall be submitted with documentary evidence, in particular a flow diagram showing the functioning of the process, the evidence indicated under point (1c), as well as other evidence aiming to substantiate the explanation given under the framework set out under point 1.

3. Applications shall include a contact address for the interested party, which shall include indications of the name and full address, telephone and/or fax numbers and/or the electronic mail address of a particular contact person that is responsible as or on behalf of the interested party.

ANNEX X

COLLECTION, TRANSPORT AND TRACEABILITY

SECTION I

COLLECTION AND TRANSPORT

CHAPTER I

Vehicles and containers

1. As from the starting point referred to in Article 4(1) of the Animal By-products Regulation, animal by-products and derived 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 derived products, *other than derived products which are placed on the market as feed in accordance with Regulation (EC) No 767/2009 and which are stored and transported in accordance with Annex II of Regulation(EC) No 183/2005* , must be maintained in a clean condition. In particular, they must be

   (a) clean and dry before use, unless they are dedicated to the carriage of particular animal by-products or derived products in a way which avoids cross-contamination; and

   (b) cleaned, washed and/or disinfected after each use to the extent *necessary* to avoid cross-contamination, *unless they are dedicated to the carriage of a particular animal by-product or derived product in a way which avoids cross-contamination.*

3. Reusable containers must be dedicated to the carriage of a particular animal by-product or derived product to the extent necessary to avoid cross-contamination. However, reusable containers may be used for the carriage of different animal by-products or derived products provided that they are *thoroughly* cleaned and disinfected, if appropriate, between the different uses in a manner which prevents cross-contamination.

4. Packaging material must be disposed of, by incineration or by other means in accordance with Union legislation.

CHAPTER II

Temperature conditions

1 The transport of animal by-products must take place at an appropriate temperature, *in the case of meat and meat products at 7°C,* 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 stored and transported chilled, frozen or ensiled, unless:

(a) it is processed within 24 hours after collection;

(b) in the case of milk or derived products from milk, it is transported chilled and in insulated containers.

3 The design of vehicles used for refrigerated transport must ensure the maintenance of an appropriate temperature throughout transport, and allow that temperature to be monitored.

CHAPTER III

Derogation for collection and transport of milk, milk-based products and milk-derived products, defined as Category 3 material

However, Chapter I shall not apply to the collection and transportation of milk products, milk based products and milk derived products, defined as Category 3 material, by operators of milk-processing establishments which have been approved in accordance with Article 4 of Regulation (EC) 853/2004, in case they are *receiving* products which *they* have previously delivered *and which are returned to them, in particular from* their customers.

SECTION II

IDENTIFICATION

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

(a) animal by-products and derived products are identifiable and kept separate and identifiable during collection where the animal by-products originate and during transportation;

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

(c) animal by-products and derived products are dispatched from one Member State to another Member State in packaging, containers or vehicles which are prominently and, at least for the period of transport, indelibly colour-coded for displaying information as provided for in this Regulation on the surface or part

of the surface of a packaging, container or vehicle, or on a label or symbol applied to them as follows:

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

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

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

(iv) in the case of imported consignments, the colour referred to for the respective material under points (i) to (iii), as from the time when the consignment has been *released for free circulation within the* European Union.

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

(a) clearly indicate the Category of the animal by-products or of the derived products, and

(b) bear the following words visibly and legibly displayed on the packaging, a container or vehicle, as applicable:

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

(ii) in the case of Category 2 material (other than manure and digestive tract content) and derived products from Category 2 material, “not for animal consumption”; however, when Category 2 material is intended for the feeding of animals referred to in Article 18(1)(a) of The Animal By-products Regulation under the conditions provided for or laid down in accordance with that Article, the label shall instead indicate “for feeding to …” completed with the name of the specific species of those animals for the feeding of which the material is intended;

(iii) in the case of Category 1 material and derived products from Category 1 material

- in case they are destined to disposal, “for disposal only”;

- *in case they are destined to the manufacture of petfood, 'for manufacture of petfood only'*.

- in case they are destined to the manufacture of a derived product referred to in Article 36 of Regulation (EC) No 1069/2009, 'for manufacture of derived products only. Not for human or animal consumption or for application to land';

(iv) in the case of manure and digestive tract content, “manure”;

(v) in the case of organic fertilisers and soil improvers, other than those which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer on which it is indicated that they are not destined for application to land *to which farmed animals have access*, 'organic fertilisers or soil improvers/ farmed animals must not be allowed access to the land for at least 21 days following application to land'.

(vi) in the case of gelatine produced from Category 3 material, 'gelatine suitable for animal consumption';

(vii) in the case of collagen produced from Category 3 material, "collagen suitable for animal consumption";

(viii) in the case of raw petfood, "for petfood only";

(ix) in the case of material *used for feeding in accordance with Chapter I of Section II of Annex VIII*, the name and the address of the collection centre, and the indication 'not for human consumption';

(x) in the case of fish and derived products from fish intended for feed for fish, *treated and packaged* before distribution, the name and address of the feed manufacturing establishment *of origin*, marked clearly and legibly, and

- in case the feed may be used for the feeding of farmed fish, bearing the words 'contains wild fish only – may be used for the feeding of farmed fish of all species';

- in case the feed may be used for the feeding of a certain species of farmed fish, bearing the words 'contains *farmed* fish of the […] species only – may be used for the feeding of farmed fish of other fish species only'.

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

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

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

6. However:

(a) *points 1 to 5 shall not apply to* the identification of milk products, milk based products and milk derived products, defined as Category 3 material, by operators of milk-processing establishments which have been approved in accordance with Article 4 of Regulation (EC) 853/2004, in case they are collecting and returning to their establishment products which they have previously supplied to their customers;

(b) *points 1, 2(b)(i),(iii),(iv),(v),(vi),(vii), 3,4, and 5 shall not apply to* derived products which are placed on the market as feed in accordance with Article 4 of Regulation (EC) No 767/2009.

SECTION III

COMMERCIAL DOCUMENTS AND HEALTH CERTIFICATES

1. During transportation, a commercial document in accordance with the model set out in this Section, or, when required by this Regulation, a health certificate must accompany animal by-products and derived products.

   However, such document or certificate shall not be necessary, provided:

   (a) derived products from Category 3 material and organic fertilisers and soil improvers are supplied within the same Member State by retailers to final users other than business operators; and

   (b) milk products, milk based products and milk derived products which are Category 3 materials are collected and returned to their establishments by operators of milk-processing establishments, which have been approved in accordance with Article 4 of Regulation (EC) No 853/2004, if they have previously supplied those materials to their customers; and

   (c) derived products are placed on the market as feed in accordance with Article 4 of Regulation (EC) No 767/2009.

2. 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.

   Member States may require that proof of the arrival of the consignments is provided by the TRACES system or by a fourth copy of the commercial document which is sent back by the receiver to the producer as proof of the arrival of the consignment.

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

4. A commercial document in accordance with the model set out under point 8 shall accompany animal by-products and derived products as from the starting point referred to in Article 4(1) of the Animal By-products Regulation, during transportation within the European Union.

However, in addition to the authorisation to transmit information by way of an alternative system as referred to in the second subparagraph of the third paragraph of Article 21 of the Animal By-products Regulation, the competent authority may require, for the transport of animal by-products and derived products on their own territory:

(a) to use a different commercial document, in paper or in electronic form, provided that such commercial document contains the information referred to in point (f) of the notes under point 6 of this Section;

(b) that the quantity of the material is expressed in weight of the material in the commercial document.

5. Records and related commercial documents or health certificates shall be kept for a period of at least two years for presentation to the competent authority.

6. Model commercial document

Notes

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

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

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

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

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

(f) The original of the commercial document must be completed and signed by the responsible person.

The commercial document must specify:

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

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

(iii) the quantity of the material;

(iv) the place of origin of the material, *from where the material is dispatched*;

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

(vi) the name and the address of the receiver and, if applicable, its approval or registration number, which has been issued under the Animal By-products Regulation or Regulations (EC) No 852/2004 or No 853/2004, as applicable; and

(vii) if appropriate, the approval or registration number of the *establishment or* plant of origin, which has been issued under the Animal By-products Regulation or Regulations (EC) No 852/2004 or No 853/2004, as applicable, and the nature and the methods of the treatment.

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

(h) *The document reference number and the local reference number shall only be issued once for the same consignment.*

Commercial document

For the transport of animal by-products and derived products not intended for human consumption in accordance with the Animal By-products Regulation within the European Union

EUROPEAN COMMUNITY **Commercial document**

Part I : Details of consignment presented

I.1. Consignor
☐ Name
Address
Postal code

I.2. Document reference number

I.2.a.Local reference number:

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code

I.6.

I.7.

I.8.Country of origin ISO code

I.9. Region of origin Code

I.10. Country of destination ISO code

I.11. Region of destination Code

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

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

I.14. Place of loading
Postal code

I.15. Date and time of departure

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

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

I.18. Description of commodity

I.19. Commodity code (CN code)

I.20. Number/quantity

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

I.22. Number of packages

I.23. Identification of container/seal number

I.24.Type of packaging

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

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

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

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

I.29.

I.30.

I.31. Identification of the commodities

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

EUROPEAN UNION **Animal by-products/derived products not intended for human consumption**

Part II: Declaration

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

II. Declaration by the consignor

I, the undersigned, declare that:

II.1. the *information in Part I is factually correct*;

II.2. all precautions have been taken to avoid contamination of the animal by-products or *derived* products with pathogenic agents and cross-contamination between various Categories**.**

Notes

Part I:

- Box reference I.9 and I.11: if appropriate.
- *Box reference I.12 and I.13: approval number or registration number.*
- Box reference I.14: complete if different from 'I.1. Consignor'.
- Box reference I.31:

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

Nature of commodity: Enter a commodity chosen among the following list: 'apiculture products', 'blood products', 'blood', 'bloodmeal', 'derived products', 'digestion residues', 'digestive tract content', 'dogchews' (*unless beyond the end point*), 'fishmeal', 'flavouring innards', 'gelatine', 'greaves', 'hides and skins', 'hydrolysed proteins', 'organic fertilizers', 'petfood', 'processed animal protein', 'processed petfood' (*unless beyond the end point*), 'raw petfood', 'rendered fats', '*compost*', '*processed manure', 'fish oil', 'milk products', 'dicalciumphosphate', 'tricalciumphosphate', 'collagen', 'egg products', 'serum of equidae', 'game trophies', 'wool', 'hair', pig bristles', 'feathers*'.

Category: Categories 1, 2 or 3. In case of Category 3, specify which letter from a to p (as under Article 10 of Regulation (EC) No 1069/2009):

In the **case** of animal by-products for use in raw petfood indicate 3a or 3b whether the animal by-products are referred to in Article 10 point a or point b of Regulation (EC) No 1069/2009.

In the **case** of hides and skins and products derived there from, indicate 3b(iii) or 3n whether the animal by-products or derived products are referred to in Article 10 point b(iii) or point n.

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

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

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

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

The signature must be in a different colour to that of the printing
Signature Done at on (place) (date)   (signature of the responsible person/consignor)   (name, in capital letters)

SECTION IV

RECORDS

CHAPTER I

General provisions

1. The records as laid down in Article 22 (1) of the Animal By-products *Regulation for animal by-products and derived products, other than derived products which are placed on the market as feed in accordance with Article 4 of Regulation (EC) No 767/2009*, shall contain:

(a) a description of:

(i) the animal species for Category 3 material and derived products therefrom, destined for use as feed material and, if applicable, in the case of whole carcasses and heads, the ear-tag number;

(ii) the quantity of the material.

(b) in the case of records kept by any person consigning animal by-products *or derived products*, the following information:

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

(ii) the name and the address of the transporter and of the receiver and, if applicable, their approval number.

(c) in the case of records kept by any person transporting animal by-products *or derived products*, the following information:

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

(ii) the place of origin of the material, *from where the material is dispatched;*

(iii) the name and the address of the receiver and, if applicable, its approval number.

(d) in the case of records kept by any person receiving animal by-products *or derived products*, the following information:

(i) the date of reception of the material;

(ii) the place of origin of the material, *from where the material is dispatched*;

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

(iv) the name and address of the transporter.

2. *By way of derogation from point 1, operators do not have to keep the information referred to in point 1(a), (b)(i), (c)(i) and (iii) and d(ii) and (iv) separately, if they keep a copy of the commercial document laid down in Section III for each consignment and make this information available in conjunction with the other information required under point 1.*

3. Operators of incineration plants and co-incineration plants that are approved for the incineration or the co-incineration, as applicable, in accordance with Article 24(1)(b) or Article 24(1)(c) of the Animal By-products Regulation, as applicable, shall keep records of the quantities *and* category of animal by-products incinerated or co-incinerated, as applicable, and the date at which those operations were carried out.

CHAPTER II

Additional requirements in case of use for special feeding purposes

In addition to the records required in accordance with Chapter I, operators shall keep the following records in relation to relevant material if animal by-products are used for special feeding purposes in accordance with Section II of Annex VIII:

1. in the case of final users, the quantity used and the date of use, and

2. in the case of collection centers:

   (i) the quantity treated in accordance with point 3 of Chapter I of Section II of Annex VIII;

   (ii) the name and address of each final user *using* 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.

CHAPTER III

Requirements in case of certain fur animals

The responsible person for the feeding referred to in Chapter II of Annex IV shall keep records at least of:

(a) the number of furs and carcases of animals fed with meat-and-bone meal of their own species; and

(b) each consignment in order to ensure the traceability of the material;

CHAPTER IV

Requirements for the application of organic fertilisers and soil improvers, other than manure, to land

The person responsible for land to which organic fertilisers and soil improvers, other than manure, are applied and to which farmed animals have access or from which herbage is cut for feeding to farmed animals, shall keep records for at least two years of:

1. the quantities of organic fertilisers and soil improvers applied;

2. the date on which and the places where organic fertilisers and soil improvers were applied to land;

3. the dates, following application of the organic fertiliser or soil improver, on which livestock has been allowed to graze the land or on which the land has been cut for herbage to be used for feeding.

CHAPTER V

Requirements for fish by-products and feeding of fish

Processing plants must keep records in relation to the daily records of quantities *and the species of origin* of fishmeal or feed *originating from aquatic animals* produced and dispatched.

CHAPTER VI

Requirements for the burial and burning of animal by-products

In the case of burning or burial as provided for in Article 19 of the Animal By-products Regulation, the person responsible for burning or burial shall keep records of:

(a) the quantities, categories and species of animal by-products buried or burned;

(b) the date and place of burial and burning.

CHAPTER VII

Requirements for photogelatine

Operators of approved photographic factories referred to in Annex XVII Section II Chapter XII shall keep records detailing the purchases and uses of photogelatine, as well as the disposal of residues and surplus material.

SECTION V

MARKING OF CERTAIN DERIVED PRODUCTS

1. In processing plants which have been approved in accordance with Article 24(1)(a) of the Animal By-products Regulation for the processing of Category 1 or Category 2 material, derived products, with the exception of liquid products destined for biogas or composting plants, *of animal by-products and derived products used for feeding to fur animals in accordance with Chapter II of Annex IV and of biodiesel produced in accordance with point D of Chapter II of Section IV of Annex VI,* shall be permanently marked with glyceroltriheptanoate (GTH) in such a way that:

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

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

2. The operators of processing plants referred to in point 1 shall have in place a system of monitoring and recording of parameters suitable to demonstrate to the competent authority that the required homogeneous minimum concentration of GTH is achieved.

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

3. The marking with GTH shall not be required for derived products obtained in accordance with Article 12(a)(ii), 12(b)(ii) and Article 13(a)(ii), 13(b)(ii) and Article 16(e) of the Animal By-products Regulation, where such products are:

   (a) moved by a closed conveyer system, which may not be by-passed, and provided such a system has been authorised by the competent authority, from the processing plant for:

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

      (ii) immediate use in accordance with a method approved for Category 1 and 2 animal by-products in accordance with Section IV of Annex VI or

   (b) intended for purposes referred to in Article 17 of the Animal By-products Regulation which have been authorised by the competent authority.

ANNEX XI

REQUIREMENTS APPLICABLE TO CERTAIN
APPROVED AND REGISTERED ESTABLISHMENTS AND PLANTS

SECTION I

GENERAL REQUIREMENTS

CHAPTER I

Co-existence on the same site

The competent authority may approve more than one *establishment or* plant on the same site, provided that the transmission of risks to public and animal health between the plants is excluded by their layout and the handling of animal by-products and derived products within the establishment or plant.

CHAPTER II

Prevention of cross-contamination within food businesses

[…]

SECTION II

PROCESSING BY ALTERNATIVE METHODS

[…]

SECTION III

MANUFACTURING OF PETFOOD

Establishments or plants manufacturing petfood as referred to in Article 24(1)(e) of the Animal By-products Regulation shall fulfil the following requirements:

(a) they shall have adequate facilities for storing and treating incoming material in complete safety; and

(b) they shall have adequate facilities for disposing of unused animal by-products remaining after the production of the products in accordance with this Regulation, or this material must be sent to a processing plant or, *in the case of Category 3 material*, to a biogas or composting plant in accordance with the Animal By-products Regulation and with this Regulation.

SECTION IV

MANUFACTURING OF ORGANIC FERTILISERS AND SOIL IMPROVERS

[…]

SECTION V

HANDLING OF ANIMAL BY-PRODUCTS AFTER THEIR COLLECTION

The requirements of this Section shall apply to the following operations involving the handling of animal by-products after their collection, as referred to in Article 24(1)(h) of the Animal By-products Regulation ("*intermediate operations*"):

(a) sorting;

(b) cutting;

(c) chilling;

(d) freezing;

(e) salting *or other preservation processes*;

(f) removal of hides and skins;

(g) removal of specified risk material;

(h) operations involving the handling of animal by-products which are carried out in compliance with obligations under Union veterinary legislation, such as post-mortem examination or the taking of samples;

(i) hygienisation/pasteurisation of animal by-products destined for transformation into biogas or composting;

(j) temporary storage;

(k) sieving.

CHAPTER I

General requirements

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

   (a) The premises shall be adequately separated from other premises such as slaughterhouses. The layout of plants shall ensure the total separation of Category 1 and Category 2 material from Category 3 material *respectively*, from reception until dispatch, unless in a completely separate building.

   (b) The plant shall have a covered space to receive *and dispatch* animal by-products, unless the animal by-products are being discharged through installations which prevent the spreading of risks to public and animal health, such as through closed tubes for liquid animal by-products.

   (c) The plant shall 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 facilities including lavatories, changing rooms, washbasins for staff and, if appropriate, office space which can be made available to the staff performing official controls.

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

   (f) Where it is necessary for the purpose of achieving the objectives of this Regulation, plants shall 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 shall 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 shall be provided for the disinfecting of vehicle wheels.

CHAPTER II

Hygiene requirements

1. The sorting of animal by-products shall be carried out in such a way as to avoid any risk of the propagation of animal diseases.

2. All the time during storage, animal by-products shall be handled and stored separately from other goods and in such a way as to prevent any propagation of pathogens.

3. Animal by-products shall be stored properly, including under appropriate temperature conditions, until re-dispatched.

SECTION VI

REQUIREMENTS FOR STORAGE OF DERIVED PRODUCTS

CHAPTER I

General requirements

Premises and facilities must meet at least the following requirements.

1. Premises storing derived products from Category 3 material shall not be at the same site as premises storing derived products from Category 1 or Category 2 material, unless cross-contamination is prevented by way of the layout and management of the premises, *such as by storage in completely separate buildings*.

2. The plant shall:

   (a) have a covered space to receive the *derived* products, unless the derived products are

      (i) being discharged through installations which prevent the spreading of risks to public and animal health, such as through closed tubes for liquid products; or

      (ii) *received in packaging, such as in big bags, or in covered leak-proof containers*.

   (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 facilities including 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 shall have adequate facilities for cleaning and disinfecting the containers or receptacles in which the *derived* products are received and the vehicles, other than ships, in which they are transported.

4. *Derived p*roducts shall be stored properly until re-dispatched.

CHAPTER II

Specific requirements for storage of certain milk and milk-derived products

1. The storage of the products referred to in Part II of Chapter IV of Section II of Annex XIII shall take place at an appropriate temperature to avoid any risk to public or animal health in a dedicated approved storage establishment or plant or in a dedicated, separate storage area within an approved storage establishment or plant.

2. Samples of the final products taken during storage or at the time of withdrawal from storage, shall at least comply with the microbiological standards set out in point 1 of Section I of Annex XIII.

SECTION VII

REGISTERED OPERATORS

1. Operators of registered plants or establishments *or other registered operators* shall handle animal by-products and derived products under the following conditions:

   (a) Premises shall be constructed in a way permitting their effective cleaning and disinfection, where appropriate.

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

   (c) Installations and equipment shall be kept in hygienic condition, where necessary.

   (d) Animal by-products and derived products shall be stored under conditions preventing contamination.

2. *Registered o*perators transporting animal by-products or derived products shall in particular

   (a) have information at their disposal with regard to the identification of their vehicles, which allows the verification of the use of the vehicles for the transport of animal by-products or derived products;

   (b) clean and disinfect their vehicles, as appropriate;

   (c) *take all other necessary measures to prevent contamination and the spreading of diseases communicable to humans or animals.*

ANNEX XII

OWN CHECKS AND HACCP

[…]

ANNEX XIII

FEED MATERIALS

SECTION I

GENERAL REQUIREMENTS FOR THE PROCESSING AND PLACING ON THE MARKET

Microbiological standards for derived products

The following standards shall apply to derived products, other than rendered fat from the processing of animal by-products, where the processed animal protein is subject to sampling to ensure compliance with these standards:

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.

SECTION II

SPECIFIC REQUIREMENTS FOR PROCESSED ANIMAL PROTEIN AND OTHER DERIVED PRODUCTS

CHAPTER I

Specific requirements for processed animal protein

A. *Raw materials*

Only animal by-products which are Category 3 or products which are derived from such animal by-products, other than materials referred to in Article 10 (n), (o) and (p) of the Animal By-products Regulation may be used for the production of processed animal protein.

B. Processing standards

1. Processed animal protein of mammalian origin must have been submitted to processing method 1.

   However,

   (a) porcine blood or fractions of porcine blood for the production of bloodmeal may be submitted instead to any of processing methods 1 to 5 or processing method 7 provided that in the case of processing method 7, a heat treatment throughout its substance at a temperature of 80 ° C has been applied.

   (b) processed animal protein of mammalian origin

      (i) may have been submitted to any of the processing methods 1 to 5 or method 7, provided that it is disposed of as waste in accordance with Union legislation or used as a fuel for combustion;

      (ii) in case it is exclusively destined for use in petfood, may have been submitted to any of the processing methods 1 to 5 or 7, provided that it is transported in dedicated containers that are not used for the transport of animal by-products or feedingstuffs for farmed animals, and provided it is consigned directly from a processing plant for Category 3 material to the petfood plant.

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 which ensures that the product complies with the microbiological standards set in Section I.

C. Storage

1. Processed animal protein must be packed and stored in new or sterilised bags or stored in properly constructed bulk bins *or in storage sheds, if authorised by the competent authority*.

Sufficient measures must be taken to minimise condensation inside bins, conveyors or elevators.

2. Products in conveyors, elevators and bins must be protected from casual contamination.

3. 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, *to the extent necessary to prevent contamination.*

4. Processed animal protein must be kept dry. Leakages and condensation in the storage area must be prevented.

CHAPTER II

Specific requirements for blood products

A. Raw material

Only blood referred to in Article 10 a, b(i) and d of the Animal By-products Regulation may be used for the production of blood products.

B. Processing standards

Blood products must have been submitted to:

(a) any of processing methods 1 to 5 or 7;

(b) a method which ensures that the blood product complies with the microbiological standards set out in Section I.

CHAPTER III

Specific requirements for rendered fats and fish oil

A. *Raw materials*

Only animal by-products which are Category 3 or products which are derived from such animal by-products, other than materials referred to in Article 10 (n), (o) and (p) of the Animal By-products Regulation may be used for the production of rendered fat and fish oil.

B. Processing standards

Unless the *fish oil or* rendered fats have been produced in accordance with Sections *VIII or* XII of Annex III to Regulation (EC) No 853/2004, *respectively*, rendered fats must be produced using any of the processing methods 1 to 5 or method 7, and fish oils may be produced using methods 1 to 7, as referred to in Section III of Annex VI, *or in accordance with a method which ensures that the product complies with the microbiological standards set in point 1 of Section I.*

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.

C. Hygiene requirements

Where rendered fat or fish oil is packaged, it must be packaged in new containers or in containers that have been cleaned *and disinfected, if necessary for the prevention of contamination* 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 be clean before use.

CHAPTER IV

Specific requirements for milk, milk-based products and colostrums

PART I

General requirements

A. *Raw material*

Only milk referred to in Article 10 (e), (f) and (h) of the Animal By-products Regulation may be used for the production of milk and milk-based products.

Colostrum may only be used provided that it originates from live animals that did no show any signs of disease communicable through the colostrums to humans or animals.

B. *Processing standards*

1. Milk must be subjected to one of the following treatments:

1.1. sterilisation at an F_0 (*) value of three or more;

1.2. UHT (**) combined with one of the following:

(a) a subsequent physical treatment, by:

(i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

(ii) lowering the pH below 6 for at least 1 hour;

(b) the condition that the milk or milk product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin;

1.3. HTST (***) applied twice;

1.4. HTST in combination with one of the following:

(a) a subsequent physical treatment, by:

(i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

(ii) lowering the pH below 6 for at least 1 hour;

(b) the condition that the milk or milk product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin.

2. Milk products must either be subjected to at least one of the treatments provided for in paragraph 1 or be produced from milk treated in accordance with paragraph 1.

3. Whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with paragraph 1 must be collected at least 16 hours after milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings.

4. In addition to the requirements laid down in paragraphs 1, 2 and 3, milk and milk products must meet the following requirements:

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* F_0 is the calculated killing effect on bacterial spores. An F0 value of 3, 00 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250 °F) in three minutes with instantaneous heating and chilling.

** UHT = Ultra High Temperature treatment at 132 °C for at least one second.

*** HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.

4.1. after completion of the processing, every precaution must be taken to prevent contamination of the products;

4.2. the final product must be labelled so as to indicate that it contains Category 3 material and is not intended for human consumption, and

(a) packed in new containers; or

(b) transported in bulk in containers or other means of transport that before use were thoroughly cleansed and disinfected.

5. Raw milk [and colostrum] must be produced under conditions offering adequate guarantees as regards animal health.

PART II

Derogation for national markets

1. The following requirements shall apply to the processing, use and storage of milk, milk-based products and milk-derived products which fall under the definition of Category 3 material, as referred to in Articles 10 (e), (f) and (h) of the Animal By-products Regulation, that have not been processed in accordance with Part I of this Chapter.

2. The competent authority shall authorise milk processing establishments approved in accordance with Article 4 of Regulation (EC) No 853/2004 to supply milk and milk-derived products for the purposes referred to in point 3 provided the establishment concerned ensures traceability of the products.

3. Milk and milk-derived products may be supplied and used as feed material

(a) in the Member State concerned and in cross-border areas where the Member States concerned have a mutual agreement to that effect, in the case of derived products, including *white* water, which have been in contact with raw milk and/or milk pasteurised in accordance with Chapter II point II.1(a) or (b) of Section IX to Regulation (EC) No 853/2004;

(b) in the Member State concerned,

(i) in the case of derived products, including *white* water, which have been in contact with milk that has only been pasteurised in accordance with Chapter II point II(a) of Section IX to Regulation (EC) No 853/2004, and whey produced from non heat-treated milk-based products, which has been collected at least 16 hours after milk clotting and where the pH must be recorded as < 6,0 before supplying the whey for feeding, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of the risk assessment for the best and worst case scenarios carried out by the Member State concerned in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease;

(ii) in the case of raw products, including *white* water that has been in contact with raw milk and other products for which the treatments referred to in points (a) and (b) cannot be ensured, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of the risk assessment for the best and worst case scenarios carried out by the Member State concerned in preparation of the contingency plans for epizootic diseases, in particular foot-and-mouth disease, and provided that the animals present in the authorised animal holdings can only be moved

- either directly to a slaughterhouse located in the same Member State; or

- to another holding in the same Member State, for which the competent authority guarantees that animals susceptible to foot-and-mouth disease may leave the holding only either directly to a slaughterhouse located in the same Member State, or if the animals have been dispatched to a holding not feeding the products referred to in this point (ii), after a 21-day standstill period has elapsed from the introduction of the animals.

CHAPTER V

Specific requirements for gelatine and hydrolysed protein

A. *Raw materials*

Only animal by-products which are Category 3 or products which are derived from such animal by-products, other than materials referred to in Article 10 (n), (o) and (p) of the Animal By-products Regulation may be used for the production of gelatine and hydrolysed protein.

B. Processing standards for gelatine

1. Gelatine must be produced by a process that ensures that Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

2. After having been subjected to the processes referred to in subparagraph 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.

3. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.

C. Other requirements for gelatine

Gelatine must be wrapped, packaged, stored and transported under satisfactory hygiene conditions.

In particular:

(a) a room *or a dedicated place* 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.

D. Processing standards for hydrolysed protein

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

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

(a) exposure of the material to a pH of more than 11 for more than three hours at a temperature of more than 80 °C and subsequently by heat treatment at more than 140 °C for 30 minutes at more than 3,6 bar; *or*

(b) exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140 °C for 30 minutes at 3 bar.

CHAPTER VI

Specific requirements for dicalcium phosphate

A. *Raw materials*

Only animal by-products which are Category 3 or products which are derived from such animal by-products, other than materials referred to in Article 10 (n), (o) and (p) of the Animal By-products Regulation may be used for the production of dicalcium phosphate.

B. Processing standards

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

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

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

(c) finally, air dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C,

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.

CHAPTER VII

Specific requirements for tricalcium phosphate

A. *Raw materials*

Only animal by-products which are Category 3 or products which are derived from such animal by-products, other than materials referred to in Article 10 (n), (o) and (p) of the Animal By-products Regulation may be used for the production of triclacium phosphate.

B. *Processing standards*

Tricalcium phosphate must be produced by a process that ensures:

(a) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);

(b) continuous cooking with steam at 145 °C during 30 minutes at 4 bars.

(c) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation; and

(d) granulation of the tricalcium phosphate after drying in a *fluidised* bed with air at 200^0 C.

CHAPTER VIII

Specific requirements for collagen

A. *Raw materials*

Only animal by-products which are Category 3 or products which are derived from such animal by-products, other than materials referred to in Article 10 (n), (o) and (p) of the Animal By-products Regulation may be used for the production of collagen.

B. *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 Union legislation shall be prohibited.

C. Other requirements

Collagen must be wrapped, packaged, stored and transported under satisfactory hygiene conditions. In particular:

(a) a room *or a dedicated place* 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.

CHAPTER IX

Specific requirements for egg products

A. *Raw materials*

Only animal by-products referred to in Article 10 (e), (f) and (k)(ii) of the Animal By-products Regulation may be used for the production of egg products.

B. *Processing standards*

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 Section I; or

(c) treated in accordance with Section X, Chapters I to III of Annex III to Regulation (EC) No 853/2004.

CHAPTER X

Specific requirements for centrifuge or separator sludge

Centrifuge or separator sludge from milk processing referred to in Article 10(e) of the Animal By-products Regulation must have been subjected to a heat treatment of at least 70°C for 60 minutes or of at least 80°C for 30 minutes, before it may be placed on the market for feeding for farmed animals.

CHAPTER XI

Specific requirements for certain Category 3 material

Category 3 material referred to in Article 10(f) and (g) of the Animal By-products Regulation may be placed on the market for feeding to farmed animals, provided that:

(a) the material is not composed of and has not been in contact with material of animal origin which has neither undergone processing in accordance with this Regulation nor undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004; and

(b) all necessary precautions have been taken to prevent the contamination of the material when it is destined to purposes other than human consumption.

SECTION III

REQUIREMENTS FOR CERTAIN FISH FEED AND FISHING BAITS

1. *Animal by-products from aquatic animals and* derived products from aquatic animals that are intended as feed for farmed fish shall:

(a) be handled and processed separately from material not authorised for that purpose;

(b) originate

(i) from wild fish or other aquatic animals, *except sea mammals, landed* for *commercial* purposes of fishmeal production, or from animal by-products from wild fish *originating* in plants manufacturing fish products for human consumption; or

(ii) from farmed fish, *provided it is fed to farmed fish* of another species; *and*

(c) be processed in a processing plant approved in accordance with Article 24(1)(a) of the Animal By-products Regulation to a standard which ensures a microbiological safe product, *including with regard to fish pathogens*;.

2. *The competent authority may, provided there is no risk for the transmission of diseases communicable to humans or animals, authorise the use of animal by-products:*

(a) *as feed for farmed fish, when the animal by-products have not been processed in accordance with point 1(c);*

(b) *as fishing bait.*

ANNEX XIV

SPECIFIC REQUIREMENTS FOR PLACING ON THE MARKET OF ORGANIC FERTILISERS, APPLICATION TO LAND

SECTION I

REQUIREMENTS FOR UNPROCESSED MANURE, PROCESSED MANURE AND PROCESSED MANURE PRODUCTS

CHAPTER I

Unprocessed manure

1. Trade in unprocessed manure of species other than poultry or equidae between Member States is subject to the following conditions:

   (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, *having regard to the origin of the manure, its destination and animal health considerations,* grant specific approval for the introduction on to its territory of:

      (i) manure intended for processing in a plant for the manufacture of derived products *which are destined* for uses outside the feed chain or *manure intended* for transformation into biogas or composting *in accordance with the Animal By-products Regulation and with this Regulation* with a view to the manufacture of the products referred to under Chapter II below; the competent authority shall take account of the origin of the manure when approving such plants; or

      (ii) manure intended for applying to land on a holding, *provided that the competent authority of the Member State of origin has communicated its agreement to such trade*.

   (c) in the cases referred to in point (b), a health certificate shall accompany the manure.

2. Trade in unprocessed poultry manure *between Member States* 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 Directive 2009/158/EC; and

(c) a health certificate shall accompany the manure.

3. Unprocessed manure of equidae may be traded between Member States, provided it does not originate from a holding subject to animal health restrictions pertaining to glanders, vesicular stomatitis, anthrax or rabies in accordance with Article 4(5) of Directive 90/426/EEC.

CHAPTER II

Processed manure and processed manure products and guano

1. The placing on the market of processed manure and processed manure products shall be subject to the following conditions:

(a) They shall come from a plant for derived products for uses outside the feed chain or *from a* biogas or a composting plant.

(b) They shall have been subjected to a heat treatment process of at least 70 °C for at least 60 minutes and they shall have been subjected to reduction in spore-forming bacteria and *toxin* formation, *where they are identified as a relevant hazard*.

(c) However, the competent authority may authorise the use of other standardised process parameters than those described in (b) provided an applicant demonstrates that such parameters ensure minimising of biological risks. This demonstration shall include a validation, which shall be carried out as follows:

(i) Identification and analysis of possible hazards including the impact of input material, based on a full definition of the processing conditions, and a risk assessment, which evaluates how the specific processing conditions are achieved in practice under normal and atypical situations.

(ii) Validation of the intended process

(ii-1) by measuring the reduction of viability/infectivity of endogenous indicator organisms during the process, where the indicator is:

– consistently present in the raw material in high numbers,

– not less heat resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor,

– relatively easy to quantify and relatively easy to identify and confirm;

or

(ii-2) by measuring the reduction of viability/infectivity, during exposure, of a well-characterised test organism or virus introduced in a suitable test body into the starting material.

(iii) The validation referred to in point (ii) must demonstrate that the process achieves the following overall risk reduction:

– for thermal and chemical processes by reduction of *Enterococcus faecalis* by at least 5 log10 and by reduction of infectivity titre of thermo resistant viruses such as *parvovirus*, where they are identified as a relevant hazard, by at least 3 log10,

– for chemical processes also by reduction of resistant parasites such as eggs of *ascaris sp*. by at least 99,9 % (3 log10) of viable stages.

iv) Designing a complete control programme including procedures for monitoring the process.

(v) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a plant as well as other critical control points shall be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant. Information relating to a process authorised under this point must be made available to the Commission on request; and

(d) Representative samples of the manure taken during or immediately after processing at the plant in order to monitor the process must comply with the following standards:

Escherichia coli: n = 5, c = 5, m= 0, M= 1 000 in 1 g;

or

Enterococaceae: n = 5, c = 5, m = 0, M = 1 000 in 1 g;

and

Representative samples of the manure taken during or on withdrawal from storage at the *plant of production or the* biogas or composting plant must comply with the following standards:

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

where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria n 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.

Processed manure or processed manure products not complying with the above requirements shall be regarded as unprocessed;

(e) They must be stored in such a way that once processed contamination or secondary infection and dampness is minimised. They must therefore be stored in:

(i) well-sealed and insulated silos *or properly constructed storage sheds*, or

(ii) properly sealed packs, *such as* plastic bags or "big bags".

2. The placing on the market, other than the importation, of non-mineralised guano is not subject to any animal health conditions.

SECTION II

REQUIREMENTS FOR CERTAIN ORGANIC FERTILISERS AND SOIL IMPROVERS, *OTHER THAN MANURE, DIGESTION RESIDUES AND COMPOST*

CHAPTER I

Conditions for the production

1. Organic fertilisers and soil improvers, other than manure, *digestive tract content, compost, milk, colostrum* and digestion residues from *the* transformation *of animal by-products or derived products* into biogas, shall be produced

   (a) by applying processing method 1, *when* Category 2 material is used as starting material;

   (b) by applying any of the processing methods 1 to 7, *when* Category 3 material is used as starting material.

2. Organic fertilisers and soil improvers which have been produced from meat and bone meal derived from Category 2 material and from processed animal protein *or from other products derived from Category 3 material*, other than those which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer on which it is indicated that they are not destined for application to *land to which farmed animals have access*, shall be mixed, in an approved or registered establishment or plant or on farm, with a component which is *authorised* by the competent authority *of the Member State where the product is to be applied to land,* according to the following:

   (a) the component consists of lime, manure, urine, compost or digestion residues from the transformation of animal by-products into biogas or other substances, such as mineral fertilisers, which are not used in animal feed and which exclude the subsequent use of the mixture for feeding purposes according to good agricultural practice;

   (b) the component is determined based on an assessment of the climatic and soil conditions for the use of the mixture as a fertiliser and the requirements laid down in Union legislation *or, where applicable, national legislation,* for the protection of the environment regarding the protection of soil and groundwater;

   (c) the component is added to a sufficient minimum proportion which ensures that the objective referred to in point (a) is met.

3. Producers of organic fertilisers and soil improvers must ensure that decontamination of pathogens is carried out prior to their application to land, in accordance with:

   – Annex XIII, Section I, point 1 in the case of processed animal protein or derived products from Category 2 *or Category 3* material;

   – Annex VII, Section III, Chapter III in the case of compost and *digestion* residues *from the transformation of animal by-products or derived products into biogas*.

CHAPTER II

Storage and transport

After processing and/or transformation, organic fertilisers and soil improvers shall be properly stored and transported

(a) in bulk, under appropriate conditions that prevent contamination; or

(b) packaged, in the case of organic fertilisers or soil improvers destined for sale to final users.

CHAPTER III

Application to land

*As referred to in Article 30(1) of the Animal By-products Regulation, t*he competent authority shall *encourage, where necessary, the development, dissemination and use of* codes of good agricultural practice for *the application of* organic fertilisers and soil improvers to land.

ANNEX XV

MANUFACTURE AND PLACING ON THE MARKET OF DERIVED PRODUCTS REGULATED BY OTHER UNION LEGISLATION

SECTION I

DERIVED PRODUCTS REFERRED TO IN ARTICLE 33 OF THE ANIMAL BY-PRODUCTS REGULATION

[…]

SECTION II

INTERMEDIATE PRODUCTS

In accordance with Article 34(2) of the Animal By-products Regulation, the following shall apply to the importation and transit through the European Union of intermediate products:

1. The import and transit of intermediate products shall be authorised, provided:

   (a) they are derived from the following materials:

      (i) Category 3 material referred to in Article 10 (a), (b), (d), (e), (f), (g), (h), (i), (j), (k), (l) and (m) of the Animal By-products Regulation;

      (ii) products derived from or generated by the animals referred to in Article 10 (i), (l) and (m) of the Animal By-products Regulation; or

      (iii) *mixtures of the materials referred to under point (i) and (ii);*

   (b) *in the case of medical devices, in vitro diagnostic medical devices and laboratory reagents, they are derived from:*

      (i) *materials referred to in point (a), which may have originated from animals referred to in Article 8(c) of the Animal By-products Regulation;*

      (ii) *Category 2 material referred to in Article 9 (f) and (h) of the Animal By-products Regulation; or*

      (iii) *mixtures of the materials referred to under point (i) and (ii);*

   (c) *in the case of active implantable medical devices, medicinal products and veterinary medicinal products, they are derived from the materials referred to in point (b), in case the competent authority considers the use of such materials justified for the protection of public or animal health;*

   (d) they come from a third country listed as a member of the World Organisation for Animal Health (OIE) in the OIE bulletin;

(e) they come from an establishment or plant registered or approved by the competent authority of a third country referred to in point (b), in accordance with the conditions set out in point 2;

(f) each consignment is accompanied by a commercial document, which

(i) must be in at least one of the official languages of the EU Member State in which inspection at the border inspection post shall be carried out and of the EU Member State of destination; these Member States may allow other languages and request official translations for declarations in such other languages;

(ii) must indicate:

- the country of origin;

- the name and address of the establishment of production; and

- that the outer packaging of intermediate products is labelled 'FOR MEDICINAL PRODUCTS/ VETERINARY MEDICINAL PRODUCTS/ MEDICAL DEVICES/ IN VITRO DIAGNOSTICS/ LABORATORY REAGENTS ONLY';

(g) each consignment is accompanied by a declaration of the importer in accordance with the model declaration set out in Chapter 20 of Annex XVIII, which must be at least in one of the official languages of the EU Member State in which the inspection at the border inspection post shall be carried out and of the EU Member State of destination; these Member States may allow other languages and request official translations for declarations in such other languages

(h) in the case of materials referred to in point (b), the importer demonstrates:

(i) *that the materials do not carry any risk of transmission of a disease communicable to humans or animals; or*

(ii) *that the materials are transported under conditions which prevent the transmission of such diseases.*

2. An establishment or plant may be registered or approved by the competent authority of a third country, as referred to in point 1(c), provided:

(a) the operator or owner of the plant or his representative:

(i) demonstrates that the plant has adequate facilities for the transformation of the materials referred to in point 1(a), to ensure the completion of the necessary design, transformation and manufacturing stages;

(ii) establishes and implements methods of monitoring and checking the critical control points on the basis of the process used;

(iii) keeps a record of the information obtained pursuant to point (ii) for a period of at least to years for submission to the competent authority;

(iv) informs the competent authority if any available information reveals the existence of a serious animal health or public health risk;

(b) the competent authority of the third country carries out, at regular intervals, inspections of the establishment or plant and supervises the plant in accordance with the following:

(i) the frequency of inspections and supervision shall depend on the size of the plant, the type of products manufactured, risk assessment and guarantees offered, based on *a system of checks which has been set up in accordance with* the HACCP principles;

(b) if the inspection carried out by the competent authority reveals that the provisions of this Regulation are not being complied with, the competent authority shall take appropriate action;

(c) the competent authority shall draw up a list of establishments or plants approved or registered in accordance with this Section and shall assign an official number to each plant, which identifies the establishment or plant with respect to the nature of its activities; the list and subsequent amendments shall be submitted to the EU Member State in which the inspection at the border inspection post shall be carried out and to the Member State of destination.

3. The intermediate products imported into the Union shall be checked at the border inspection post of first entry in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post of entry into the Union either:

(a) to a registered establishment or plant for the production of the derived products referred to in Article 33 of the Animal By-products Regulation, where the intermediate products shall be further mixed, used for coating, assembled, packaged or labelled before they are placed on the market or put into services in accordance with the Union legislation applicable to the derived product;

(b) to an establishment or plant which has been approved in accordance with Article 24(1)(h), from where they shall only be dispatched to an establishment or plant referred to in point (a) for the uses referred to in that point.

4. *By way of derogation to Article 34(2) of the Animal By-products Regulation, intermediate products which have been transported to an establishment or plant referred to in point 3, may be handled without further restrictions under the Animal By-products Regulation and under this Regulation, provided that:*

(a) *the establishment or plant has adequate facilities for the receipt of the intermediate products, which prevent the transmission of diseases communicable to humans or animals;*

(b) *the intermediate products do not pose any risk of transmission of diseases communicable to humans or animals, due to their purification or to other*

treatments to which the animal by-products in the intermediate product have been submitted, due to the concentration of animal by-products in the intermediate product or due to adequate bio-security measures for the handling of the intermediate products;

(c) *the establishment or plant keeps records on the amount of materials received, their category, if applicable, and the establishment, plant or operator to whom they have supplied their products; and*

(d) *unused intermediate products or other surplus materials from the establishment or plant, such as expired products, are disposed of in accordance with the Animal By-products Regulation.*

5. Intermediate products in transit through the Union shall be transported in accordance with Article 11 of Directive 97/78/EC.

6. The official veterinarian at the border inspection post concerned shall inform the authority in charge of the establishment or plant at the place of destination of the consignment by means of the TRACES system.

7. The outer packaging of intermediate products shall be labelled 'FOR MEDICINAL PRODUCTS/ VETERINARY MEDICINAL PRODUCTS/ MEDICAL DEVICES/ IN VITRO DIAGNOSTICS/ LABORATORY REAGENTS ONLY'.

8. The operator or owner of the establishment or plant of destination or his representative shall use and/or dispatch the intermediate products exclusively for the purposes specified in point 2(a).

9. The operator or owner of the establishment or plant of destination or his representative shall keep records in accordance with Article 22 of the Animal By-products Regulation and shall provide the competent authority on request with the necessary details of purchases, sales, uses, stocks and disposals of surplus of the intermediate products for the purposes of checking compliance with this Regulation.

10. The competent authority shall ensure, in accordance with Directive 97/78/EC, that the consignments of intermediate products are sent from the EU Member State in which the inspection at the border inspection post shall be carried out to the plant of destination, as referred to in point 2(a) or, in the case of transit, to the post of exit.

11. The competent authority shall carry out documentary checks at regular intervals for the purpose of reconciliation of the quantities of intermediate products imported on the one hand, and stocked, used, dispatched or disposed of on the other, in order to check compliance with this Regulation.

12. For consignments of intermediate products in transit, the competent authorities responsible for the border inspection posts of entry and of exit respectively shall cooperate as necessary to ensure that effective checks are carried out and to ensure the traceability of such consignments.

ANNEX XVI

PETFOOD AND CERTAIN OTHER DERIVED PRODUCTS

CHAPTER I

General provisions

1. The use of Category 1 material referred to in Article 8 points (a), (b), (d), (e), (f) and (g) of the Animal By-products Regulation for the manufacture of derived products which are intended to be ingested by or applied to humans or animals, other than derived products referred to in Articles 33 and 36 of The Animal By-products Regulation, is prohibited.

2. Plants producing derived products referred to in this *Annex* shall

   (a) have adequate facilities for storing and treating incoming material under conditions which prevent the introduction of risks to public and animal health;

   (b) have adequate facilities for disposing of unused animal by-products and derived products remaining after production, unless the unused material is sent for processing or disposal to another establishment or plant, in accordance with this Regulation.

CHAPTER II

Petfood and dogchews

1. Raw petfood

   Raw petfood may only be manufactured from animal by-products referred to in Article 35(a)(iii) of the Animal By-products Regulation. Raw petfood must be packed in new packaging preventing any leakage. Effective steps must be taken to ensure that the product is not exposed to contamination throughout the production chain and up to the point of sale.

2. Raw material for processed petfood and for dogchews

   The only animal by-products that may be used to produce petfood and dogchews are those referred to in Article 35(a)(i) and (a)(ii) of the Animal By-products Regulation.

3. Processed petfood

   (a) Canned petfood must be subjected to heat treatment to a minimum Fc value of 3.

   (b) Processed petfood other than canned petfood must:

(i) be subjected to a heat treatment of at least 90°C throughout the substance of the final product;

(ii) be subjected to a heat treatment to at least 90°C of the ingredients of animal origin; or

(iii) be produced as regards *feed materials* of animal origin exclusively using:

- meat or meat products which have been subject to a heat treatment of at least 90°C throughout their substance;

- the following derived products which have been *produced* in accordance with the requirements of this Regulation: milk and milk based products, gelatine, hydrolysed protein, egg products, collagen, blood products, processed animal protein including fishmeal, rendered fat, fish oils, dicalcium phosphate, tricalcium phosphate or flavouring innards

(iv) *if authorised by the competent authority, be subject to a treatment such as drying or fermentation, which ensures that the petfood poses no unacceptable risks to public and animal health;*

(v) *in the case of aquatic and terrestrial invertebrates referred to in Article 10(l) and animal by-products referred to in Article 10 (m) of the Animal By-products Regulation, and if authorised by the competent authority, be subject to a treatment which ensures that the petfood poses no unacceptable risks to public and animal health.*

After production, every precaution must be taken to ensure that such processed petfood is not exposed to contamination.

The processed petfood must be packaged in new packaging.

4. Dogchews must be subjected to a treatment sufficient to destroy pathogenic organisms, including salmonella.

After that treatment, every precaution must be taken to ensure that such dogchews are not exposed to contamination.

The dogchews must be packed in new packaging.

5. Random samples must be taken *from processed petfood other than canned petfood and from dogchews* 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.

6. *Random samples must be taken from raw petfood* 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 = 5000 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.

7. End point for processed petfood *and dogchews*

(a) Processed petfood which has been manufactured and packaged in *the Union in* accordance with point 3 and which has been tested in accordance with point 5 may be placed on the market without restrictions in accordance with this Regulation.

(b) *Dogchews which have been manufactured and packaged in the Union in accordance with point 4 and which has been tested in accordance with point 5 may be placed on the market without restrictions in accordance with this Regulation.*

CHAPTER III

Flavouring innards for the manufacture of petfood

1. Only animal by-products referred to in Article *35 (a)* of the Animal By-products Regulation may be used for the production of liquid / dehydrated *derived* products of animal origin used to enhance the palatability values of pet food.

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 Chapter II, paragraph 5 to this Annex. 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.

CHAPTER IV

Requirements for blood and blood products from equidae

The placing on the market of blood and blood products from equidae *for purposes other than in feed for farmed animals* shall be subject to the following conditions:

1. Blood may be placed on the market provided that:

   (a) it has been collected from equidae which:

      (i) at inspection on the date of blood collection do not show clinical signs of any of the compulsorily notifiable diseases listed in Annex A to Directive 90/426/EEC and of Equine influenza, Equine piroplasmosis, Equine rhinopneumonitis and Equine viral arteritis listed in point 4 of Article 1.2.3. of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), 2009 Edition;

      (ii) have been kept for at least 30 days prior to the date of and during blood collection on holdings under veterinary supervision which were not subject to a prohibition order pursuant to Article 4(5) of Directive 90/426/EEC or restrictions pursuant to Article 5 thereof;

      (iii) for the periods laid down in Article 4(5) of Directive 90/426/EEC had no contact with equidae from holdings which were subject to a prohibition order for animal health reasons pursuant to that Article and for at least 40 days prior to the date of and during blood collection had no contact with equidae from a Member State or third country not considered free of African horse sickness in accordance with Article 5(2)(a) of that Directive;

   (b) it has been collected under veterinary supervision either:

      (i) in slaughterhouses approved in accordance with Regulation (EC) No 853/2004; or

(ii) in facilities approved, furnished with a veterinary approval number and supervised by the competent authority for the purpose of collecting blood from equidae for the production of blood products for purposes *other than feeding to farmed animals.*.

2. Blood products may be placed on the market provided that:

(a) all precautions have been taken to avoid contamination of the blood products with pathogenic agents during production, handling and packaging;

(b) the blood products have been produced from blood which:

(i) either fulfils the conditions set out in paragraph 1(a); or

(ii) has been subjected to at least one of the following treatments, followed by an effectiveness check, for the inactivation of possible causative pathogens for African horse sickness, equine encephalomyelitis of all types including Venezuelan equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and glanders (*Burkholderia mallei*):

– heat treatment at a temperature of 65°C for at least three hours;

– irradiation at 25 kGy by gamma rays;

– change in pH to pH 5 for two hours;

– heat treatment of at least 80°C throughout their substance.

3. Blood and blood products from equidae must be packed in sealed impermeable containers which:

(a) are clearly labelled "BLOOD AND BLOOD PRODUCTS FROM EQUIDAE, NOT FOR HUMAN OR ANIMAL CONSUMPTION"';

(b) bear the approval number of the establishment of collection referred to in paragraph 1(b).

CHAPTER V

Hides and skins of ungulates

A. Establishments and plants

The competent authority may authorise plants handling hides and skins to supply trimmings and splittings of these hides and skins for the production of gelatine in accordance with Annex XIII Section I and Section II Chapter V, provided that

(a) the plant fulfils the conditions for a special authorisation in accordance with Annex III Section XIV Chapter I point 5 of Regulation (EC) No 853/2004;

(b) in case of trimmings and splittings derived from limed hides, the trimmings and splittings are submitted to a treatment which ensures that no risks to public and animal health remain.

B. Placing on the market

1. Fresh and chilled hides and skins may be placed on the market subject to the health conditions applicable to fresh meat pursuant to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.

2. Treated hides and skins as defined in point 40 of Annex I may be placed on the market, provided that:

(a) they have not been in contact with other animal products or live animals presenting a risk of spreading a serious transmissible disease; and

(b) the commercial document laid down in Section III of Annex X contains a statement to this effect.

C. End point for hides and skins

3. Hides and skins of ungulates complying with the requirements of Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin, *which pursuant to the decision of an operator as referred to in Article 2(1)(b) of the Animal By-products Regulation are destined for purposes other than human consumption*, may be placed on the market without *additional* restrictions in accordance with this Regulation.

4. The following hides and skins may be placed on the market without restrictions in accordance with this Regulation:

(a) hides and skins of ungulates having undergone the complete process of tanning;

(b) ‘wet blue’;

(c) 'pickled pelts’; and

(d) limed hides (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).

CHAPTER VI

Game trophies and other preparations from animals

A. The provisions of this Chapter are without prejudice to the measures adopted pursuant to Regulation (EC) No 338/97.

B. Safe sourcing

The following game trophies are not subject to any restrictions:

(a) game trophies *or other preparations from animals which eliminate potential risks to public and animal health,* of species other than ungulates and birds.

(b) game trophies *or other preparations from animals which eliminate potential risks to public and animal health,* which

(i) have undergone

- a complete taxidermy treatment ensuring their preservation at ambient temperatures, *including mounted whole animals and mounted parts of animals*;

- *an anatomical preparation such as by plastination; or*

- *in the case of animals of the biological class Insecta or Arachnida, a treatment such as drying to prevent any transmission of diseases communicable to humans or animals;* and

(ii) 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.

C. Safe treatment

1. Game trophies *or other preparations* of ungulates and birds which have undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures are not subject to any restrictions.

2. Game trophies *or other preparations, other than those referred to under point 1,* which 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, shall:

(a) in case of game trophies *or other preparations* solely of bone, horns, hooves, claws, antlers or teeth,

(i) *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;

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

(iii) *have* be*en* 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

(iv) be accompanied by a document or *health* certificate certifying that the above conditions have been met;

(b) in case of game trophies *or other preparations* consisting solely of hides or skin,

(i) be either

- dried;

- dry- or wet-salted for a minimum of 14 days before dispatch; or

- preserved by a treatment other than tanning;

(ii) *have* be*en* 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

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

CHAPTER VII

Wool, hair, pig bristles, feathers and parts of feathers

A. Raw material

1. *Untreated* wool, un*treated* hair, *untreated* pig bristles and *untreated* feathers and parts of feathers must have been obtained from animal by-products referred to in Article 10 (b) (iii), (iv), or, (v) of the Animal By-products Regulation.

They must be securely enclosed in packaging and dry.

However, in the case of *untreated* feathers and parts of feathers sent directly from the slaughterhouse to the processing plant, the competent authority may allow a derogation from the requirement *to dry the feathers*, provided that:

(a) all necessary measures are taken to avoid any possible spread of disease;

(b) the transport takes place in *water*-proof containers and/or vehicles which must be cleansed and disinfected immediately after each use; and

(c) the Member State notifies the Commission when such derogation is given.

2. Movements of pig bristles from regions in which African swine fever is endemic are prohibited except for pig bristles that have:

(a) been boiled, dyed or bleached; or

(b) 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.

3. 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. End point

4. [Factory-washed wool] may be placed on the market without restrictions in accordance with this Regulation.

CHAPTER VIII

Furs

End point

Furs which have been dried at an ambient temperature of 18°C for two days at a humidity of 55% may be placed on the market without restrictions in accordance with this Regulation.

CHAPTER IX

Apiculture by-products

Apiculture by-products intended exclusively for use in apiculture must:

1. not come from an area which is subject of a prohibition order associated with an occurrence of:

(a) 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;

(b) acariosis (Acarapis woodi (Rennie), except where the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC;

(c) small hive beetle (Aethina tumida); or

(d) Tropilaelaps spp. (Tropilaelaps spp); and

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

[CHAPTER X

Rendered fats from *Category 1 or* Category 2 materials for oleochemical purposes

1. Rendered fats derived from *Category 1 material or* from Category 2 material for oleochemical purposes must be produced using methods 1 to 5 as referred to in Section III of Annex VI.

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.]

CHAPTER XI

Fat derivatives

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

1. transesterification or hydrolysis at least 200 °C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters);

2. saponification with NaOH 12M (glycerol and soap):

   (a) in a batch process at 95 °C for three hours; or

   (b) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or

3. *hydrogenation at 160°C at 12 bars (12 000 hPa) for 20 minutes.*

CHAPTER XII

Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilisers or soil improvers

The placing on the market of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers shall be subject to the following conditions:

1. they must originate from animals that:

   (a) either have been slaughtered in a slaughterhouse, after undergoing an ante-mortem inspection, and were found fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation; or

(b) did not show clinical signs of any disease communicable through that product to humans or animals.

2. they must have undergone a heat treatment for one hour at a core temperature of at least 80° C;

3. the horns must be removed without opening the cranial cavity;

4. at any stage of processing, storage or transport, every precaution shall be taken to avoid cross-contamination;

5. they shall be packed either in new packaging or containers; or transported in vehicles or bulk containers which have been disinfected prior to loading using a product approved by the competent authority;

6. the packaging or containers must:

(a) indicate the type of product (horns, horn products, hooves or hoof products);

(b) be clearly labelled "NOT FOR HUMAN AND ANIMAL CONSUMPTION";

(c) be marked with the name and address of the approved *or registered establishment or* plant of destination.

ANNEX XVII

IMPORT, EXPORT AND TRANSIT

SECTION I

SPECIFIC REQUIREMENTS FOR IMPORT *AND TRANSIT* OF CATEGORY 3 MATERIAL FOR USES IN THE FEED CHAIN *OTHER THAN FOR PETFOOD OR FOR FEED TO FUR ANIMALS*

CHAPTER I

As referred to in Article 41(3) of the Animal By-products Regulation, imported consignments of Category 3 material *and consignments of Category 3 material in transit:*

(a) must consist of or have been produced from, as applicable, Category 3 material referred to in the column "raw materials" of the following table;

(b) must comply with the import conditions set out in the relevant column of the following table;

(c) must come from a third country or part of a third country listed in the relevant column of the following table; and

(d) shall be accompanied during transportation to the point of entry into the Union where the veterinary checks take place by the health certificate referred to in the relevant column of the following table; or

(e) *shall be presented at the point of entry into the Union where the veterinary checks take place accompanied by a document corresponding to the model referred to in the relevant column of the following table.*

No.	Product	Raw materials (*reference to provisions of the Animal By-products Regulation*)	Import *and transit* conditions	Third countries' lists	Certificates/ *model documents*
1	Processed animal protein	Materials referred to in Article 10 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l) and (m)	(a) The processed animal protein must have been produced in accordance with Annex XIII, Section II, Chapter I; and (b) The processed animal protein shall comply with the additional requirements set out in Chapter II to this Section.	(a) In the case of processed animal proteins excluding fishmeal: Third countries listed in part 1 of Annex II to Commission Regulation [insert: (EU) NO 206/20104787/2009]. (b) In the case of fishmeal: Third countries listed in the Annex II to Commission Decision 2006/766/EC.	Annex XVIII, Chapter 1
2	Blood products for feed material	Materials referred to in Article 10 (a), (b)(i) and	The blood products must have been produced in accordance with Annex XIII, Section II, Chapter II.	(a) In the case of blood products from ungulates: Third countries or parts of countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, from which imports of all	Annex XVIII, Chapter 4(B)

		(d)		categories of fresh meat of the respective species are authorised. (b) In the case of blood products from other species: Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010	
3	Rendered fats	(a) In the case of rendered fats excluding fish oil: Materials referred to in Article 10 (a), (b), (c), (d), (e), (f), (g), (k) and (m) (b) In the case of fish oil: Materials referred to in Article 10 (e), (h), (i) and (j)	(a) The rendered fat must have been produced in accordance with Annex XIII, Section II, Chapter III; and (b) The rendered fat shall comply with the additional requirements set out in Chapter III to this Section.	(a) In the case of rendered fats excluding fish oil: Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010. (b) In the case of fish oil: Third countries listed in the Annex to Commission Decision 2006/766/EC	(a) In the case of rendered fats excluding fish oil: Annex XVIII, Chapter 10 (A) (b) In the case of fish oil: Annex XVIII, Chapter 9

4	Milk and milk-based products	Materials referred to in Article 10 (e), (f) and (h)	The milk and the milk-based products shall comply with the requirements set out in Chapter IV to this Section.	Authorised third countries listed in Annex I to Decision 2004/438/EC	Annex XVIII, Chapter 2
5	Gelatine and hydro-lysed protein	Materials referred to in Article 10 (a), (b), (d), (e), and (h)	The gelatine and the hydrolysed protein must have been produced in accordance with Annex XIII, Section II, Chapter V.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, and the following countries: (KR) The Republic of Korea (MY) Malaysia (PK) Pakistan (TW) Taiwan.	(a) In the case of gelatine: Annex XVIII, Chapter 11 (b) In the case of hydrolysed protein: Annex XVIII, Chapter 12
6	Dicalcium phosphate	Materials referred to in Article 10 (a), (b), (d) and (e)	The dicalcium phosphate must have been produced in accordance with Annex XIII, Section II, Chapter VI.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, and the following countries: (KR) The Republic of Korea (MY) Malaysia	Annex XVIII, Chapter 12

				(PK) Pakistan (TW) Taiwan	
7	Tri-calcium phosphate	Materials referred to in Article 10 (a), (b), (d) and (e)	The tricalcium phosphate must have been produced in accordance with Annex XIII, Section II, Chapter VII.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, and the following countries: (KR) The Republic of Korea (MY) Malaysia (PK) Pakistan (TW) Taiwan	Annex XVIII, Chapter 12
8	Collagen	Materials referred to in Article 10 (a), (b), (d), (e) and (h)	The collagen must have been produced in accordance with Annex XIII, Section II, Chapter VIII.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, and the following countries: (KR) The Republic of Korea (MY) Malaysia (PK) Pakistan (TW) Taiwan	Annex XVIII, Chapter 11

9	Egg products	Materials referred to in Article 10 points (e), (f) and (k)(ii)	The egg products must have been produced in accordance with Annex XIII, Section II, Chapter IX.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, and third countries or parts of third countries from which Member States authorise imports of fresh poultrymeat, which are listed in Part 1 of Annex I to Regulation (EC) No 798/2008.	Annex XVIII, Chapter 15

CHAPTER II

Import of processed animal protein

The following additional requirements shall apply to the importation of processed animal protein:

1. Before consignments are released for free circulation within the Union, the competent authority must sample processed animal protein *from imported consignments* at the border inspection post to ensure compliance with the requirements of Annex XIII, Section I. 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.

2. 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.

3. Competent authorities must keep a record for at least *three* years of the results of sampling carried out on all consignments that have undergone sampling.

4. Where a consignment proves to be positive for salmonella *or enterobacteriaceae*, it must either:

   (a) be dealt with in accordance with the procedure laid down by Article 17(2)(a) of Directive 97/78/EC; or

   (b) reprocessed in a processing plant or decontaminated by a treatment authorised by the competent authority. The consignment must not be released until it has been treated, tested for salmonella by the competent authority in accordance with point 1 of Section I of Annex XIII, and a negative result obtained.

CHAPTER III

Import of rendered fats

The following additional requirements shall apply to the importation of rendered fats:

Rendered fat shall:

(a) be entirely or partly derived from *porcine* 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,

(b) be 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,

(c) be 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

(d) where there has been an outbreak of one of the abovementioned diseases during the relevant period mentioned above, have been subjected to one of the following heat treatment processes:

– at least 70° C for at least 30 minutes, or

– at least 90° C for at least 15 minutes, and details of the critical control points are recorded and maintained so that the owner, operator or their representative and, as necessary, the competent authority can monitor the operation of the plant. The information must include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed-rate and fat recycling rate;

CHAPTER IV

Import of milk, milk-based products and colostrum

The following requirements shall apply to the importation of milk and milk-based products:

1. Milk and milk-based products shall:

   (a) have undergone at least one of the treatments provided for in paragraphs 1.1, 1.2, 1.3 and point (a) of paragraph 1.4 of Part I of Chapter IV of Section II of Annex XIII;

   (b) comply with paragraphs 2 and 4, and, in the case of whey, paragraph 3 of Part I of Chapter IV of Section II of Annex XIII.

2. By way of derogation from paragraph 1.4 of Part I of Chapter IV of Section II, milk and milk products may be imported from third countries so authorised in Column "A" of Annex I to Commission Decision 2004/438/EC provided that the milk or milk products have undergone a single HTST treatment and have been produced:

   (a) either at least 21 days before shipping and that during this period no case of foot-and-mouth disease has been detected in the exporting country; or

   (b) have been presented at an EU border inspection post at least 21 days after production and that during this period no case of foot-and-mouth disease has been detected in the exporting country.

SECTION II

SPECIFIC REQUIREMENTS FOR THE IMPORT *AND TRANSIT* OF ANIMAL BY-PRODUCTS FOR USES OUTSIDE THE FEED CHAIN FOR FARMED ANIMALS

CHAPTER I

General provisions

1. The importation *and the transit* of the following animal by-products is prohibited:

   (a) unprocessed manure;

   (b) *untreated* feathers and parts of feathers; and

   (c) beeswax in the form of honeycomb.

2. The importation *and the transit* of non-mineralised guano *are* not subject to any animal health conditions.

CHAPTER II

Specific provisions

As referred to in Article 41 paragraphs (2)(c) and (3) of The Animal By-products Regulation, imported consignments of animal by-products and products derived therefrom *and consignments in transit*

   (a) must consist of or have been produced from animal by-products referred to in the column "raw materials" of the following table;

   (b) must comply with the import *and transit* conditions set out in the relevant column of the following table;

   (c) must come from a third country or part of a third country listed in the relevant column of the following table; and

   (d) shall be accompanied during transportation to the point of entry into the Union where the veterinary checks take place by the health certificate referred to in the relevant column of the following table; or

   (e) *shall be presented at the point of entry into the Union where the veterinary checks take place accompanied by a document corresponding to the model referred to in the relevant column of the following table.*

No.	Product	Raw materials (*reference to provisions of the Animal By-products Regulation*)	Import *and transit* conditions	Third countries' lists	Certificates/ *model documents*
1	Processed manure and processed manure products	Material referred to in Article 9 (a)	The processed manure and the processed manure products must have been produced in accordance with Annex XIV, Section I, Chapter II.	Third countries listed in: (a) Part 1 of Annex II to Commission Regulation (EU) No 206/2010; (b) Annex I to Commission Decision 2004/211/EC; or (c) Part 1 of Annex I to Commission Regulation (EC) No 798/2008.	Annex XVIII, Chapter 17
2	Blood products, excluding from equidae, for the	Material referred to in Article 8 (c) and Article 10 (a), (b)	The blood products must have been produced in accordance with Chapter III.	The following third countries: (a) in the case of untreated blood products of ungulates: Third countries or parts of third countries	(a) In the case of untreated blood products: Annex XVIII, Chapter 4 (C)

	manufacture of derived products for uses outside the feed chain	and (f))		listed in Part 1 of Annex II to Commission Regulation (EU) No 206/2010 from which imports of fresh meat of any domestic ungulate species is authorised and only for the period indicated in column 7 and 8 of that Part, Japan (b) in the case of untreated blood products of poultry and other avian species: Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EC) No 798/2008. Japan. (c) in the case of untreated blood products of other animals: Third countries listed either in Part 1 of Annex II to Commission Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008, or in Part 1 of Annex I to Regulation (EC) No 119/2009. Japan. (d) in the case of treated blood products of any species: Third countries listed in Part 1 to Annex II of	(b) In the case of treated blood products: Annex XVIII, Chapter 4 (D)

				Commission Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008 or in Part 1 of Annex I to Commission Regulation (EC) No 119/2009 Japan.	
3	*Blood and blood products from* equidae	Materials referred to in Article 10 (a), (b), (c) and (f)	The *blood and the blood products* shall comply with the requirements set out in Chapter IV.	The following third countries: (a) in the case of blood that has been collected in accordance with point 1 of Chapter IV of Annex XVI or where blood products have been produced in accordance with point 2(b)(i) of that Chapter: Third countries or parts of third countries listed in Annex I to Decision 2004/211/EC, from which the importation of equidae for breeding and production is allowed. (b) in the case of blood products which have been treated in accordance with point 2(b)(ii) of Chapter IV of Annex XVI: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat of domestic equidae.	Annex XVIII, Chapter 4(A)
4	Fresh or chilled hides and	Materials referred to in Article	The hides and skins shall comply with the requirements set out in Chapter V points 1 and 3.	The hides and skins come from a third country, or, in the case of regionalisation in accordance with Union legislation, a part of a	Annex XVIII, Chapter 5(A)

	skins of ungulates	10 (b)(i) and (iii)		third country listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat from the same species.	
5	Treated hides and skins of ungulates	Materials referred to in Article 10 (b)(i) and (iii) and (n)	The hides and skins shall comply with the requirements set out in Chapter V points 2 and 3.	(a) In the case of treated hides and skins of ungulates: Third countries or parts of third countries listed in Part 1 to Annex II to Commission Regulation (EU) No 206/2010. (b) In the case of treated hides and skins of ruminants that are intended for dispatch to the European Union and which have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation: Any third country.	(a) In the case of treated hides and skins of ungulates: Annex XVIII, Chapter 5(B) (b) In the case of treated hides and skins of ruminants and of equidae that are intended for dispatch to the European Union and which have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation: The official declaration set out in Annex XVIII, Chapter 5(C)

6	Game trophies *and other pre-parations from animals*	Materials referred to in Articles 9(f) derived from wild animals not suspected of being infected with a disease communic able to humans or animals and in Article 10 (a), (b)(i), (iii) and (v) and (n)	The game trophies shall comply with the requirements set out in Chapter VI.	(a) In the case of game trophies referred to in Chapter VI paragraph 2: Any third country. (b) In the case of game trophies referred to in Chapter VI paragraph 3: (i) Game trophies from birds: Third countries listed in Part 1 of Annex I to Commission Regulation (EC) No 798/2008, from which the Member States authorise imports of fresh poultrymeat, and the following countries: (GL) Greenland (TN) Tunisia. (ii) Game trophies from ungulates: Third countries listed in the appropriate columns for fresh meat of ungulates in part 1 of Annex II to Commission Regulation (EU) No 206/2010, including any restrictions laid down in the column for special remarks for fresh meat.	(a) In the case of game trophies referred to in Chapter VI paragraph 2: Annex XVIII, Chapter 6(A) (b) In the case of game trophies referred to in Chapter VI paragraph 3: Annex XVIII, Chapter 6(B)
7	Pig bristles	Materials referred to in Article	The pig bristles must have been obtained from animals originating, and slaughtered in a	(a) In the case of untreated pig bristles: Third countries, or, in the case of	(a) In case no case African swine fever has occurred

		10 (b)(iv)	slaughterhouse, in the country of origin.	regionalisation, regions thereof, listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, which are free of African swine fever for the 12 months prior to the date of importation. (b) In the case of treated pig bristles: Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, which may not be free of African swine fever for the last 12 months.	during the 12 previous months: Annex XVIII, Chapter 7(A) (b) In case one or more cases of African swine fever have occurred during the previous 12 months: Annex XVIII, Chapter 7(B)
8	Un-processed wool and hair	Materials referred to in Article 10 (h) and (n)	The *untreated* wool and hair must be (a) securely enclosed in packaging and dry; and (b) sent directly to a plant producing derived products for uses outside the feed chain or an intermediate plant in conditions such that any spread of pathogenic agents is avoided.	Any third country	For imports of *untreated* wool and hair, no health certificate is required.
9	Processed feathers	Materials referred to	The processed feathers or parts of feathers shall comply with the	Any third country.	For imports of processed feathers

	and parts of feathers	in Article 10 (b)(v)	requirements set out in Chapter VII.		and parts of feathers, no health certificate is required.
10	Apiculture by-products	Materials referred to in Article 10 (e)	(a) In the case of apiculture by-products intended for use in apiculture: (i) The apiculture by-products have been subjected to a temperature of -12°C or lower for at least 24 hours; or (ii) In the case of wax, the material has been rendered and refined before importation. (b) In the case of beeswax for purposes *other than feeding to farmed animals*, the beeswax has been refined or rendered before importation.	(a) In the case of apiculture by-products intended for use in apiculture: Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010. (b) In the case of beeswax for purposes *other than feeding to farmed animals*: Any third country.	(a) In the case of apiculture by-products intended for use in apiculture: Annex XVIII, Chapter 13 (b) In the case of beeswax for purposes *other than feeding to farmed animals*: A commercial document attesting the refinement or rendering.
11	Bones and bone products (excluding	Materials referred to in Article 10 (a) and	The products shall comply with the requirements set out in Chapter VIII.	Any third country.	The products shall be accompanied by:

	bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) for uses other than as feed material, organic fertiliser or soil improver	(b)(i), (iii), (e) and (h)			(a) a commercial document as et out in Chapter VIII point 2; and (b) a declaration of the importer in accordance with Annex XVIII, Chapter 16 in at least one official language of the Member State through which the consignment first enters the Union and in at least one official language of the Member State of destination.
12	Petfood and dogchews	(a) In the case of raw petfood: Materials referred to in Article	The petfood and the dogchews must have been produced in accordance with Annex XVI Chapter II.	(a) In the case of raw petfood: Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, in Annex I to Decision 94/984/EC, or in Annex I to Commission Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is	(a) In the case of canned petfood: Annex XVIII, Chapter 3(A) (b) In the case of processed petfood other than canned

		35 (a)(iii) (b) In the case of processed petfood and dogchews: Materials referred to in Article 35 (a)(i) and (ii)		authorised. In the case of fish materials, third countries listed in Annex II to Commission Decision 2006/766/EC. (b) In the case of dogchews and petfood other than raw petfood: Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, and the following countries: (JP) Japan (EC) Ecuador (LK) Sri Lanka (TW) Taiwan	petfood: Annex XVIII, Chapter 3(B) (c) In the case of dogchews: Annex XVIII, Chapter 3(C) (d) In the case of raw petfood: Annex XVIII, Chapter 3(D).
13	Flavouring innards for the manufacture of petfood	Materials referred to in Article 35 (a)	The flavouring innards must have been produced in accordance with Annex XVI, Chapter III.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, 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 from fish materials, third countries listed in Annex II to Commission Decision 2006/766/EC.	Annex XVIII, Chapter 3(E)
14	Animal by-	(a) Materials	The products shall comply with the	(a) In the case of animal by-products for the	(a) In the case of animal by-

	products for the manu-facture of petfood and of derived products for uses outside the feed chain	referred to in Article 10 (a) to (k) (b) In the case of materials for the manu-facture of petfood, materials referred to in Article 8 (c)	requirements set out in Chapter IX.	manufacture of petfood: (i) In the case of 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 Commission Regulation (EU) No 206/2010, from which imports of fresh meat for human consumption is authorised. (ii) 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 Part 1 of Annex I to Commission Regulation (EC) No 798/2008. (iii) Raw material from fish: Third countries listed in Annex II to Commission Decision 2006/766/EC. (iv) Raw material from other wild land mammals and leparopidae: Third countries listed in Part 1 of Annex II to Commission Regulation (EU) No 206/2010 or in part 1 of Annex I to Regulation (EC) No	products for the manufacture of processed petfood: Annex XVIII, Chapter 3(F) (b) In the case of animal by-products for the manufacture of products for uses outside the feed chain: Annex XVIII, Chapter 8

				798/2008. (b) In the case of animal by-products for the manufacture of pharmaceuticals: Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, in Part 1 of Annex I to Commission Regulation (EC) No 798/2008 or in Part 1 of Annex I to Commission Regulation (EC) No 119/2009, and the following third countries: (JP) Japan (PH) Philippines (TW) Taiwan. (c) In the case of animal by-products for the manufacture of products for uses outside the feed chain, other than pharmaceuticals: Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010 from which imports of that Category of fresh meat of the respective species is authorised, in Part 1 of Annex I to Commission Regulation (EC) No 798/2008, in Part 1 of Annex I to Commission Regulation (EC) No 119/2009, *or, in the case of material from fish, third countries listed in Annex II to Commission Decision 2006/766/EC.*	

15	Animal by-products for use in raw petfood	Materials referred to in Article 10 (a) and (b)(i) and (ii)	The products shall comply with the requirements set out in Chapter IX.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is authorised. In the case of fish materials, third countries listed in Annex II to Commission Decision 2006/766/EC.	Annex XVIII, Chapter 3(D)
16	Animal by-products for use in feed for farmed fur animals	Materials referred to in Article 10 (a) to (k)	The products shall comply with the requirements set out in Chapter IX.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, in Annex I to *Commission Regulation (EC) No 798/2008*, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is authorised. In the case of fish materials, third countries listed in Annex II to Commission Decision 2006/766/EC.	Annex XVIII, Chapter 3(D)
17	Rendered fats for oleo-chemical purposes	Materials referred to in Article 9 of Regulation (EC) No	The rendered fats shall comply with the requirements set out in Chapter X.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010.	Annex XVIII, Chapter 10(A)

		…			
18	Fat deri-vatives	Materials referred to in Article 9 (c), (e) and (f) and in Article 10 (a), (b)(i), (d) and (e)	The fat derivatives shall comply with the requirements set out in Chapter XI.	Any third country.	(a) In the case of fat derivatives for uses outside the feed chain: Annex XVIII, Chapter 14(A) (b) In the case of fat derivatives for use as feed or for uses outside the feed chain: Annex XVIII, Chapter 14(B)
19	Photo-gelatine	Materials referred to in Article 8(b)and 10	The imported photogelatine shall comply with the requirements set out in Chapter XII.	Photogelatine may only be imported from establishments of origin in the United States and in Japan that are authorised in accordance with Chapter XII.	Annex XVIII, Chapter 19
20	Rendered fats for certain purposes outside the feed chain	Materials referred to in Articles 8, 9 and 10	The rendered fats shall comply with the requirements set out in Chapter XIII.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010 and, in the case of fish materials, third countries listed in Annex II to Commission Decision 2006/766/EC.	Annex XVIII, Chapter 10(C)

21	Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, for the pro-duction of organic fertilisers or soil improvers	Materials referred to in Article 10 (a), (b), (h) and (n)	The products shall comply with the requirements set out in Chapter XIV.	Any third country.	Annex XVIII, Chapter 18

CHAPTER III

Import of blood and blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain

The following requirements shall apply to the import of blood and blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain:

1. The blood products must originate from a plant for the production of derived products for uses outside the feed chain which meets the specific conditions laid down in this Regulation or from the establishment of collection.

2. The blood from which blood products for the manufacture of derived products for uses outside the feed chain are produced must have been collected:

   (a) in slaughterhouses approved in accordance with Union legislation;

   (b) in slaughterhouses approved and supervised by the competent authority of the third country; or

   (c) from live animals in facilities approved and supervised by the competent authority of the third country.

3. In the case of blood products for the manufacture of derived products for uses outside the feed chain which have been derived from animals belonging to the taxa Artiodactyla, Perissodactyla and Proboscidea, including their crossbreeds, they must comply with the conditions of either point (a) or (b):

   (a) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in point (b):

      (i) heat treatment at a temperature of 65°C for at least three hours, followed by an effectiveness check,

      (ii) irradiation at 25 kGy by gamma rays, followed by an effectiveness check,

      (iii) heat treatment of at least 80 °C throughout their substance, followed by an effectiveness check,

      (iv) in the case of animals other than Suidae and Tayassuidae only: change in pH to pH 5 for two hours, followed by an effectiveness check;

   (b) in case of blood products not treated in accordance with point (a) the products originate from a country or region:

(i) where no case of rinderpest, peste des petits ruminants and Rift Valley fever has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months.

(ii) where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination has not been carried out against this disease for at least 12 months

or

where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination programmes against foot-and-mouth disease are being officially carried out and controlled in domestic ruminant animals for at least 12 months; in this case, following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the registered establishment or plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

In addition to point (i) and (ii), in the case of animals other than Suidae and Tayassuidae, one of the following conditions must be complied with:

- in the country or region of origin no case of vesicular stomatitis and bluetongue (including the presence of seropositive animals) has been recorded for 12 months and vaccination has not been carried out against those diseases for at least 12 months in the susceptible species,

- following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the plant of destination and all precautions, including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

In addition to point (i) and (ii), in the case of Suidae and Tayassuidae, in the country or region of origin no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for at least 12 months, vaccination has not been carried out against those diseases for at least 12 months and one of the following conditions are complied with:

- in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for 12 months and vaccination has not been carried out against this disease for at least 12 months in the susceptible species,

- following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the registered establishment or plant of destination and all precautions,

including safe disposal of waste, unused or surplus material, must be taken to avoid risks of spreading diseases to animals or humans.

4. In the case of blood products for the manufacture of derived products for uses outside the feed chain which have been derived from poultry and other avian species, they must comply with the conditions of either point (a) or (b):

   (a) the products have undergone one of the following treatments guaranteeing the absence of pathogens of the diseases referred to in point (b):

      (i) heat treatment at a temperature of 65°C for at least three hours, followed by an effectiveness check,

      (ii) irradiation at 25 kGy by gamma rays, followed by an effectiveness check,

      (iii) heat treatment of at least 70°C throughout their substance, followed by an effectiveness check;

   (b) in case of blood products not treated in accordance with point (a) the products originate from a country or region:

      (i) which has been free from Newcastle disease and highly pathogenic avian influenza as defined in the Terrestrial Animal Health Code of the OIE,

      (ii) which during the last 12 months has not carried out vaccination against avian influenza,

      (iii) where the poultry or other avian species from which the products derive have not been vaccinated against Newcastle disease with vaccines prepared from a Newcastle disease master strain showing a higher pathogenicity than lentogenic virus strains.

CHAPTER IV

Import of blood and blood products from equidae

1. The blood must comply with the conditions set out in point 1(a) of Chapter IV of Annex XVI and must be collected under veterinary supervision either in:

   (a) slaughterhouses

      (i) approved in accordance with Regulation (EC) No 853/2004; or

      (ii) approved and supervised by the competent authority of the third country; or

   (b) facilities approved, furnished with a veterinary approval number and supervised by the competent authority of the third country for the purpose of collecting blood

from equidae for the production of blood products for purposes *other than feeding for farmed animals*.

2. The blood products must comply with the conditions set out in point 2 of Chapter IV of Annex XVI.

In addition, the blood products referred to in point 2(b)(i) of Chapter IV of Annex XVI must be produced from blood collected from equidae which have been kept for a period of at least three months, or since birth if less than three months old, prior to the date of collection on holdings under veterinary supervision in the third country of collection which during that period and the period of blood collection has been free of:

(a) African horse sickness in accordance with Article 5(2)(a) of Directive 90/426/EEC;

(b) Venezuelan equine encephalomyelitis for a period of at least two years;

(c) glanders:

(i) for a period of three years; or

(ii) for a period of six months where the animals have shown no clinical signs of glanders (*Burkholderia mallei*) during the post-mortem inspection in the slaughterhouse referred to in paragraph 1(a), including a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum;

(d) vesicular stomatitis for six months.

3. Blood products must come from an approved or registered establishment or plant approved by the competent authority of the third country.

4. Blood and blood products shall be packed and labelled in accordance with point 3(a) of Chapter IV of Annex XVI.

CHAPTER V

Import of hides and skins of ungulates

1. Fresh or chilled hides and skins may be imported if:

(a) they come from a third country referred to in the applicable column of row 4 of Chapter II which, as appropriate to the species concerned:

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

— classical swine fever,

— African swine fever, and

— rinderpest, and

(ii) has been free for at least 12 months before dispatch from foot-and mouth disease and where, for 12 months before dispatch, no vaccination has been carried out against foot-and-mouth disease;

(b) 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; and

(c) they have undergone all precautions to avoid recontamination with pathogenic agents.

2. Treated hides and skins may be imported if:

(a) they come either from:

(i) a third country or, in the case of regionalisation in accordance with Union legislation, from a part of a third country, appearing on the list set out in point (a) of the applicable column of row 5 of Chapter II from which imports of fresh meat of the corresponding species are authorised and they have been treated as referred to in Annex I, point 40 (a), (b) and (c);

(ii) a third country appearing on the list set out in point (a) of the applicable column of row 5 of Chapter II and they have been treated as referred to in Annex I, point 40 (c) or (d); or

(iii) equidae or ruminant animals from a third country appearing on the list set out in point (b) of the applicable column of row 5 of Chapter II, which have been treated as referred to in Annex I, point 40 (a), (b) and (c) and after treatment have been kept separate for at least 21 days; and

(b) in the case of salted hides and skins transported by ship, they have been treated as referred to in Annex I, point 40 (b) or (c) and have been kept separated after treatment during transportation for at least 14 days in the case of the treatment referred to in point (b) or seven days in the case of the treatment referred to in point (c) before importation and the health certificate accompanying the consignment attests such treatment and the duration of the transportation.

3. 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 VI

Import of game trophies and other preparations from animals

1. Game trophies or other preparations from animals which fulfil the conditions referred to in Annex XVI Chapter VI points B (a) and C.1 may be imported without restrictions.

2. Treated game trophies or other preparations from birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, from third countries may be imported if they comply with the requirements of Annex XVI, Chapter VI, points C.2.(a), (i) to (iii) and (b)(i) and (ii).

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.

3. Game trophies or other preparations from birds and ungulates consisting of entire anatomical parts, not having been treated in any way may be imported 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 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;

CHAPTER VII

Import of processed feathers and parts of feathers

Processed feathers and parts of feathers may be imported if:

(a) they are treated decorative feathers, treated feathers carried by travellers for their private use or consignments of treated feathers sent to private individuals for non-industrial purposes; or

(b) they are accompanied by a commercial document stating that the feathers or parts of feathers have been treated with a steam current or by another method ensuring the inactivation of pathogens and are securely enclosed in packaging and dry.

CHAPTER VIII

Import 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 fertilizers or soil improvers

1. Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) may be imported to produce derived products for uses outside the food or feed chain 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 Union and are not transhipped at any port or place outside the Union;

   (c) following the document checks provided for in Directive 97/78/EC, the products are conveyed directly to the registered establishment or plant of destination.

2. Each consignment must be accompanied by a commercial document stamped by the competent authority supervising the establishment of origin, including the following information:

   (a) the country of origin,

   (b) the name of the establishment or plant of production,

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

   (d) the fact that the product was:

      (i) derived from healthy animals slaughtered in a slaughterhouse, or

      (ii) dried for 42 days at an average temperature of at least 20° C, or

      (iii) heated for one hour to at least 80°C to the core before drying, or

      (iv) ashed for one hour to at least 800°C to the core before drying, or

      (v) 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.

3. On dispatch to the Union 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 registered establishment or plant of destination.

4. Following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the material must be transported direct to the registered establishment or plant of destination

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 IX

Import of animal by-products for the manufacture of feed for farmed fur animals, petfood and derived products for uses outside the feed chain

Animal by-products intended for the manufacture of feed for farmed fur animals, petfood, and for derived products for uses outside the feed chain may be imported *provided that*:

1. *the animal by-products* have been deep-frozen at the plant of origin or have been preserved in accordance with Union legislation in such a way to prevent spoiling between dispatch and delivery to the *establishment or* plant of destination;

2. *the animal by-products* have undergone all precautions to avoid contamination with pathogenic agents;

3. *the animal by-products* were packed in new packaging preventing any leakage;

4. following the border checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the *animal by-products* are transported directly either:

   (a) to a petfood plant or a registered establishment or plant of destination, which has given the guarantee that the animal by-products shall be used only for the purpose of producing the products for which it has been registered or approved, as applicable, as specified by the competent authority if necessary, and shall not leave the plant untreated other than for direct disposal; or

   (b) to an establishment or plant which has been approved in accordance with Article 24 (1)(h) of the Animal By-products Regulation;

   (c) to a 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; or

   (d) to an establishment or plant which has been approved in accordance with Article 24(1)(a) of the Animal By-products Regulation;

and

5.1. in the case of raw material for petfood production referred to in Article 35(a)(ii) of the Animal By-products Regulation, *the raw material* shall:

(a) be marked in the third country before entry into the territory of the Union by a cross of liquefied charcoal or activated carbon, on each outer side of each frozen block, *or, when the raw material is transported in pallets which are not divided into separate consignments during transport to the petfood plant of destination, on each outer side of each pallet,* 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 Union by spraying it with liquefied charcoal or by applying charcoal powder in such a way that the charcoal is clearly visible on the material;

(c) be transported directly to:

(i) the petfood plant of destination in accordance with point 4(a) above; or

(ii) an establishment or plant of destination which has been approved in accordance with Article 24 (1)(h) of the Animal By-products Regulation, in accordance with point 4(b) above and from there directly to the petfood plant referred to under (i), provided that the plant of destination:

– only handles material covered by this point 6.1, or

– only handles material destined for a petfood plant as referred to under (i);

and

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

5.2. *in the case of consignments* made up of raw material, which has been treated as referred to in 6.1 above and other non-treated raw material, all the raw materials in the consignment *have been* marked as laid down in point 6.1(a) and (b) above.

5.3. the marking referred to in points 6.1 (a) and (b) and 6.2 remains visible from the dispatch and until the delivery to the petfood plant of destination.

6. *In the petfood plant of destination, raw material for petfood production referred to in Article 35(a)(ii) of the Animal By-products Regulation shall be stored before production under conditions authorised by the competent authority, which allow official controls on the amounts of material received, used for production and*

disposed of, if applicable. The competent authority may authorise the operator of the petfood plant to store such materials together with Category 3 material.

CHAPTER X

Import of rendered fats from Category 2 material for oleochemical purposes

1. Rendered fats derived from Category 2 material may be imported if they are destined for processing using a method that at least meets the standards of one of the processes described in Annex XVI, Chapter X.

2. The rendered fats must be conveyed by land and/or sea from the country of origin direct to a border inspection post in the Union.

3. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, rendered fats must be directly transported to an *establishment or plant registered for the production of Category 2 oleochemicals* where they are to be processed into fat derivatives.

4. The health certificate accompanying the consignment must state that:

   (a) 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 Annex XVI, Chapter X; and

   (b) the resulting fat derivatives shall only be used in organic fertiliser or soil improvers or other uses outside the feed chain, other than in cosmetics, pharmaceuticals and medical devices.

5. The health certificate referred to in paragraph 4 must be presented to the competent authority at the border inspection post at the first point of entry of the goods into the Union, and thereafter a copy must accompany the consignment until their arrival at the plant of destination.

CHAPTER XI

Import of fat derivatives

1. Fat derivatives may be imported if the health certificate accompanying the consignment states:

   (a) whether 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 Annex XVI, Chapter X and

(ii) shall only be used in organic fertiliser or soil improvers or other uses outside the feed chain, other than in cosmetics, pharmaceuticals and medical devices.

2. The health certificate provided for in paragraph 1 must be presented to the competent authority at the border inspection post at the first point of entry of the goods into the Union, and thereafter a copy must accompany the consignment until its arrival at the plant of destination.

3. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the fat derivatives shall be transported directly to the *registered establishment or* plant of destination.

CHAPTER XII

Import of photogelatine

1. Gelatine which has been produced from material containing bovine vertebral column classified as Category 1 material in accordance with Article 8(b) of the Animal By-products Regulation and which is intended for the photographic industry (photogelatine) may be imported, provided the photogelatine:

(a) originates from one of the establishments indicated in the following table;

(b) has been produced in accordance with point 6 of this Chapter;

(b) is imported through one of the border inspection points of first entry indicated in the following table; and

(c) is destined for production in an approved photographic factory indicated in the following table.

Table: Import of photogelatine

Third country of origin	*Plants of origin*	*Member State of destination*	*Border inspection post of first entry*	*Approved photographic factories*
Japan	Nitta Gelatin Inc., 2-22 Futamata Yao-City, Osaka 581-0024 Japan Jellie Co. Ltd- 7-1, Wakabayashi 2-Chome, Wakabayashi-ku, Sendai-City; Miyagi, 982 Japan NIPPI Inc. Gelatine Division 1 Yumizawa-Cho Fujinomiya City Shizuoka 418-0073 Japan	The Netherlands	Rotterdam	FUJIFILM Europe B.V., Oudenstaart 1, 5047 TK Tilburg, The Netherlands
	Nitta Gelatin Inc., 2-22 Futamata Yao-City, Osaka 581-0024 Japan	United Kingdom	Liverpool Felixstowe Heathrow	Kodak Ltd. Headstone Drive, Harrow, MIDDX, HA4 4TY, The United Kingdom
		Czech Republic	Hamburg	FOMA BOHEMIA spol. s.r.o. Jana Krušinky 1604 501 04 Hradec Králove, The Czech

				Republic
United States of America	Eastman Gelatine Corporation, 227 Washington Street, Peabody, MA, 01960 USA Gelita North America, 2445 Port Neal Industrial Road Sergeant Bluff, Iowa, 51054 USA	Luxembourg	Antwerp Zaventem Luxembourg	DuPont Teijin Luxembourg SA PO Box 1681 L-1016 Luxembourg
		United Kingdom	Liverpool Felixstowe Heathrow	Kodak Ltd. Headstone Drive, Harrow, MIDDX, HA4 4TY, The United Kingdom
		Czech Republic	Hamburg	FOMA BOHEMIA spol. s.r.o. Jana Krušinky 1604 501 04 Hradec Králove, The Czech Republic

2. Once the photogelatine has entered the Member State of destination, it shall not be traded between Member States but shall only be used in the approved photographic factory in the same Member State of destination and solely for photographic production purposes.

3. Following the checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the photogelatine shall be transported directly to the approved photographic factory of destination.

4. The transport referred to in point 3 shall be carried out in vehicles or containers in which the photogelatine is physically separated from any products intended for food or feed.

5. In the approved photographic factory of destination, the operator shall ensure that any surpluses or residues of and other waste derived from the photogelatine are:

(a) transported in sealed leak-proof containers labelled 'for disposal only' in vehicles under satisfactory hygiene conditions;

(b) disposed of in accordance with Article 12 (a)(i) of The Animal By-products Regulation or exported to the country of origin in accordance with Regulation (EC) No 1013/2006.

6. Photogelatine shall be produced according to the following:

(a) Photogelatine shall only be produced in plants which do not produce gelatine for food or feed intended for dispatch to the European Union, and which are approved by the competent authority of the third country concerned.

(b) Photogelatine shall be produced by a process that ensures that raw material is treated by processing method 1 as referred to in Section III of Annex VI or subjected to a treatment with acid or alkali for at least two days, washing with water, and:

(i) following an acid treatment, treating with alkaline solution for at least 20 days; or

(ii) following an acid treatment, treating with an acid solution for 10 to 12 hours.

The pH must then be adjusted and the material purified by means of filtration and sterilisation at 138-140°C for 4 seconds.

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

(d) The photogelatine shall be wrapped, packaged in new packages, stored and transported in sealed leak-proof, labelled containers in a vehicle under satisfactory hygiene conditions. If leakage is observed, the vehicle and containers shall be thoroughly cleaned and inspected before re-use.

(e) Wrapping and packages containing the photogelatine must carry the words 'photogelatine for the photographic industry only'.

CHAPTER XIII

Import of rendered fats for certain purposes outside the feed chain

Rendered fats may be imported for purposes other than the production of feed for farmed animals, of cosmetics, of medicinal products or of medical devices, provided:

(a) they are derived from animal by-products referred to in Article 8 point (c), Article 9 points (d) and (f)(i) or Article 10 of the Animal By-products Regulation;

(b) they have been processed by pressure sterilisation or in accordance with one of the methods referred to in Section III of Annex VI;

(c) they have been marked before shipment to the European Union, by a registered establishment, plant or operator, in accordance with points 1 and 2 of Section V of Annex X;

(d) they are transported under conditions which prevent contamination;

(e) they bear labels, on the packaging or container indicating "NOT FOR HUMAN OR ANIMAL CONSUMPTION".

CHAPTER XIV

Import of horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers

Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers, may be imported, provided.

1. they have been produced in accordance with Chapter XI of Annex XVI;

2. they are conveyed following the veterinary checks in the border inspection post *at the point of entry into the Union* provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, directly to an approved *or registered establishment or* plant.

SECTION III

TRADE SAMPLES

[…]

SECTION IV

SPECIFIC REQUIREMENTS FOR TRANSIT AND EXPORT OF ANIMAL BY-PRODUCTS

1. This Section shall apply to the specific movements of animal by-product consignments coming from and destined to the Russian Federation directly or via another third country, by road or by rail through the European Union, between designated Union border inspection posts listed in Annex to Decision 2001/881/EC.

2. Member States shall authorise specific movements referred to in point 1, provided that the following conditions are met:

   (a) the consignment shall be sealed with a serially numbered seal at the border inspection post of entry to the EC by the veterinary services of the competent authority;

   (b) the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC shall be stamped “ONLY FOR TRANSIT TO RUSSIA VIA THE EC” on each page by the official veterinarian of the competent authority responsible for the border inspection post;

   (c) the procedural requirements provided for in Article 11 of Directive 97/78/EC shall be complied with;

   (d) the consignment is certified as acceptable for transit on the Common Veterinary Entry Document by the official veterinarian of the border inspection post of introduction.

5. Unloading or storage, as defined in Article 12(4) or Article 13 of Directive 97/78/EC of such consignments shall not be allowed on the territory of a Member State.

6. Regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the Union territory matches the number and quantities entering.

SECTION V

LISTING OF ESTABLISHMENTS AND PLANTS IN THIRD COUNTRIES

1. As referred to in the second subparagraph of Article 41(4), lists of establishments and plants in third countries shall be entered into the TRACES system in accordance with technical specifications which are published by the Commission on its website.

2. Each list shall be kept up-to-date regularly.

ANNEX XVIII

MODEL HEALTH CERTIFICATES

The model health certificates in this Annex shall apply to the importation from third countries and to the transit through the European Union of the animal by-products and the derived products referred to in the respective model health certificates.

Notes

(a) Veterinary certificates shall be produced by the exporting country, based on the models appearing in this Annex, 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) Where the model certificate states that certain statements shall be kept as appropriate, statements which are not relevant may be crossed out and initialled and stamped by the certifying officer, or completely deleted from the certificate.* (c) The original of each certificate shall consist of a single *sheet of paper*, both sides, or, where more text is required; it shall be in such a form that all *sheets of paper* needed are part of an integrated whole and indivisible. (d) It shall be drawn up in at least one of the official languages of the EU Member State in which the inspection at the border post shall be carried out and of the EU Member State of destination. However, these Member States may allow other languages, accompanied, if necessary, by an official translation. (e) If for reasons of identification of the items of the consignment, additional *sheets of paper* are attached to the certificate, these *sheets of paper* 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 *sheets of paper*.	(f) 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. (g) The original of the certificate must be completed and signed by an official veterinarian. In doing so, the competent authorities of the exporting country shall ensure that the principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed. (h) 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. (i) The original of the certificate must accompany the consignment at the EU border inspection post. (j) If health certificates are used for consignments in transit, box No I.5 (“Consignee”) of the relevant health certificate shall be completed with the name and address of the border inspection post through which the consignment is intended to leave the European Union.

CHAPTER 1

Health certificate

For processed animal protein not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit[2] through the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff | Technical use | Other

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight	Batch number

COUNTRY **Processed animal protein not intended for human consumption including mixtures and products other than petfood containing such protein**

	II.a. Certificate reference number	II.b.

II. **Health attestation**

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10 thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XIII, Section II, Chapter I, and Annex XVII, Section I, thereof and certify that:

II.1. the processed animal protein or product described above contains exclusively processed animal protein not intended for human consumption that;

(a) has been prepared and stored in an establishment or plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009[(2)], and

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

([2]) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

([2]) and/or [— carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;
(iv) pig bristles;
(v) feathers;]

([2]) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals, obtained from the animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation]

([2]) and/or [— animals by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

([2]) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]

([2]) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

([2]) and/or [— blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

([2]) and/or [— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

COUNTRY **Processed animal protein not intended for human consumption including mixtures and products other than petfood containing such protein**

	II.a. Certificate reference number	II.b.

([2]) and/or [— animal-by products from aquatic animals originating from establishments or plants manufacturing products for human consumption;]

([2]) and/or [— the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

– hatchery by-products,

– eggs,

– egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

and

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

(2) either [heating to a core temperature of more than 133°C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars produced by saturated steam, with a particle size prior to processing of not more than 50 millimetres;]

(2) or [in the case of non-mammalian protein other than fishmeal, the processing method 1-2-3-4-5-7 as set out in Annex VI, Section III, of Regulation (EC) No 1069/2009;]

(2) or [in the case of fishmeal the processing method 1-2-3-4-5-6-7…… as set out in Annex VI, Section III, of Regulation (EC) No 1069/2009;]

(2) or [in the case of porcine blood, the processing method 1-2-3-4-5-7……as set out in Annex VI, Section III to Regulation (EC) No 1069/2009, where in case of method 7 a heat treatment of at least 80 °C has been applied throughout its substance;]

II.2. the competent authority examined a random sample immediately prior to dispatch and found it to comply with the following standards ([3]):

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

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

II.3. the end product :

(2) either [was packed in new or sterilised bags,]

(2) or [was transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

which bear labels indicating “NOT FOR HUMAN CONSUMPTION”

II.4. the end product was stored in enclosed storage;

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

COUNTRY

Processed animal protein not intended for human consumption including mixtures and products other than petfood containing such protein

	II.a. Certificate reference number	II.b.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.05; 05.06; 05.07 or 23.01

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1a]) OJ L …, …

([1b]) OJ L …, …

([2]) Delete as appropriate.

([3]) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 2

Health certificate

For milk and milk products not intended for human consumption for dispatch to or for transit[2] through the Union

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.N°		I.2. Certificate reference number	I.2.a
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel.N°		I.6. Person responsible for the load in EU Name Address Postal code Tel.N°	
I.7.Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17. No.(s) of CITES	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20.Quantity	
I.21 Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Identification of container/Seal number		I.24.Type of packaging	
I.25. Commodities certified for: Animal feedingstuff ☐ Further process ☐ Technical use ☐ Other ☐			
I.26. For transit through EU to 3rd Country ☐ 3rd country ISO code		I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species Approval number of establishments Manufacturing plant Net weight Batch number			

COUNTRY **Milk and milk products not for human consumption**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health information

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009[(1)], and in particular Article 10 thereof, and Regulation (EU) No .../… , and in particular Chapter IV of Section II of Annex XIII thereof, and certify that the milk[(2)] or the milk products[(2)] referred to in box I.28 comply with the following conditions:

II.1. they were produced and derived in ……..…… (*insert name of exporting country*)[(3)], ……..…… (*insert name of region*) [(3)], which is listed in the Annex to Decision 2004/438/EC, and which has been free from foot-and-mouth disease (FMD) and rinderpest for 12 months immediately prior to export and has not practiced vaccination against rinderpest during that period;

II. 2. they were produced from raw milk derived from animals which at the time of milking did not show clinical signs of any disease transmissible through milk to humans or animals, and which had been kept for at least 30 days prior to production on holdings that were not subject to official restrictions due to foot-and-mouth disease or rinderpest;

II. 3. they are milk or milk products that:

[(2)]either [have undergone one of the treatments or combinations thereof described in point II. 4]

[(2)]*or* [where they comprise whey to be fed to animals of species susceptible to foot-and-mouth disease, that whey was collected from milk subjected to one of the treatments described in point II. 4 and

[(2)] either [the whey was collected at least 16 hours after clotting and has a pH below 6]

[(2)] or [the whey has been produced at least 21 days before the shipping and in this period no cases of FMD have been detected in the exporting country;]

[(2)] or [the whey has been produced on ../../.., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union][(4)]]

II. 4. they have been subject to one of the following treatments:

[(2)]either [High Temperature Short Time pasteurisation at 72°C for at least 15 seconds, or an equivalent pasteurisation achieving a negative reaction to a phosphatase test, in combination with:

[(2)]*either* [a subsequent second High Temperature Short Time pasteurisation at 72°C for at least 15 seconds or an equivalent pasteurisation which itself achieves a negative reaction to a phosphatase test]

[(2)]or [a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72°C or higher,]

[(2)]or [a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6;]

[(2)(4)]*or* [the condition that the milk/milk product has been produced at least 21 days before the shipping and in this period no cases of FMD have been detected in the exporting country;]

[(2)(4)]*or* [the milk/milk product has been produced on .../../…., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union]

[(2)]*or* [sterilisation at a level of at least $F_0$3]

[(2)]*or* [Ultra High Temperature treatment at 132°C for at least one second in combination with:

[(2)]either a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72°C or higher,]

[(2)]*or* a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6.]

[(2)(4)]*or* the condition that the milk/milk product has been produced at least 21 days

COUNTRY **Milk and milk products not for human consumption**

	II.a. Certificate reference number	II.b.

before the shipping and in this period no cases of FMD has been detected in the exporting country;]

(2)(4)or the milk/milk product has been produced on .../../…., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a Border Inspection Post of the European Union]

II. 5. every precaution was taken to avoid contamination of the milk/milk product after processing;

II. 6. the milk/milk product was packed :

*(2)*either [in new containers,]

*(2)*or [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority,]

and the containers are marked so as to indicate the nature of the milk/milk product and bear labels indicating that the product is Category 3 material and not intended for human consumption.

Notes

Part I:

- Box reference I.6: Person responsible for the load in EU: this box is to be filled in only if it is a certificate for transit commodity.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the Border Inspection Post of the European Union] .
- Box reference I.19: use the appropriate Harmonised System (HS) code of the World Customs Organisation: 23.09.10, 23.09.90, 35.01, 35.02 or 35.04.
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be included.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
- Box reference I.28: “Manufacturing plant”: provide the registration number of treatment or processing establishment.

Part II:

([1]) OJ L 300, 14.11.2009, p. 1.

([2]) Delete as appropriate.

([3]) For completion if the authorisation to import into the European Union is restricted to certain regions of the third country concerned.

([4]) this condition applies only to third countries listed in column "A" of Annex I to Decision 2004/438/EC

- The signature and the seal must be in a different colour from that of the printing.
- Note for the importer: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the Border Inspection Post of the European Union] .

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

— Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the Border Inspection Post of the European Union].

COUNTRY **Milk and milk products not for human consumption**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 3(A)

Health certificate

For canned petfood intended for dispatch to or for transit[2] through the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
23.09.10

I.20.Quantity

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

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

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

I.26. For transit to 3rd Country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities
Species (Scientific name) | Approval number of establishments: Manufacturing plant | Net weight | Batch number

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009] [1a] and in particular Articles 8 and 10 thereof, and Regulation (EU) No …/…[1b], and in particular Annex XV, Chapter II and Annex XVII, Section II, thereof and certify that the petfood described above:

II.1. has been prepared and stored in an establishment or plant approved and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;

II.2. has been prepared exclusively with the following animal by-products :

(2) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [— carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

(2) and/or [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]

(2) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [— blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2) and/or [— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [— animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

	II.a. Certificate reference number	II.b.

(2) and/or [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

– hatchery by-products,

– eggs,

– egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

([2]) and/or [— animal-by products from aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]

(2) and/or [— material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 35(1)(a)(ii) of Regulation (EC) No 1069/2009].

II.3. has been subjected to heat treatment to a minimum Fc value of 3 in hermetically sealed containers;

II.4. was analysed by a random sampling of at least five containers from each processed batch by laboratory diagnostic methods to ensure adequate heat treatment of the whole consignment as foreseen under point II.3;

II.5. has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1a) OJ …

(1b) OJ …

(2) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary

COUNTRY **Canned Petfood**

	II.a. Certificate reference number	II.b.
purposes and has to accompany the consignment until it reaches the border inspection post.		

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 3(B)

Health certificate

For processed petfood other than canned petfood, intended for dispatch to or for transit[2] through the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
☐ Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
23.09.10

I.20.Quantity

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

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

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

I.26. For transit to 3rd Country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments Manufacturing plant	Net weight	Batch number

COUNTRY **Processed petfood other than canned petfood**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Articles 8 and 10 thereof, and Regulation (EU) No …/… [(1b)], and in particular Annex XVI, Chapter II and Annex XVII, Section II thereof and certify that the petfood described above :

II.1. has been prepared and stored in a plant approved and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;

II.2. has been prepared exclusively with the following animal by-products :

(2) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [— carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

(2) and/or [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [— blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2) and/or [— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [— animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

COUNTRY **Processed petfood other than canned petfood**

	II.a. Certificate reference number	II.b.

(2) and/or [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

– hatchery by-products,

– eggs,

– egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

([2]) and/or [— animal-by products from aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]

(2) and/or [— material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 35(1)(a)(ii) of Regulation (EC) No 1069/2009].

II.3.

(2) either [was subjected to a heat treatment of at least 90 °C throughout its substance;]

(2) or [was produced as regards ingredients of animal origin using exclusively products which had been

(a) in the case of meat or meat products subjected to a heat treatment of at least 90 oC throughout its substance;

(b) in the case of milk and milk based products,

(i) if they are from third countries or parts of third countries listed in column B of Annex I to Decision 2004/438/EC(3) submitted to a pasteurisation treatment sufficient to produce a negative phosphatase test,

(ii) with a pH reduced to less than 6 from third countries or parts of third countries listed in column C of Annex I to Decision 2004/438/EC, first submitted to a pasteurisation treatment sufficient to produce a negative phosphatase test

(iii) if they are from third countries or parts of third countries listed in column C of Annex I to Decision 2004/438/EC, submitted to a sterilisation process or a double heat treatment where each treatment was sufficient to produce a negative phosphatase test on its own

(iv) if they are from third countries or parts of third countries listed in column C of Annex I to Decision 2004/438/EC where there has been an outbreak of foot-and-mouth disease in the last 12 months or where vaccination against foot-and-mouth disease has been carried out in the last 12 months submitted to

either

— a sterilisation process whereby an Fc value equal or greater than 3 is achieved

or

— an initial heat treatment with a heating effect at least equal to that achieved by a pasteurisation process of at least 72° C for at least 15 seconds and sufficient to produce a

	II.a. Certificate reference number	II.b.

negative reaction to a phosphatase test, followed by

either

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

or

— an acidification process such that the pH has been maintained at less than 6 for at least one hour;

(c) in the case of gelatine, produced using a process that ensures that unprocessed Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses with subsequent adjustment of the pH and subsequent, if necessary repeated, extraction by heat, followed by purification by means of filtration and sterilisation;

(d) in the case of hydrolysed protein produced using a production process involving appropriate measures to minimise contamination of raw Category 3 material, using only material with a molecular weight below 10000 Dalton and, in the case of hydrolysed protein entirely or partly derived from ruminant hides and skins produced in a processing plant dedicated only to hydrolysed protein production, using a process involving the preparation of raw Category 3 material by brining, liming and intensive washing followed by

(i) exposure of the material to a pH of more than 11 for more than three hours at a temperature of more than 80° C and subsequently by heat treatment at more than 140° C for 30 minutes at more than 3,6 bar; or

(ii) exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140° C for 30 minutes at 3 bar;

(e) in the case of egg products submitted to any of the processing methods 1 to 5 or 7, as referred to in Section III of Annex VI to Regulation (EC) No 1069/2009; or treated in accordance with Chapter II of Section X of Annex III to Regulation (EC) No 853/2004 (4);

(f) in the case of collagen submitted to a process ensuring that unprocessed Category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion, the use of preservatives other than those permitted by Union legislation being prohibited;

(g) in the case of blood products, produced using any of the processing methods 1 to 5 or 7, as referred to in Section III of Annex VI to Regulation (EC) No 1069/2009;

(h) in the case of mammalian processed animal protein submitted to any of the processing methods 1 to 5 or 7 and, in the case of porcine blood, submitted to any of the processing methods 1 to 5 or 7 provided that in the case of method 7 a heat treatment throughout its substance at a minimum temperature of 80 ° C has been applied;

(i) in the case of non-mammalian processed protein with the exclusion of fishmeal submitted to any of the processing methods 1 to 5 or 7 as referred to in Section III of Annex VI to Regulation (EC) No 1069/2009;

(k) in the case of fishmeal submitted to any of the processing methods or to a method and parameters which ensure that the products complies with the microbiological standards set in Section I of Annex XIII to Regulation (EC) No 1069/2009;

COUNTRY **Processed petfood other than canned petfood**

	II.a. Certificate reference number	II.b.

(l) in the case of rendered fat, including fish oils, submitted to processing methods 1 to 5 or 7 (and method 6 in the case of fish oil) as referred to in Section III of Annex VI to Regulation (EC) No 1069/2009 or produced in accordance with Chapter II of Section XII of Annex III to Regulation (EC) No 853/2004(4); rendered fats from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not excess 0.15% in weight;

(m) in the case of dicalcium phosphate produced by a process that

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

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

(iii) finally, air dries the precipitate of dicalcium phosphate with inlet temperature of 65° C to 325° C and end temperature between 30° C and 65° C;

(n) in the case of tricalcium phosphate produced by a process that ensures

(i) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);

(ii) continuous cooking with steam at 145° C during 30 minutes at 4 bar;

(iii) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation; and

(iv) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200° C];

II.4. was analysed by a random sampling of at least five samples from each processed batch taken during or after storage at the processing plant and complies with the following standards [(5)]:

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

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

II.5. has undergone all precautions to avoid contamination with pathogenic agents after treatment;

II.6. was packed in new packaging, which, if the petfood is not dispatched in ready-to-sell packages on which it is clearly indicated that the content is destined for feeding to pets only, bear labels indicating “NOT FOR HUMAN CONSUMPTION “.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

COUNTRY **Processed petfood other than canned petfood**

	II.a. Certificate reference number	II.b.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1a) OJ …

(1b) OJ …

(2) Delete as appropriate.

(3) OJ L 226, 25.06.2004, p. 22.

(4) OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22.

(5) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 3(C)

Health certificate

For dogchews intended for dispatch to or for transit[2] through the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
42.05.00

I.20.Quantity

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

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

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

I.26. For transit to 3rd Country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities
Species (Scientific name) | Approval number of establishments: Manufacturing plant | Net weight | Batch number

COUNTRY **Dogchews**

Part II: Certification

	II.a. Certificate reference number	II.b.

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009, [1a] and in particular Article 10, and Regulation (EU) No …/… [1b], and in particular Annex XVI, Chapter II and Annex XVII, Section II thereof, and certify that the dogchews described above :

II.1. have been prepared exclusively with the following animal by-products :

(2) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [—carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

(2) and/or [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

(2) and/or [— material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 35(1)(a)(ii) of Regulation (EC) No 1069/2009].

II.2. have been subjected

(2) either [in the case of dogchews made from hides and skins of ungulates or from fish, to a treatment sufficient to destroy pathogenic organisms (including salmonella); and the dogchews are dry];

(2) or [in the case of dogchews made from animal by-products other than hides and skins of ungulates or from fish, to a heat treatment of at least 90°C throughout their substance;]

II.3. were examined by random sampling of at least five samples from each processed batch taken during or after storage at the processing plant and complies with the following standards ([3]):

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

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

	II.a. Certificate reference number	II.b.

II.4. have undergone all precautions to avoid contamination with pathogenic agents after treatment;

II.5. were packed in new packaging.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

(1a)

(1b)

(2) Delete as appropriate.

(3) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post**.**

COUNTRY **Dogchews**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 3(D)

Health certificate

For raw petfood for direct sale or animal by-products to be fed to farmed fur animals, intended for dispatch to or for transit[2] through the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff | Technical use | Other

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight	Batch number

COUNTRY **Raw petfood for direct sale or animal by products to be fed to farmed fur animals**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10 thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XVI, Chapter I and Annex XVII, Section II thereof, and certify that the raw petfood or animal by-product described above :

II.1. consist of animal by-products that satisfy the health requirements below;

II.2. consist of animal by-products:

(a) derived from meat which satisfies the relevant animal and public health requirements laid down in :

— Council Decision 79/542/EEC[(2)] and provided the animals from which the meat is derived come from a territory or part of a territory ……(ISO code) as listed in that Decision which has been free of foot and mouth disease, rinderpest, classical swine fever, African swine fever and swine vesicular disease for the last 12 months and where no vaccination has taken place during that time (only as relevant for the susceptible species),

— and/or Commission Decision 2006/XXX/EC(3), and provided the animals from which the meat is derived come from a territory or part of a territory ……(ISO code) as listed in that Decision which has been free from Newcastle disease and Avian Influenza for the last 12 months,

— and/or Commission Decision 2000/585/EC(4) , and provided the animals from which the meat is derived come from a territory or part of a territory ……(ISO code) as listed which has been free from foot and mouth disease, rinderpest, classical swine fever, African swine fever, swine vesicular disease, Newcastle disease and Avian Influenza for the last 12 months and where no vaccination has taken place during that time (only as relevant for the susceptible species),

(b) derived from animals that, at the slaughterhouse, have passed the ante-mortem health inspection during the 24 hours before the slaughter and have shown no evidence of the diseases referred in the Decisions above for which the animals are susceptible, and

(c) derived from animals that have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EC(5) on animal welfare;

II.3. consist only of the following animal by-products:

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

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

II.4. have been obtained and prepared without contact with other material not complying with the conditions required in the Decisions above, and it has been handled so as to avoid contamination with pathogenic agents;

II.5. have been packed in final packaging which bear labels indicating “RAW PETFOOD - NOT FOR HUMAN CONSUMPTION” or “ANIMAL BY-PRODUCTS FOR FEED FOR FUR ANIMALS - NOT FOR HUMAN CONSUMPTION” and then in leak-proof and officially sealed boxes/containers or in new packaging preventing any leakage and officially sealed boxes/containers which bear labels indicating “RAW PETFOOD - NOT FOR HUMAN CONSUMPTION” or “ANIMAL BY-PRODUCTS FOR FEED FOR FUR ANIMALS - NOT FOR HUMAN CONSUMPTION”, the name and the address of the

	II.a. Certificate reference number	II.b.

establishment of destination;

II.6. in the case of raw petfood:

(a) have been prepared and stored in a plant approved and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009 and

(b) were examined by random sampling of at least five samples from each batch taken during storage (before dispatch) and complies with the following standards (6):

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

Enterobacteriacae: n=5, c=2, m=10, M=300 in 1 gram.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.91; 05.11.99 or 23.09.90.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: select raw petfood or animal by-product.

Part II:

([1]) Delete as appropriate.

([1a])

([1b])

([2]) Council Decision 79/542/EEC of 21 December 1976 drawing up a list of third countries or parts of third countries, and laying down animal and public health and veterinary certification conditions, for importation into the Union of certain live animals and their fresh meat.

([3]) Commission Decision 2006/696/EC. OJ No. L 295, 25.10.2006, p. 1.

([4]) Commission Decision 2000/585/EC of 7 September 2000 laying down animal and public health conditions and veterinary certifications for import of wild and farmed game meat and rabbit meat from third countries and repealing Commission Decisions 97/217/EC, 97/218/EC, 97/219/EC and 97/220/EC. OJ L 251,

	II.a. Certificate reference number	II.b.

6.10.2000, p. 1.

([5]) [Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing. OJ L 340, 31.12.1993, p. 21.]

([6]) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 3(E)

Health certificate

For flavouring innards for use in the manufacture of petfood, intended for dispatch to or for transit[2] through the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

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

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight	Batch number

COUNTRY **Flavouring innards for use in the manufacture of petfood**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009[1a] and in particular Article 10 thereof, and Regulation (EU) No …/…[1b], and in particular Annex XVI, Chapter III and Annex XVII, Section II thereof and certify that the flavouring innards products described above :

II.1. consist of animal by-products that satisfy the animal health requirement below;

II.2. have been prepared including the following animal by-products which are exclusively :

(2) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [— carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from the animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation];

(2) and/or [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]

(2) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [— blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2) and/or [— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [— animal-by products from aquatic animals originating from plants or establishments

COUNTRY **Flavouring innards for use in the manufacture of petfood**

	II.a. Certificate reference number	II.b.

manufacturing products for human consumption;]

(2) and/or [— the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

— hatchery by-products,

— eggs,

— egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

(2) and/or [— animal-by products from aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]

(2) and/or [- material from animals which have been treated with certain substances which are prohibited pursuant to Directive 96/22/EC, the import of the material being permitted in accordance with Article 35(1)(a)(ii) of Regulation (EC) No 1069/2009]

II.3. have been subjected to processing in accordance with Annex XVI, Chapter III of Regulation (EC) No …/…, in order to kill pathogenic agents;

II.4. have been examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards (3):

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

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

II.5. the end product was :

(2) either [packed in new or sterilised bags,]

(2) or [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”;

II.6. the end product was stored in enclosed storage;

II.7. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number

	II.a. Certificate reference number	II.b.

(aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.04 or 05.11.91.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: define the innard product.

Part II:

([1a])

([1b])

([2]) Delete as appropriate.

([3]) Where:

n = number of samples to be tested;

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

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

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

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 3(F)

Health certificate

For animal by-products for the manufacture of petfood, intended for dispatch to or for transit through [2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code | I.8. Region of origin Code

I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff Further process Technical use Other

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Animal by-products for the manufacture of petfood**

	II.a. Certificate reference number	II.b.

Part II: Certification

II.1. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009[1a] and Regulation (EU) No …/… and certify that the animal by-products described above :

II.1.1. consist of animal by-products that satisfy the animal health requirements below;

II.1.2. have been obtained in the territory of: ……[2] from animals:

[3] either [(a) that have remained in this territory since birth or for at least the last three months before slaughter;]

[3] or [(b) killed in the wild in this territory[4];]

II.1.3. have been obtained from animals:

[3] either [(a) coming from holdings :

(i) where, for the following diseases for which the animals are susceptible, there has been neither case/outbreak of rinderpest, swine vesicular disease, Newcastle disease or highly pathogenic avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days; nor in the holdings situated in their vicinity within 10 km, during the prior 30 days, and

(ii) where there has been neither case/outbreak of foot and mouth disease during the prior 60 days, nor in the holdings situated in their vicinity within 25 km, during the prior 30 days, and

(b) which :

(i) were not killed to eradicate any epizootic disease,

(ii) have remained in their holdings of origin for at least forty days before departure and which have been transported directly to the slaughterhouse without contact with other animals which did not comply with the same health conditions,

(iii) at the slaughterhouse, have passed the ante-mortem health inspection during the 24 hours before the slaughter and have shown no evidence of the diseases referred to above for which the animals are susceptible, and

(iv) have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EC on animal welfare;]

[3] or [(a) captured and killed in the wild in an area :

(i) in which within 25 km there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot and mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the prior 30 days , nor of classical or African swine fever during the prior 40 days and

(ii) that is situated at a distance that exceeds 20 km from the borders separating another territory of a country or part thereof, which is not authorised at these dates for exporting this material to the European Union, and

(b) which after killing were transported within 12 hours for chilling either to a collection centre and immediately afterwards to a game establishment, or directly to a game establishment;]

	II.a. Certificate reference number	II.b.

II.1.4. have been obtained in an establishment around which, within a radius of 10 km, there has been no case/outbreak of diseases referred to in point II.1.3 for which the animals are susceptible during the prior 30 days or, in the event of a case of disease, the preparation of raw material for exportation to the European Union has been authorised only after removal of all meat, and the total cleaning and disinfection of the establishment under the control of an official veterinarian;

II.1.5. have been obtained and prepared without contact with other material not complying with the conditions required above, and it has been handled so as to avoid contamination with pathogenic agents;

II.1.6. have been packed in new packaging preventing any leakage and in officially sealed containers bearing the label indicating "RAW MATERIAL ONLY FOR THE MANUFACTURE OF PETFOOD" and the name and address of the EU establishment of destination;

II.1.7. consist only of the following animal by-products :

(2) either [- carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [-carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [- animals by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

(2) and/or [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells form shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

– hatchery by-products,

– eggs,

– egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

	II.a. Certificate reference number	II.b.

(2) and/or [— animal-by products from aquatic or terrestrial invertebrates, other than species pathogenic to humans or animals;]

II.1.8. have been deep-frozen at the plant of origin or have been preserved in accordance with EU legislation in such a way that they will not spoil between dispatch and delivery to the plant of destination;

II.1.9. in the case of raw material derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC for the manufacture of petfood, the import being permitted in accordance with Article 35(1)(a)(ii) of Regulation (EC) No 1069/2009:

(a) it has been marked in the third country before entry into the territory of the Union by a cross of liquefied charcoal or activated carbon on each outer side of each frozen block in a way that the marking covers at least 70 % of the diagonal length of the frozen block and be of at least 10 cm width,

(b) in case of material which is not frozen, the raw material has been marked in the third country before entry into the territory of the Union by spraying it with liquefied charcoal or by applying charcoal powder in a way that the charcoal is clearly visible on the material, and

(c) in the case the animal by-products are made up of raw material which has been treated as referred to above and other non-treated raw material, all the raw materials have been marked as laid down in point (a) and (b) above.

(3) (6) [II.2. Specific requirements

(3) (7) II.2.1. The by-products in this consignment come from animals that have been kept in the territory mentioned under (II.1.2), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled in domestic bovine animals.

(3) (8) II.2.2. The by-products in this consignment consists only of animal by-products derived from trimmed offal of domestic ruminants, which have maturated at an ambient temperature of more than +2°C for at least three hours, or in the case of masseter muscles of bovine animals and de-boned meat of domestic animals, for at least 24 hours.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.91 or 05.11.99.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the veterinary control number of the approved

	II.a. Certificate reference number	II.b.

establishment.

Part II:

(*) Excluding raw blood, raw milk, hides and skins, hooves and horn, pig bristles and feathers (see relevant specific certificates for the import of these products).

([1a]) OJ

([1b]) OJ

([2]) The name and ISO code number of the exporting country as laid down in:

— part 1 of Annex II of Council Decision 79/542/EEC ;

— the Annex to Commission Decision 94/984/EC , and;

— the Annex to Commission Decision 2000/585/EC .

In addition the ISO code of regionalisation in this Annex (where applicable for the susceptible species concerned) should be included.

([3]) Delete as appropriate.

([4]) Only for countries from where game meat intended for human consumption of the same animal species is authorised for importation into the European Union.

([5]) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

([6]) Supplementary guarantees to be provided when the material of domestic ruminants originated in the territory of a South American or South African country or part thereof from where only maturated and de-boned fresh meat of domestic ruminants for human consumption is permitted for exportation to the European Union. In the case of offal only trimmed offal of domestic ruminants which must be exclusively offal from which the bones, cartilage, trachea and main bronchi, lymphatic glands, adhering connective tissue, fat and mucus have been completely removed is permitted. The whole masseter muscles of bovine animals, incised in accordance with paragraph 41(a) of Chapter VIII of Annex I to Council Directive 64/433/EEC, are also permitted.

([7]) Only for certain South American countries.

([8]) Only for certain South American and South African countries.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

COUNTRY **Animal by-products for the manufacture of petfood**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 4(A)

Health certificate

For the import of blood and blood products from equidae to be used outside the feed chain, for dispatch to or for transit[2] through the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
30.02

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities
Species | (Scientific name) | Approval number of establishments
Manufacturing plant

COUNTRY **Blood and blood products from equidae for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009(1) and in particular Article 8(1)(c) and Article 10 thereof, and Regulation (EU) No …/…, and in particular Chapter IV of Annex XVI thereto, and certify that the blood or blood products of equidae described above :

II.1. consist of blood or blood products from equidae that satisfy the health requirements below;

II.2. consist exclusively of blood or blood products of equidae not intended for human nor animal consumption;

II.3. come from a third country, territory or part thereof listed in row no. 3 of the table in Chapter II of Section II of Annex XVII to Regulation (EU) No …/… where the following diseases are compulsorily notifiable: African horse sickness, dourine, glanders (*Burkholderia mallei)*, equine encephalomyelitis (all types including VEE), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;

II.4. have been derived from blood which was collected under the supervision of a veterinarian, from equidae, which on inspection at the time of collection were free from clinical signs of infectious disease:

(2) *either* [in slaughterhouses approved in accordance with Regulation (EC) No 853/2004(3),]

(2) *or* [in slaughterhouses approved and supervised by the competent authority of the country of export,]

(2) *or* [in facilities approved and supervised by the competent authority of the country of export for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding for farmed animals.]

II.5. have been derived from blood which was collected from equidae

II.5.1. which on inspection on the date of blood collection did not show clinical signs of any of the compulsorily notifiable diseases listed in Annex A to Directive 90/426/EEC(4), and of Equine influenza, Equine piroplasmosis, Equine rhinopneumonitis and Equine viral arteritis listed in point 4 of Article 1.2.3. of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), 2008 Edition;

II.5.2. which have been kept for at least 30 days prior to the date of and during blood collection on holdings under veterinary supervision which were not subject to a prohibition order pursuant to Article 4(5) or restrictions for African horse sickness in accordance with Article 5 of Directive 90/426/EEC;

II.5.3. which had no contact with equidae from a holding which was subject to a prohibition order for animal health reasons pursuant to Article 4(5) of Directive 90/426/EEC.

II.5.4. have been derived from blood which was collected from equidae for which the period for the prohibition order referred to in points II.5.2. and II.5.3 has been determined as followed:

(2) *either* [where not all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected the period of prohibition has been:

- six months in the case of glanders (*Burkholderia mallei)*, beginning on the date on which the equidae infected with the disease are slaughtered;
- six months in the case of equine encephalomyelitis of any type, including Venezuelan equine encephalomyelitis, beginning on the date on which the equidae infected with the disease are slaughtered;
- in the case of equine infectious anaemia, until the date on which, the infected animals having been slaughtered, and the remaining animals have shown a negative reaction to two Coggins tests

COUNTRY **Blood and blood products from equidae for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

carried out three months apart;
- during six months from the date of the last recorded case of vesicular stomatitis;
- during one month from the date of the last recorded case of rabies;
- during 15 days from the date of the last recorded case of anthrax.]

([2]) or [if all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected, the period of prohibition shall be 30 days, beginning on the date on which the animals were slaughtered and the premises disinfected, except in the case of anthrax, where the period of prohibition shall 15 days]

II.6. blood products must come from a plant approved by the competent authority of the third country meeting the specific conditions set out in Article 17 or 18 of Regulation (EC) No 1774/2002.

II.7. blood products have been produced from blood which fulfils the conditions referred in II.4. and II.5 and

([2]) either [has been produced from blood collected from equidae which have been kept for a period of at least three months, or since birth if less than three months old, prior to the date of collection on holdings under veterinary supervision in the country of collection which during that period and the period of blood collection has been free of:

(a) African horse sickness for two years

(b) Venezuelan equine encephalomyelitis for a period of at least two years;

(c) glanders

[(2)] either [for a period of three years;]

[(2)] or [for a period of six months where the animals have passed the post-mortem inspection for glanders in the slaughterhouse referred to in paragraph 1, including a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum;]

(d) vesicular stomatitis for six months;]

([2]) or [has been subjected to at least one of the following treatments, followed by an effectiveness check, for the inactivation of possible causative pathogens for African horse sickness, equine encephalomyelitis of all types including Venezuelan equine encephalomyelitis, equine infectious anaemia, vesicular stomatitis and glanders (*Burkholderia mallei*):

[(2)] either [heat treatment at a temperature of 65°C for at least three hours]]

[(2)] or [irradiation at 25 kGy by gamma rays]]

[(2)] or [change in pH to pH 5 for two hours]]

[(2)] or [heat treatment of at least 80°C throughout their substance]]

II.8. all precautions have been taken to avoid contamination of the blood and blood products with pathogenic agents during production, handling and packaging;

II.9. blood and blood products were packed in sealed impermeable containers clearly labelled "NOT FOR HUMAN OR ANIMAL CONSUMPTION" and bearing the approval number of the establishment of collection;

COUNTRY **Blood and blood products from equidae for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

II.10. the products were stored in enclosed storage;

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the veterinary control number of the registered establishment of collection.

Part II:

([1]) OJ L 300, 14.11.2009, p. 1

([2]) Delete as appropriate

([3]) OJ No. L 139, 30.04.2004, p. 55

([4]) OJ L 224, 18.8.1990, p. 42

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 4(B)

Health certificate

For blood products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

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

COUNTRY **Blood products that could be used as feed**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] and Regulation (EC) No …/… [1b] and certify that the blood products described above :

II.1. consist of blood products that satisfy the health requirements below;

II.2. consist exclusively of blood products not intended for human consumption;

II.3. have been prepared and stored in a plant, approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;

II.4. have been prepared exclusively with the following animal by-products :

([2]) either [blood of slaughtered animals, which is fit for human consumption in accordance with Union legislation, but is not intended for human consumption for commercial reasons;]

([2]) and/or [blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to humans or animals, derived from carcasses that are fit for human consumption in accordance with Union legislation;]

II.5. have been submitted

([2]) either [to processing in accordance with processing method …….. (3) as set out in Annex VI, Section III of Regulation (EU) No …/…]

([2]) or [to a method and parameters which ensure that the product complies with the microbiological standards set in Annex XIII, Section I to Regulation (EU) …/…,]

in order to kill pathogenic agents;

II.6. have been examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards (4):

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

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

II.7. the end product was :

([2]) either [packed in new or sterilised bags,]

([2]) or [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,] and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”;

II.8. the end product was stored in enclosed storage;

II.9. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

COUNTRY **Blood products that could be used as feed**

	II.a. Certificate reference number	II.b.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.91 or 05.11.99.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1a]) OJ

([1b]) OJ

([2]) Delete as appropriate.

([3]) Insert method 1 to 5 or 7 as applicable.

([4]) Where:

n = number of samples to be tested,

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

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

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

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

COUNTRY **Blood products that could be used as feed**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 4(C)

Health certificate

For untreated blood products, excluding of equidae, for the manufacture of derived products for uses outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
☐ Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code | I.8. Region of origin Code

I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
30.02

I.20.Quantity

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

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Technical use ☐

I.26. For transit to 3rd Country vis-à-vis EU ☐
3rd country ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

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

COUNTRY **Untreated blood products, excluding of equidae, for derived products**

		II.a. Certificate reference number	II.b.

Part II: Certification

II.	Health attestation
	I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a),] and in particular Article 8(c) and (d) and Article 10 thereof, and Regulation (EU) No …/… [(1b)], and in particular Annex XVII, Section II thereof, and certify that:
II.1.	the blood products described above consist of blood products that satisfy the health requirements below;
II.2.	they consist exclusively of blood products not intended for human or animal consumption;
II.3.	they have been prepared and stored in a plant supervised by the competent authority or in the establishment of collection[(2)], exclusively with the following animal by-products:
[(2)]either	[- blood of slaughtered animals, which is fit for human consumption in accordance with Union legislation, but is not intended for human consumption for commercial reasons;]
(2) and/or	[- blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to humans or animals, derived from carcasses that are fit for human consumption in accordance with Union legislation;]
[(2)]and/or	[- blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation;]
[(2)]and/or	[- blood and blood products originating from live animals that are not immediately destined for slaughter and did not show signs of any disease communicable through that product to humans or animals;]
II.4.	the blood from which such products are manufactured has been collected:
[(2)]either	[in slaughterhouses approved in accordance with Union legislation,]
[(2)]or	[in slaughterhouses approved and supervised by the competent authority of the third country,]
[(2)]or	[from live animals in facilities approved and supervised by the competent authority of the third country.]
[(2)][II.5.	in the case of blood products derived from animals belonging to the taxa Artiodactyla, Perissodactyla and Proboscidea, including their crossbreds, the products come:
II.5.1.	from a country where no case of rinderpest, peste des petits ruminants and Rift Valley fever has been recorded for 12 months and in which vaccination has not been carried out against those diseases for at least 12 months.
[(2)][II.5.2. either	[from the territory of a country or region with code …. (3) where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination has not been carried out against this disease for at least 12 months]
[(2)][II.5.2. or	[from the territory of a country or region with code …. (3) where no case of foot-and-mouth disease has been recorded for 12 months and in which vaccination programmes against foot-and-mouth disease are being officially carried out and controlled in domestic ruminant animals for at least 12 months(4)]]
[(2)][II.5.3.	In addition, in case of animals other than Suidae and Tayassuidae:
[(2)]either	[in the country or region of origin no case of vesicular stomatitis and bluetongue(2) (including the presence of seropositive animals) has been recorded for 12 months and in which vaccination

COUNTRY **Untreated blood products, excluding of equidae, for derived products**

	II.a. Certificate reference number	II.b.

has not been carried out against those diseases for at least 12 months,]

(2)or [in the country or region of origin vesicular stomatitis and bluetongue(2) seropositive animals are present(4)]

(2)[II.5.4. In addition, in case of Suidae and Tayassuidae:

[II.5.4.1. [in the country or region of origin no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for at least 12 months and vaccination has not been carried out against those diseases for at least 12 months in the susceptible species]

(2)[II.5.4.2. either [in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for 12 months and in which vaccination has not been carried out against this disease for at least 12 months,]

(2)[II.5.4.2. o [in the country or region of origin vesicular stomatitis seropositive animals are present(4)]]

(2)[II.6. in the case of blood products derived from poultry or other avian species the animals and the products come from the territory of a country or region with code …. (5)]

which has been free from Newcastle disease and highly pathogenic avian influenza as defined in the Terrestrial Animal Health Code of the OIE

which for at least 12 months has not carried out vaccination against avian influenza

where the animals from which the products derive have not been vaccinated against Newcastle disease with vaccines prepared from a Newcastle disease master strain showing a higher pathogenicity than lentogenic virus strains.]

II.7. the products were:

(2) either [packed in new or sterilised bags or bottles,]

(2) or [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

the outer packaging or containers bear labels indicating “NOT FOR HUMAN OR ANIMAL CONSUMPTION”;

II.8. the products were stored in enclosed storage;

II.9. the products have undergone all precautions to avoid contamination with pathogenic agents during transport.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number

	II.a. Certificate reference number	II.b.

(aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1a]) OJ

([1b]) OJ

([2]) Delete as appropriate.

([3]) Code of the territory as it appears in Part 1 of Annex II to Decision 79/542/EEC.

([4]) In this case following the border check provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the plant of destination.

(5) Code of the territory as it appears in Part 1 of Annex II to Decision 2006/696/EC.

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

— Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 4(D)

Health certificate

For treated blood products, excluding of equidae, for the manufacture of derived products for uses outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code | I.8. Region of origin Code

I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
30.02

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

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

COUNTRY **Treated blood products, excluding of equidae, for products other than feeding to farmed animals**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 (1a) and in particular Article 8(c) and 8(d) and Article 10 and Regulation (EU) No …/… (1b), and in particular Annex XVII, Section II thereof, and certify that:

II.1. the blood products described above consist of blood products that satisfy the requirements below;

II.2. they consist exclusively of blood products not intended for human or animal consumption;

II.3. they have been prepared and stored in a plant supervised by the competent authority exclusively with the following animal by-products:

(2) either [— blood of slaughtered animals, which is fit for human consumption in accordance with Union legislation, but is not intended for human consumption for commercial reasons;]

(2) and/or [— blood of slaughtered animals, which is rejected as unfit for human consumption but is not affected by any signs of diseases communicable to humans or animals, derived from carcasses that are fit for human consumption in accordance with Union legislation;]

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

(2) and/or [— blood and blood products originating from live animals that did not show clinical signs of any disease communicable through these products to humans or animals.]

II.4. the blood from which such products are manufactured has been collected:

(2) either [in slaughterhouses approved in accordance with Union legislation,]

(2) or [in slaughterhouses approved and supervised by the competent authority of the third country,]

(2) or [from live animals in facilities approved and supervised by the competent authority of the third country.]

(2) [II.5. In case of blood products derived from Artiodactyla, Perissodactyla and Proboscidea including their crossbreeds, other than Suidae and Tayassuidae, the products have undergone one of the following treatments, guaranteeing the absence of pathogens of foot-and-mouth disease, vesicular stomatitis, rinderpest, peste des petits ruminants, Rift Valley fever and bluetongue:

(2) either [heat treatment at a temperature of 65°C for at least three hours, followed by an effectiveness check,]

(2) or [irradiation at 25 kGy by gamma rays, followed by an effectiveness check,]

(2) or [change in pH to pH 5 for two hours, followed by an effectiveness check,]

(2) or [heat treatment of at least 80°C throughout their substance, followed by an effectiveness check]]

(2) [II.6. In the case of blood products derived from Suidae, Tayassuidae, poultry and other avian species, the products have undergone one of the following treatments guaranteeing the absence of pathogens of the following diseases: foot-and-mouth disease, vesicular stomatitis, swine vesicular disease, classical swine fever, African swine fever, Newcastle disease and highly pathogenic avian influenza as appropriate to the species;

(2) either [heat treatment at a temperature of 65°C for at least three hours, followed by an effectiveness check,]

COUNTRY **Treated blood products, excluding of equidae, for products other than feeding to farmed animals**

	II.a. Certificate reference number	II.b.

(2) or [irradiation at 25 kGy by gamma rays, followed by an effectiveness check,]

(2) or [heat treatment of at least 80°C for Suidae/Tayassuidae (2) and at least 70°C for poultry and other avian species(2) throughout their substance, followed by an effectiveness check]]

(2) [II.7. In the case of blood products derived from species other than listed under II.5. or II.6. the products have undergone of the following treatment (please specify):…….]

II.8. The products were :

(2) either [packed in new or sterilised bags or bottles,]

(2) or [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

he outer packaging or containers bear labels indicating “NOT FOR HUMAN OR ANIMAL CONSUMPTION”;

II.9. the products were stored in enclosed storage;

II.10. the products have undergone all precautions to avoid contamination with pathogenic agents after treatment.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1a]) OJ

([1b]) OJ

([2]) Delete as appropriate.

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

— Note for the person responsible for the consignment in the European Union: this certificate is only for

COUNTRY **Treated blood products, excluding of equidae, for products other than feeding to farmed animals**

	II.a. Certificate reference number	II.b.
veterinary purposes and has to accompany the consignment until it reaches the border inspection post.		
Official veterinarian Name (in capital letters): Qualification and title: Date: Signature: Stamp:		

CHAPTER 5(A)

Health certificate

For fresh or chilled hides and skins of ungulates, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No.(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

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

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments: Manufacturing plant	Net weight

COUNTRY **Fresh or chilled hides and skins of ungulates**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10 thereof, and Regulation (EU) No …/… [(1b)], and in particular Annex XVII, Section II thereof, and certify that the hides and skins described above :

II.1. have been obtained from animals that [(2)]:

(a) were slaughtered and their carcasses are fit for human consumption in accordance with Union legislation or

(b) were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were considered fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation;

II.2. originate from a country or, in the case of regionalisation in accordance with Union legislation, from a part of a country from which imports of all categories of fresh meat of the corresponding species are authorised and which :

(a) for at least 12 months before dispatch, has been free from the following diseases [(3)]:

[— classical swine fever, and African swine fever,]

[— rinderpest,]

and

(b) has been free for at least 12 months before dispatch from foot-and-mouth disease and where, for 12 months before dispatch, no vaccination has been carried out against foot-and-mouth disease [(3)];

II.3. have been obtained from :

[animals that have remained in the territory of the country of origin for at least three months before being slaughtered or since birth in the case of animals less that three months old;]

[in the case of hides and skins from bi-ungulates, animals that come from holdings in which there has been no outbreak of foot-and-mouth disease in the previous 30 days, and around which within a radius of 10 km there has been no case of foot-and-mouth disease for 30 days;]

[in the case of hides and skins from swine, animals that come from holdings in which there has been no outbreak of swine vesicular disease in the previous 30 days, or of classical or African swine fever in the previous 40 days, and around which within a radius of 10 km there has been no case of these diseases for 30 days;]

[animals that have shown no evidence of [foot-and-mouth disease], [rinderpest], [classical swine fever], [African swine fever] or [swine vesicular disease](3) during ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter;]

II.4. have undergone all precautions to avoid recontamination with pathogenic agents.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

	II.a. Certificate reference number	II.b.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 41.01; 41.02 or 41.03.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1a]) OJ

([1b]) OJ

([2]) Delete as appropriate.

([3]) Delete diseases not applicable to the species concerned.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 5(B)

Health certificate

For treated hides and skins of ungulates, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
☐ Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No.(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

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

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

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

I.26. For transit to 3rd Country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities
Species (Scientific name) | Approval number of establishments Manufacturing plant | Net weight

COUNTRY **Treated hides and skins of ungulates**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1)] and in particular Article 10 thereof, and Regulation (EU) No …/… [(1b)], and in particular Annex XVII, Section II thereof, and certify that the hides and skins described above :

II.1. have been obtained from animals that [(2)]:

(a) were slaughtered and their carcasses are fit for human consumption in accordance with Union legislation or

(b) were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were considered fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation or

(c) did not show any clinical signs of any disease communicable to humans or animals through the hide or skin, and were not killed to eradicate any epizootic disease;

[(2)]either [II.2 come from animals originate from a third country or, in the case of regionalisation in accordance with Union legislation, from a part of a third country listed in part 1 of Annex II to Decision 79/542/EEC(3) from which imports of fresh meat of the corresponding species are authorised and have been:

[(2)]either [dried;]

[(2)]or [dry-salted or wet-salted for at least 14 days prior to dispatch;]

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

[(2)]or [salted for seven days in sea salt with the addition of 2% of sodium carbonate;]

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

[(2)]or [II.2. come from animals originate from a third country or, in the case of regionalisation in accordance with Union legislation, from a part of a third country listed in part 1 of Annex II to Decision 79/542/EEC from which imports of fresh meat of the corresponding species are NOT authorised and have been::

[(2)]either [salted for seven days in sea salt with the addition of 2% of sodium carbonate;]

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

[(2)]or [dried for 42 days at a temperature of at least 20°C;]

II.3. the consignment has not been in contact with other animal products or with live animals presenting a risk of spreading a serious transmissible disease.

COUNTRY **Treated hides and skins of ungulates**

	II.a. Certificate reference number	II.b.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) and information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 41.01; 41.02 or 41.03.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1a]) OJ

([1b]) OJ

([2]) Delete as appropriate.

([3]) OJ L 146, 14.6.1979, p. 15.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 5(C)

Official declaration

For treated hides and skins of ruminants and of equidae that are intended for dispatch to or for transit through[2] the European Union and have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No.(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff | Technical use | Other

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities
Species (Scientific name) | Approval number of establishments Manufacturing plant | Net weight

COUNTRY

Treated hides and skins of Ruminants and of Equidae that have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation

Part II: Certification

	II.a. Certificate reference number	II.b.

II. Declaration

I, the undersigned declare that the hides and skins described above :

II.1. have been obtained from animals that [(1)] :

(a) were slaughtered and their carcasses are fit for human consumption in accordance with Union legislation or

(b) were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were considered fit, as a result of such inspection, for slaughter for human consumption in accordance with Union legislation or

(c) did not show any clinical signs of any disease communicable to humans or animals through the hide or skin, and were not killed to eradicate any epizootic disease;

II.2. have been:

[(1)] either [dried;]

[(1)] or [dry-salted or wet-salted for at least 14 days prior to dispatch;]

[(1)] or [salted for seven days in sea salt with the addition of 2% of sodium carbonate;]

II.3. have not been in contact with other animal products or with live animals presenting a risk or spreading a serious transmissible disease;

[(1)] either [II.4. have been kept separate immediately before dispatch for 21 days under official supervision after the treatment described under point (II.2).]

[(1)] or [II.4. following the declaration of the transporter, the duration of the transport period is foreseen to be at least 21 days.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 41.01; 41.02 or 41.03.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

COUNTRY **Treated hides and skins of Ruminants and of Equidae that have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation**

	II.a. Certificate reference number	II.b.

Part II:

([1]) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: This declaration is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 6(A)

Health certificate

For treated game trophies of birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins, for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No.(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21.

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Other

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities
Species | (Scientific name) | Nature of commodity | Number of packages

COUNTRY **Treated game trophies of birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins**

Part II: Certification

II.a. Certificate reference number	II.b.

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] and Regulation (EU) No …/…[1b], and in particular Annex XVII, Section II thereof, and certify that the game trophies described above :

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

[2] either[II.2. in the case of game trophies consisting solely of hides or skin :

[2] either [have been dried.]

[2] or [have been dry-salted or wet-salted for a minimum of 14 days before dispatch.]

[2] or [were dry-salted or wet-salted on ……..… (date) and, according to the declaration of the transporter, will be transported by ship and the duration of the transport will be such that they will have undergone a minimum of 14 days salting before they reach the EC border inspection post.]]

[2] or [II.2. in the case of game trophies consisting solely of bone, horns, hooves, claws, antlers or teeth :

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

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

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.19: use the appropriate HS code: 05.05; 05.06; 05.07 or 97.05.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: for nature of commodity, specify choosing one or more possibilities among the following: [bones], [horns], [hooves], [claws], [antlers], [teeth], [hides] or [skins]

Part II:

COUNTRY **Treated game trophies of birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins**

	II.a. Certificate reference number	II.b.

([1a])	OJ
([1b])	OJ
([2])	Delete as appropriate.
—	The signature and the stamp must be in a different colour to that of the printing.
—	Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 6(B)

Health certificate

For game trophies of birds and ungulates consisting of entire parts not having been treated, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code | I.8. Region of origin Code

I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No.(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21.

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Other

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities
Species (Scientific name) Number of packages

COUNTRY **Game trophies of birds and ungulates consisting of entire parts not having been treated**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and Regulation (EU) No …/…[(1b)], and in particular Annex XVII, Section II thereof, and certify that the game trophies described above :

[(2)] either [II.1. with respect to game trophies of cloven-hoofed animals, excluding swine :

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

(b) the game trophies described above :

(i) were obtained from animals which were killed in the territory of that region, which is authorised for export of fresh meat of the corresponding susceptible domestic species and where, during the last 60 days, there have been no animal health restrictions because of outbreaks of diseases to which the game animals are susceptible, and

(ii) originated from animals that were killed at a distance of at least 20 km from the borders of another third country or part of a third country not authorised to export untreated game trophies of cloven-hoofed animals other than swine to the Union;]

[(2)] or [II.1. with respect to game trophies of wild swine :

(a) …… (region) during the last 12 months was free from classical swine fever, African swine fever, swine vesicular disease, foot-and-mouth disease and porcine enteroviral encephalmiyelitis (Teschen disease) and no vaccinations have been carried out against any of those diseases during the last 12 months, and

(b) the game trophies described above :

(i) were obtained from animals which were killed in that territory, which is authorised for export of fresh meat of the corresponding susceptible domestic species and where, during the last 60 days, there have been no animal health restrictions because of outbreaks of diseases to which the swine are susceptible, and

(ii) originated from animals that were killed at a distance of at least 20 km from the borders of another third country or part of a third country not authorised to export untreated game trophies of wild swine to the Union;]

[(2)] or [II.1. with respect to game trophies of solipeds, the game trophies described above were obtained from wild solipeds that were killed in the territory of the exporting country mentioned above;]

[(2)] or [II.1. with respect to game trophies of game birds :

(a) …… (region) is free from highly pathogenic avian influenza and Newcastle disease, and

(b) the game trophies described above were obtained from wild game birds that were killed in that region and where during the last 30 days there have been no animal health restrictions because of outbreaks of disease to which the wild birds are susceptible;]

II.2. The game trophies described above have been packaged without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination.

COUNTRY **Game trophies of birds and ungulates consisting of entire parts not having been treated**

	II.a. Certificate reference number	II.b.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.05; 05.06 or 05.07.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1a]) OJ

([1b]) OJ

([2]) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 7 (A)

Health certificate

For pig bristles from third countries or regions thereof that are free from African swine fever, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
05.02

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

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

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities
Approval number of establishments
Manufacturing plant | Number of packages | Net weight

COUNTRY **Pig bristles from third countries or regions thereof that are free from African swine fever**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] , and in particular Article 10(b)(iv) thereof, and Regulation (EU) No …/…[1b], and in particular Annex XVII Section II thereof, and certify that :

II.1. the pig bristles described above have been obtained from pigs originating, and slaughtered in a slaughterhouse, in the country of origin;

II.2. the pigs, from which the pig bristles have been obtained, did not show during inspection, carried out at the time of slaughtering, signs of diseases communicable to humans or animals and were not killed to eradicate any epizootic disease;

II.3. the country of origin or, in case of regionalisation according to Union legislation, the region of origin, has been free from African swine fever for at least 12 months;

II.4. the pig bristles are dry and securely enclosed in packaging.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the veterinary control number of the registered establishment.

Part II:

([1a]) OJ

([1b]) OJ

([2]) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

COUNTRY **Pig bristles from third countries or regions thereof that are free from African swine fever**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 7 (B)

Health certificate

For pig bristles from third countries or regions thereof that are not free from African swine fever, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code | I.8. Region of origin Code

I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
05.02

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

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

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities
Approval number of establishments
Manufacturing plant Number of packages Net weight

COUNTRY **Pig bristles from third countries or regions thereof that are not free from African swine fever**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10(b)(iv) thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XVII, Section II thereof, and certify that :

II.1. the pig bristles described above have been obtained from pigs originating, and slaughtered in a slaughterhouse, in the country of origin;

II.2. the pigs from which the pig bristles have been obtained did not show during inspection, carried out at the time of slaughtering, signs of diseases communicable to humans or animals and were not killed to eradicate any epizootic disease;

II.3. the pig bristles mentioned above have been :

[(2)] either [boiled;]

[(2)] or [dyed;]

[(2)] or [bleached;]

II.4. the pig bristles are dry and securely enclosed in packaging.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the veterinary control number of the registered establishment.

Part II:

([1a]) OJ

([1b]) OJ

([2]) Delete as appropriate.

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

COUNTRY **Pig bristles from third countries or regions thereof that are not free from African swine fever**

	II.a. Certificate reference number	II.b.

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 8

Health certificate

For animal by-products to be used for the production of derived products for uses outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Animal by-products for the manufacture of derived products for uses outside the feed chain**

Part II: Certification

II.a. Certificate reference number	II.b.

II.1. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10 thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XVII, Section II thereof certify that the animal by-products described above :

II.1.1. consist of animal by-products that satisfy the animal health requirements below;

II.1.2. have been obtained in the territory of:……..……[(2)] from animals:

[(3)] either [(a) that have remained in this territory since birth or for at least the last three months before slaughter;]

[(3)] or [(b) killed in the wild in this territory[(4)]]

II.1.3. have been obtained from animals:

[(3)] either [(a) coming from holdings :

(i) where, for the following diseases for which the animals are susceptible, there has been neither case/outbreak of rinderpest, swine vesicular disease, Newcastle disease or highly pathogenic avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days; nor in the holdings situated in their vicinity within 10 km, during the prior 30 days, and

(ii) where there has been neither case/outbreak of foot and mouth disease during the prior 60 days, nor in the holdings situated in their vicinity within 25 km, during the prior 30 days, and

(b) which :

(i) were not killed to eradicate any epizootic disease,

(ii) have remained in their holdings of origin for at least forty days before departure and which have been transported directly to the slaughterhouse without contact with other animals which did not comply with the same health conditions,

(iii) at the slaughterhouse, have passed the ante-mortem health inspection during the 24 hours before the slaughter and have shown no evidence of the diseases referred to above for which the animals are susceptible, and

(iv) have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EC on animal welfare]

[(3)] or [(a) captured and killed in the wild in an area :

(i) in which within 25 km there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot and mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the prior 30 days nor of classical or African swine fever during the prior 40 days and

(ii) that is situated at a distance that exceeds 20 km from the borders separating another territory of a country or part thereof, which is not authorised at these dates for exporting this material to the European Union, and

(b) which after killing were transported within 12 hours for chilling either to a collection centre and immediately afterwards to a game establishment, or directly to a game establishment]

II.1.4. have been obtained in an establishment around which, within a radius of 10 km, there has been no

	II.a. Certificate reference number	II.b.

case/outbreak of diseases referred to in point II.1.3 for which the animals are susceptible during the prior 30 days or, in the event of a case of disease, the preparation of raw material for exportation to the European Union has been authorised only after removal of all meat, and the total cleaning and disinfection of the establishment under the control of an official veterinarian;

II.1.5. have been obtained and prepared without contact with other material not complying with the conditions required above, and it has been handled so as to avoid contamination with pathogenic agents;

II.1.6. have been packed in new packaging preventing any leakage and in officially sealed containers bearing the label indicating "RAW MATERIAL ONLY FOR THE MANUFACTURE OF DERIVES PRODUCTS/ NOT FOR HUMAN OR ANIMAL CONSUMPTION OR APPLICATION TO LAND " and the name and address of the EU establishment of destination;

II.1.7. consist only of the following animal by-products :

(2) either[── carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [── carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [── blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

(2) and/or [── animals by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [── products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [── petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [── blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2) and/or [── aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

COUNTRY **Animal by-products for the manufacture of derived products for uses outside the feed chain**

	II.a. Certificate reference number	II.b.

(2) and/or [── animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

(2) and/or [── the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;

(ii) the following originating from terrestrial animals:

── hatchery by-products,

── eggs,

── egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

II.1.8. have been deep-frozen at the plant of origin or have been preserved in accordance with EU legislation in such a way that they will not spoil between dispatch and delivery to the plant of destination.

(3) (6) [II.2. Specific requirements

(3)(7) II.2.1. The by-products in this consignment come from animals that have been obtained in the territory mentioned under (II.1.2), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled in domestic bovine animals.

(3)(8) II.2.2. The by-products in this consignment consists of animal by-products derived from offal or de-boned meat.]

Notes

Part I:

── Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

── Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

── Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

── Box reference I.19: use the appropriate HS code: 05.11.91; 05.11.99 or 30.01.

── Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

── Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

── Box reference I.28: Manufacturing plant: provide the veterinary control number of the approved establishment.

COUNTRY **Animal by-products for the manufacture of derived products for uses outside the feed chain**

	II.a. Certificate reference number	II.b.

Part II:

(*) Excluding raw blood, raw milk, hides and skins of ungulates or ruminants and pig bristles (see relevant specific certificates for the import of these products) as well as wool, hair, feathers or parts of feathers.

([1]) OJ.

([2]) The name and ISO code number of the exporting country as laid down in:

part 1 of Annex II of Council Decision 79/542/EEC ;

the Annex to Commission Decision 94/984/EC , and;

the Annex to Commission Decision 2000/585/EC .

In addition the ISO code of regionalisation in this Annex (where applicable for the susceptible species concerned) should be included.

([3]) Delete as appropriate.

([4]) Only for countries from where game meat intended for human consumption of the same animal species is authorised for importation into the European Union.

([5]) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

([6]) Supplementary guarantees to be provided when the material of domestic ruminants originated in the territory of a South American or South African country or part thereof from where only maturated and de-boned fresh meat of domestic ruminants for human consumption is permitted for exportation to the European Union. In the case of offal only trimmed offal of domestic ruminants which must be exclusively offal from which the bones, cartilage, trachea and main bronchi, lymphatic glands adhering connective tissue, fat and mucus have been completely removed is permitted. The whole masseter muscles of bovine animals, incised in accordance with paragraph 41(a) of Chapter VIII of Annex I to Council Directive 64/433/EEC, are also permitted.

([7]) Only for certain South American countries.

([8]) Only for certain South American and South African countries.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 9

Health certificate

For fish oil not intended for human consumption to be used as feed material or for purposes outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8.

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff | Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Fish oil to be used as feed material or for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] and in particular Article 10 thereof, and Regulation (EU) No …/…[1b], and in particular Annex XVII, Section II thereof, and certify that the fish oil described above :

II.1. consists of fish oil that satisfy the health requirements below;

II.2. contains exclusively fish oil not intended for human consumption;

II.3. has been prepared and stored in a dedicated fish plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;

II.4. has been prepared exclusively with the following animal by-products :

(2) and/or [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [- animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

II.5. the fish oil:

(a) has been subjected to processing in accordance with Annex XIII, Section II, Chapter III of Regulation …/… , in order to kill pathogenic agents,

(b) has not been in contact with other types of oils including rendered fats from other animal species, and

(2) either [(c) is packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination,]

(2) or [(c) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the product from the manufacturing plant either directly on to the ship or into shore tanks or direct to plants have been inspected and found to be clean before use,]

and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

COUNTRY **Fish oil to be used as feed material or for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

— Box reference I.19: use the appropriate HS code: 15.04 or 15.18.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.

Part II:

([1]) [ ]

([2]) Delete as appropriate

([3]) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 10(A)

Health certificate

For rendered fats not intended for human consumption to be used as feed material or for uses outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code I.8.

I.9. Country of destination ISO code I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Rendered fats not intended for human consumption to be used as feed material or outside the feed chain**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10 thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XVII, Section II thereof, and certify that the rendered fats described above :

II.1. consist of rendered fats that satisfy the health requirements below;

II.2. consist of rendered fats not intended for human consumption;

II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009 or in accordance with Article 4(2) of Regulation (EC) No 853/2004[(2)] , in order to kill pathogenic agents;

II.4. have been prepared exclusively with the following animal by-products :

(2) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [— carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of:

– animals, other than ruminants requiring TSE testing; and

– ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;

(iv) pig bristles;
(v) feathers;]

(2) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from the following animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation:

(i) animals other than ruminants requiring TSE testing; and
(ii) ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;]

(2) and/or [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health

COUNTRY **Rendered fats not intended for human consumption to be used as feed material or outside the feed chain**

	II.a. Certificate reference number	II.b.

arises;]

(2) and/or [── blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2) and/or [── aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [── animal-by products from aquatic animals originating form plants or establishments manufacturing products for human consumption;]

(2) and/or [── the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

– hatchery by-products,

– eggs,

– egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

II.5. if derived from ruminant animals were purified in such way that the maximum levels of remaining total insoluble impurities does not exceed 0.15 % in weight;

II.6. the rendered fats :

(a) have been subjected to processing in accordance with Annex XIII, Section II, Chapter III of Regulation (EC) No …/… , or treatment in accordance with Section XII of Annex III to Regulation (EC) No 853/2004, in order to kill pathogenic agents, and

(4) either [(b) are packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination,]

(4) or [(b) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the product from the manufacturing plant either directly on to the ship or into shore tanks or direct to plants have been inspected and found to be clean before use,]

and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”.

Notes

Part I:

── Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

── Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

── Box reference I.15: Registration number (railway wagons or container and lorries), flight number

COUNTRY **Rendered fats not intended for human consumption to be used as feed material or outside the feed chain**

	II.a. Certificate reference number	II.b.

(aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 15.02; 15.03; 15.04; 15.05; 15.06; 15.16.10; 15.17 or 15.18.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.

Part II:

([1a]) [ ]

([1b]) [ ]

([2])

([3]) Delete as appropriate

([5]) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 10(B)

Health certificate

For rendered fats not intended for human consumption to be used outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8.

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Rendered fats to be used for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] and in particular Article 10 thereof, and Regulation (EU) No …/…[1b], and in particular Annex XVII, Section II thereof, and certify that the rendered fats described above :

II.1. consist of rendered fats that satisfy the health requirements below;

II.2. consist of rendered fats not intended for human or animal consumption;

II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, in order to kill pathogenic agents;

II.4. have been prepared exclusively with the following animal by-products :

[2] either [Category 2 materials[3]]

[2] or [a mixture of Category 2 materials with Category 3 materials[4]]

II.5. if derived from ruminant animals were purified in such way that the maximum levels of remaining total insoluble impurities does not exceed 0.15 % in weight;

II.6. the rendered fats :

(a) have been subjected to processing in accordance with Annex XIII, Section II, Chapter III of Regulation (EC) No …/… , in order to kill pathogenic agents, and

[2]either [(b) are packaged in new containers or in containers that have been cleaned and all precautions taken to prevent their contamination,]

[2]or [(b) where bulk transport is intended, the pipe, pumps and bulk tanks and any other bulk container or bulk road tanker used in the transportation of the product from the manufacturing plant either directly on to the ship or into shore tanks or direct to plants have been inspected and found to be clean before use,]

and which bear labels indicating “NOT FOR HUMAN OR ANIMAL CONSUMPTION”.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 15.01; 15.02; 15.03; 15.04; 15.05; 15.06; 15.16.10; 15.17 or 15.18.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable)

	II.a. Certificate reference number	II.b.

should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.

Part II:

([1]) [ ]

([2]) Delete as appropriate

([3]) **List of Category 2 materials**:

(a) manure, non-mineralised guano and digestive tract content;

(b) animal by products collected during the treatment of waste water required by Annex VI Section I Chapter II of Regulation (EC) No …/…, from establishments or plants processing Category 2 material, or from slaughterhouses other than those covered by Article 8 (e) of Regulation (EC) No 1069/2009;

(c) animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels as referred to in Article 15(3) of Directive 96/23/EC;

(d) products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;

(e) products of animal origin, other than Category 1 material, that are:

(i) imported or introduced from a third country and which fail to comply with the Union veterinary legislation for their importation or introduction into the Union except where Union legislation allows their importation or introduction subject to specific restrictions or their return to the third country; or

(ii) dispatched to another Member State and fail to comply with requirements laid down or authorised by Union legislation except where they are returned with the authorisation of the competent authority of the Member States of origin.

(f) animals and parts of animals, other than those referred to in Article 8 or 10 of Regulation (EC) No 1069/2009,

(i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes, and

(ii) foetuses, embryos and semen which are not destined for breeding purposes; and

(iii) dead-in-shell poultry;

(g) mixtures of Category 2 material with Category 3 material;

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

([4]) **List of Category 3 materials:**

(a) carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are

COUNTRY **Rendered fats to be used for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

not intended for human consumption for commercial reasons;

(b) carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;
(iv) pig bristles;
(v) feathers;

(c) blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants, that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;

(d) animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;

(e) products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;

(ea) petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises

(f) blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;

(g) aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;

(h) fresh animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;

(i) the following material originating form animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

— hatchery by-products,

— eggs,

— egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons.

COUNTRY **Rendered fats to be used for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

(j) aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;

(k) dead animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8 (a)(iii),(iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;

(l) hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals other than those referred to in point (b) of this list;

(la) adipose tissue from animals which did not show any signs of disease communicable throught that material to humans or animals, which were slaughtered in a slaughterhouse and which were considere fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;

(m) catering waste other than as referred to in Article 8(f) of Regulation (EC) No 1069/2009

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 10(C)

Health certificate

For rendered fats not intended for human consumption to be used for certain purposes outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code I.8.

I.9. Country of destination ISO code I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Rendered fats not intended for human consumption for uses outside the feed chain**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] and in particular Articles 8, 9 and 10 thereof, and Regulation (EU) No …/… [1b], and in particular Annex XVII, Section II thereof, and certify that the rendered fats described above :

II.1. consist of rendered fats not intended for human consumption that satisfy the health requirements below;

II.2. have been prepared exclusively with the following animal by-products:

(2) either [── animal by-products which have been derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;]

(2) and/or [── products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;]

(2) and/or [── animals and parts of animals, other than those referred to in Articles 8 and 10 of Regulation (EC) No 1069/2009, that died other than being slaughtered or killed for human consumption, including animals killed for disease control purposes;]

(2) and/or [── carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [── carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of:

– animals, other than ruminants requiring TSE testing; and

– ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;

(iv) pig bristles;
(v) feathers;]

(2) and/or [── blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from the following animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation:

(i) animals other than ruminants requiring TSE testing; and
(ii) ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;]

(2) and/or [── animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [── products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or

	II.a. Certificate reference number	II.b.

packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [── petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [── blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2) and/or [── aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [── animal-by products from aquatic animals originating form plants or establishments manufacturing products for human consumption;]

(2) and/or [── the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

– hatchery by-products,

– eggs,

– egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

II.3. the rendered fats :

(a) have been subjected to processing in accordance with method ……. as laid down in Annex VI, Section III of Regulation (EC) No …/… , in order to kill pathogenic agents, and

(b) have been permanently marked before shipment to the European Union by a registered establishment, plant or operator with glyceroltriheptanoate (GTH), following a preceding sanitising thermal treatment at a core temperature of at least 80°C and under conditions which prevent subsequent re-contamination, so that a homogenous minimum concentration of at least 250 mg GTH per kilogram fat is achieved; and

(c) have been transported under conditions which prevent their contamination, and

(d) and which bear labels on the packaging or container indicating “NOT FOR HUMAN OR ANIMAL CONSUMPTION”.

Notes

Part I:

── Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

── Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom

	II.a. Certificate reference number	II.b.

warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 15.02; 15.03; 15.04; 15.05; 15.06; 15.16.10; 15.17 or 15.18.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.

Part II:

([1a]) [ ]

([1b]) [ ]

([2])

([3]) Delete as appropriate

([5]) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 11

Health certificate

For gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code | I.8.

I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed chain**

Part II: Certification

	II.a. Certificate reference number	II.b.

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] and in particular Article 10 thereof, and Regulation (EU) No …/…[1b], and in particular Annex XVII, Section II thereof, and certify that the gelatine/collagen[2] described above :

II.1. consists of gelatine/collagen[2] that satisfy the health requirements below;

II.2. consist exclusively of gelatine/collagen[2] not intended for human consumption;

II.3. has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, in order to kill pathogenic agents;

II.4. has been prepared exclusively with the following animal by-products :

(2) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [— carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [— animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

II.5. the gelatine/collagen[2] :

(a) was wrapped, packaged, stored and transported under satisfactory hygiene conditions, and in particular wrapping and packaging took place in a dedicated room, and only preservatives permitted

COUNTRY **Gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

under Union legislation were used.

Wrappings and packages containing gelatine/collagen(2) carry the words "GELATINE/COLLAGEN(2) SUITABLE FOR ANIMAL CONSUMPTION", and

(2) either [(b) in the case of gelatine, has been produced by a process that ensuring that unprocessed Category 3 material is subjected to a treatment with acid or alkali, followed by one or more rinses, involving pH adjustment, extraction by heating one or several times in succession, followed by purification by means of filtration and sterilisation, in order to kill pathogenic agents.]

(2) or [(b) in the case of collagen, has been produced by a process that ensuring that unprocessed Category 3 material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion, in order to kill pathogenic agents.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 35.03 or 35.04.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: select gelatine or collagen.

Manufacturing plant: provide the registration number of treatment/processing establishment.

Part II:

(1) [ ]

(2) Delete as appropriate

(3) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

COUNTRY **Gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 12

Health certificate

For hydrolysed protein, dicalcium phosphate and tricalcium phosphate not intended for human consumption to be used as feed material or for uses outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code | I.8.

I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Hydrolysed protein, dicalcium phosphate and tricalcium phosphate to be used as feed material or outside the feed chain**

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] and in particular Article 10 thereof, and Regulation (EU) No …/…[1b], and in particular Annex XVII, Section II thereof, and certify that the hydrolysed protein/dicalcium phosphate/tricalcium phosphate[2] described above :

II.1. consists of hydrolysed protein/dicalcium phosphate/tricalcium phosphate(2) that satisfy the health requirements below;

II.2. consists exclusively of hydrolysed protein/dicalcium phosphate/tricalcium phosphate[2]not intended for human consumption;

II.3. has been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, in order to kill pathogenic agents;

II.4. has been prepared exclusively with the following animal by-products :

(2) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [— carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

(2) and/or [— animals by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [— blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

COUNTRY **Hydrolysed protein, dicalcium phosphate and tricalcium phosphate to be used as feed material or outside the feed chain**

	II.a. Certificate reference number	II.b.

(2) and/or [—— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [—— animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

(2) and/or [—— the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

—— hatchery by-products,

—— eggs,

—— egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

II.5. the hydrolysed protein/dicalcium phosphate/tricalcium phosphate(2):

(a) was wrapped and packaged in packaging which bear labels indicating "NOT FOR HUMAN CONSUMPTION" and stored and transported under satisfactory hygiene conditions, and in particular wrapping and packaging took place in a dedicated room, and only preservatives permitted under Union legislation were used, and

(2)either [(b) in the case of hydrolysed protein, has been produced by a process involving appropriate measures to minimise contamination of raw Category 3 material.

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

(i) exposure of the material to a pH of more than 11 for more than 3 hours at temperature of more than 80 C and subsequently by heat treatment at more than 140°C for 30 minutes at more than 3.6 bar; and

(ii) exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed by heat treatment at 140°C for 30 minutes at 3 bar.]

(2)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 a pH of less than 1,5) over a period of at least two days,

(ii) followed by treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7, and

(iii) finally air-dries this precipitate for 15 minutes, with inlet temperature of 270° to 325°C and end temperature between 60° and 65°C.]

COUNTRY **Hydrolysed protein, dicalcium phosphate and tricalcium phosphate to be used as feed material or outside the feed chain**

	II.a. Certificate reference number	II.b.

[(2)]or [(b) in the case of tricalcium phosphate, has been produced by a process ensuring :

(i) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm),

(ii) continuous cooking with steam at 145°C during 30 minutes at 4 bars,

(iii) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation, and

(iv) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200°C.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 28.35 or 35.04.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: specify if hydrolysed protein, dicalcium phosphate or tricalcium phosphate.

Manufacturing plant: provide the registration number of treatment/processing establishment.

Part II:

([1]) [ ]

([2]) Delete as appropriate

([3]) Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

COUNTRY **Hydrolysed protein, dicalcium phosphate and tricalcium phosphate to be used as feed material or outside the feed chain**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 13

Health certificate

For apiculture by-products, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff | Technical use | Other

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10 thereof, and Regulation (EU) No …/… [(1b)], and in particular Annex XVII, Section II thereof, and certify that the apiculture by-products described above :

II.1. come from an area where the diseases mentioned below are officially notifiable and which is not subject to any restrictions associated with:

(a) American foul brood (Paenibacillus larvae larvae),

(b) Acariosis (Acarapis woodi (Rennie)),

(c) Small hive beetle (Aethina tumida), and

(d) Tropilaelaps mites (Tropilaelaps spp);

II.1. have been

[(2)] either [subjected to a temperature of -12°C or lower for at least 24 hours;]

[(2)] or [in the case of wax refined or rendered.]

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.19: use the appropriate HS code: 05.11.99 and specify the commodity as listed under note Box reference I.28.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Nature of commodity: means honey, beeswax, royal jelly, propolis or pollen used in bee-keeping;

Part II:

([1]) [ ]

([2]) Delete as appropriate.

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

COUNTRY **Apiculture by-products**

	II.a. Certificate reference number	II.b.

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 14(A)

Health certificate

For fat derivatives not intended for human consumption to be used outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
15.16.10

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY

For fat derivatives to be used for purposes outside the feed chain

	II.a. Certificate reference number	II.b.

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10 thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XVII, Section II thereof, and certify that the fat derivatives described above :

II.1. consist of fat derivatives that satisfy the health requirements below;

II.2. consist of fat derivatives containing exclusively fat derivatives not intended for human nor animal consumption;

II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, in order to kill pathogenic agents;

II.4. have been prepared from rendered fats exclusively produced from Category 2 and/or Category 3 materials[(3)];

II.5. the fat derivatives produced from Category 2 materials :

(a) have been produced using the following methods :

[(2)] either [transesterification or hydrolysis at least 200°C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters), and]

[(2)] or [saponification with NaOH 12M (glycerol and soap) :

[(2)] either [in a batch process at 95°C for three hours, and]

[(2)] or [in a continuous process at 140°C, 2 bars (2000 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”

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of treatment/processing

COUNTRY **For fat derivatives to be used for purposes outside the feed chain**

	II.a. Certificate reference number	II.b.

establishment.

Part II:

([1]) [ ]

([2]) Delete as appropriate

([3]) List of Category 2 materials:

(b) animal by-products collected during the treatment of waste water required by Annex VI Section I Chapter II of Regulation …/… from establishments or plants processing Category 2 material, or from slaughterhouses other than those covered by Article 8(e) of Regulation (EC) No 1069/2009;

(c) animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels as referred to in Article 15(3) of Directive 96/23/EC;

(d) products of animal origin which have been declared unfit for human consumption due to the presence of physical residues in those products;

(e) products of animal origin, other than Category 1 material, that are:

(i) imported or introduced from a third country and which fail to comply with the Union veterinary legislation for their importation or introduction into the Union except where Union legislation allows their importation or introduction subject to specific restrictions or their return to the third country; or

(ii) dispatched to another Member State and which fail to comply with requirements laid down or authorised by Union legislation except where they are returned with the authorisation of the competent authority responsible for the plant or establishment of origin.

(e) animals and parts of animals, other than those referred to in Article 8 or 10 of Regulation (EC) No 1069/2009, that died other than by being slaughtered for human consumption or, in the case of game, that died other than by being killed for human consumption, including animals killed for disease control purposes, and foetuses, embryos and semen which are not destined for breeding purposes,; and dead-in-shell poultry;

(f) mixtures of Category 2 material with Category 3 material;

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

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 14 (B)

Health certificate

For fat derivatives not intended for human consumption to be used as feed or outside the feed chain, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
15.16.10

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff | Technical use

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **For fat derivatives to be used as feed or outside the feed chain**

	II.a. Certificate reference number	II.b.

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [1a] and in particular Article 10 thereof, and Regulation (EU) No …/…[1b], and in particular Annex XVII, Section II thereof, and certify that the fat derivatives described above :

II.1. consist of fat derivatives that satisfy the health requirements below;

II.2. consist of fat derivatives containing exclusively fat derivatives not intended for human nor animal consumption;

II.3. have been prepared and stored in a plant approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, in order to kill pathogenic agents;

II.4. have been prepared from rendered fats exclusively produced from the following Category 3 materials:

(2) either [— carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

(2) and/or [— carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;
(ii) heads of poultry;
(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals, other than ruminants;
(iv) pig bristles;
(v) feathers;]

(2) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

(2) and/or [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects form which no risk to public or animal health arise;]

(2) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [— blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2) and/or [— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [— animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

COUNTRY **For fat derivatives to be used as feed or outside the feed chain**

	II.a. Certificate reference number	II.b.

(2) and/or [— the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

— hatchery by-products,

— eggs,

— egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

II.5. are packaged in new containers or in which bear labels indicating "NOT FOR HUMAN CONSUMPTION", that have been cleaned, and all precautions are taken to prevent its contamination.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: Manufacturing plant: provide the registration number of treatment/processing establishment.

Part II:

([1]) [ ]

([2]) Delete as appropriate

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

COUNTRY **For fat derivatives to be used as feed or outside the feed chain**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 15

Health certificate

For egg products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin ISO code | I.8. Region of origin Code

I.9. Country of destination ISO code | I.10.

I.11. Place of origin
Name Approval number
Address

I.12. Place of destination
Custom warehouse
Name Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
35.02

I.20.Quantity

I.21 Temperature of product
Ambient Chilled Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff

I.26. For transit to 3rd Country vis-à-vis EU
3rd country ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species	(Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Egg products not intended for human consumption that could be used as feed**

Part II: Certification

	II.a. Certificate reference number	II.b.

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 10 thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XVII, Section II thereof, and certify that the egg products described above :

II.1. consist of egg products that satisfy the health requirements below;

II.2. consist exclusively of egg products not intended for human consumption;

II.3. have been prepared and stored in a plant, approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009 or Article 4(2) of Regulation (EC) No 853/2004 [(2)], in order to kill pathogenic agents;

II.4. have been prepared (derived) exclusively with the following animal by-product :

— eggs originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals;

II.5. have been subjected to processing :

[(3)] either [in accordance with processing method …….. [(4)] as set out in Annex VI, Section III of Regulation (EC) No …/… ;]

[(3)] or [in accordance to a method and parameters which ensure that the products complies with the microbiological standards set in Annex XIII, Section I to Regulation …/…;]

[(3)] or [treated in accordance with Section X, Chapters I to III of Annex III to Regulation (EC) No 853/2004;]

II.6. have been examined by the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards [(5)]:

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

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

II.7. meet Union standards on residues of substances that are harmful or might alter the organoleptic characteristics of the product or make its use as feed dangerous or harmful to animal health;

II.8. the end product was :

[(3)] either [packed in new or sterilized bags,]

[(3)] or [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

and which bear labels indicating “NOT FOR HUMAN CONSUMPTION”;

II.9. the end product was stored in enclosed storage;

II.10. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment.

COUNTRY **Egg products not intended for human consumption that could be used as feed**

	II.a. Certificate reference number	II.b.

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Part II:

([1]) [ ].

([2]) OJ L 212, 22.07.1989, p. 89.

([3]) Delete as appropriate

([4]) Insert method 1 to 5 or 7 as applicable.

([5]) Where:

n = number of samples to be tested,

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

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

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

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

— Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

COUNTRY **Egg products not intended for human consumption that could be used as feed**

	II.a. Certificate reference number	II.b.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

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 Union

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

I, the undersigned, declare that the following products [(1)]:

(a) bones and bone products (excluding bone meal);
(b) horns and horn products (excluding horn meal);
(c) hooves and hoof products (excluding hoof meal);

are intended to be imported by me into the Union, and I declare that these products will not be diverted at any stage for any use in food, feed material, organic fertilizers or soil improvers and will be conveyed directly for the purpose of further processing or treatment to:

Name:_____ Address:_____

The importer:

Name: _____ Address: _____

Done at _____ on _____

(place) *(date)*

Signature _____

Reference number as indicated on the common veterinary entry document (CVED) provided for in Annex III to Commission Regulation (EC) 136/2004:

_____

Official stamp of the border inspection post of entry into the EC [(2)]

Signature: _____

(Signature of the official veterinarian of the border inspection post) [(2)]

Name: _____

(Name in capital letters)

_____

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

CHAPTER 17

Health certificate

For processed manure and processed manure products intended for dispatch to or for transit through[2] the European Union

COUNTRY **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name
Address
Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval number
Address

I.12. Place of destination
Custom warehouse
Name | Approval number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane | Ship | Railway wagon
Road vehicle | Other
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

I.21 Temperature of product
Ambient | Chilled | Frozen

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Animal feedingstuff | Technical use | Other

I.26. For transit to 3rd Country vis-à-vis EU
3rd country | ISO code

I.27. For import or admission into EU

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Net weight

COUNTRY **Processed manure and processed manure products**

Part II: Certification

	II.a. Certificate reference number	II.b.

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Article 9 thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XVII, Section II thereof, and certify that the processed manure or processed manure products described above:

II.1. come from a plant for the manufacture of products foe purposes other than feeding to farmed animals, a biogas plant or a composting plant approved by the competent authority of the third country meeting the special conditions laid down in Regulation (EC) No 1069/2009 and in Regulation (EU) No …/…;

II.2.[(2)] have been subjected to:

[a heat treatment process of at least 70 °C for at least 60 minutes] or

[an equivalent treatment validated and authorized by the importing Member State in accordance with the specific conditions laid down in Regulation (EC) No 1069/2009 and in Regulation (EU) No …/… as follows:

.....

.....

.....]

II.3. are:

(a) free from Salmonella (no salmonella in 25 g treated product);

(b) free from Escherichia coli or from enterobacteriacea (based on the aerobic count: less than 1000 cfu per gram of treated product); and

(c) have been subjected to reduction in spore-forming bacteria and toxic formation.

II.4. are securely enclosed in:

(a) well-sealed and insulated containers, or

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

Notes

Part I:

— Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.

COUNTRY **Processed manure and processed manure products**

	II.a. Certificate reference number	II.b.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.31: Nature of commodity: enter if processed manure or if processed manure products.

Part II:

([1]) [ ]

([2]) Delete as appropriate.

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

— Note for the person responsible for the consignment in EU: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 18

Health certificate

For horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, intended for the production of organic fertilizers or soil improvers intended for dispatch to or for transit through [(2)] the European Union

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor
Name

Address

Tel.N°

I.2. Certificate reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name

Address
Postal code
Tel.N°

I.6. Person responsible for the load in EU
Name

Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin

Name | Approval number
Address

I.12. Place of destination

Custom warehouse ☐

Name | Approval number
Address

Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17. No.(s) of CITES

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

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

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:

Animal feedingstuff ☐ Further process ☐ Technical use ☐ Other ☐

I.26. For transit through EU to 3rd Country ☐

3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species | Approval number of establishments
Manufacturing plant | Net weight | Batch number

COUNTRY

Horns and horn products and hooves and hoof products intended to produce organic fertilizers or soil improvers

II. Health information	II.a. Certificate reference number	II.b.

Part II: Certification

Part II: Certification

II. Health attestation

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 ([1]), and Regulation (EU) No …/…, and in particular Chapter II of Section II of Annex XVII thereof, and certify that the horns and horn products, excluding horn meal and hooves and hoof products, excluding hoof meal ([2]) described above:

[(2)]either [originate from animals that were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption]

[(2)]*or* [originate from animals that did not show clinical signs of any disease communicable through that product to humans or animals]

II.2. horns must have undergone a heat treatment for one hour at a core temperature of at least 80 °C

II.3. horns must be removed without opening the cranial cavity.

II.4. at any stage of processing, storage or transport every precaution shall be taken to avoid cross-contamination.

II.5. the horns and horn products, excluding horn meal and hooves and hoof products, excluding hoof meal were packed:

[(2)]either [in new packaging or containers]

[(2)]*or* [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority]

and [the packaging or containers are marked so as to indicate the type of the animal by-product ([3]) and bear labels indicating 'NOT FOR HUMAN AND ANIMAL CONSUMPTION' and the name and address of the EU establishment of destination].

Notes

Part I:

– Box reference I.6: Person responsible for the consignment in EU: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.

– Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit must only be stored in free zones, free warehouses and custom warehouses.

– Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

– Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be given.

– Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

– Box reference I.28: Nature of commodity

COUNTRY

Horns and horn products and hooves and hoof products intended to produce organic fertilizers or soil improvers

II. Health information	II.a. Certificate reference number	II.b.

Part II:

([1]) OJ L 300, 14.11.2009, p. 1.

([2]) Delete as appropriate.

([3]) **Type of product**: horns, horn products, hooves, hoof products.

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

– Note for the person responsible for the consignment in EU: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 19

Health certificate

For gelatine not intended for human consumption to be used by the photographic industry, intended for dispatch to the European Union

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.N°		I.2. Certificate reference number	I.2.a
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel.N°		I.6.	
I.7.Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12.	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17. No.(s) of CITES	
I.18. Description of commodity		I.19. Commodity code (HS code) **3503**	
		I.20.Quantity	
I.21 Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Identification of container/Seal number		I.24.Type of packaging	
I.25. Commodities certified for: Technical use ☐			
I.26.		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species	(Scientific name)	Approval number of establishments manufacturing plant	Net weight	Batch number

COUNTRY

Gelatine not intended for human consumption to be used by the photographic industry

	II.a. Certificate reference number	II.b.

Part II: Certification

Health attestation

I, the undersigned official, declare that I have read and understood Regulation (EC) No 1069/2009 [(1a)] and in particular Articles 8 and 10 thereof, and Regulation (EU) No …/…[(1b)], and in particular Annex XVII, Section II thereof, and certify that the photographic gelatine described above:

II.1. consists exclusively of photographic gelatine for photographic uses and is not intended for any other purpose;

II.2. has been prepared and stored in a plant registered and supervised by the competent authority in accordance with Article 23 of Regulation (EC) No 1069/2009, which do not produce gelatine for food, feed or other uses intended for dispatch to the European Union;

II.3. has been prepared with Category 3 animal by-products and/or bovine vertebral column classified as Category 1 material;

II.4. has been wrapped, packaged, stored and transported under satisfactory hygiene conditions.

II.5. has been produced by a process ensuring that the raw material is:

(a) treated by pressure sterilisation as defined in Article 3 no. 19 of Regulation (EC) No …1069/2009 or

(b) subjected to:

(i) treatment with acid for at least two days, washing with water and treatment with an alkaline solution for at least 20 days; the pH must be adjusted and the material purified by means of filtration and sterilised at 138-140 ˚C for 4 seconds; or

(ii) treatment with alkali for at least two days, washing with water and treatment with an acid solution for 10-12 hours; the pH must be adjusted and the material purified by means of filtration and sterilised at 138-140 ˚C for 4 seconds.

II.6. has been wrapped and packaged in wrappings and packages carrying the words “PHOTGRAPHIC GELATINE FOR THE PHOTOGRAPHIC INDUSTRY ONLY”.

Notes

Part I:

— Box reference I.5: The intended destination of the photographic gelatine can only be the Czech Republic, Luxembourg, the Netherlands or the United Kingdom.

— Box reference I.9: Country of destination: only applicable for the Czech Republic, Luxemburg, United Kingdom or the Netherlands.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.

— Box reference I.23: Identification of container/seal number: only where applicable.

Part II:

([1]) [ ]

(re Pressure sterilisation (method 1) is also referred to in Annex VI Section III of Regulation (EC) No /… as follows:

COUNTRY **Gelatine not intended for human consumption to be used by the photographic industry**

	II.a. Certificate reference number	II.b.

"Reduction

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

   Time, temperature and pressure

2. After reduction the animal by-products must be heated to a core temperature of more than 133°C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars produced by saturated steam; 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."

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

— Note for the person responsible for the load in EU: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the factory of destination from the border inspection post..

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

CHAPTER 20

Model declaration

Declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices, in vitro diagnostics and laboratory reagents

COUNTRY **Model declaration**

Part I : Details of dispatched consignment

I.1. Consignor
☐ Name
Address
Tel.N°

I.2. Document reference number | I.2.a

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel.N°

I.6. Person responsible for the consignment in EU
Name
Address
Postal code
Tel.N°

I.7.Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10. Region of destination | Code

I.11. Place of origin
Name | Approval/Registration number
Address

I.12. Place of destination
Custom warehouse ☐
Name | Approval/Registration number
Address
Postal code

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20.Quantity

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

I.22. Number of packages

I.23. Identification of container/Seal number

I.24.Type of packaging

I.25. Commodities certified for:
Technical use ☐ Other ☐

I.26. For transit to 3rd Country vis-à-vis EU ☐
3rd country | ISO code

I.27. For import or admission into EU ☐

I.28. Identification of the commodities
Approval/Registration number of establishments
Species (Scientific name) | Manufacturing plant | Net weight | Batch number

COUNTRY **Intermediate products**

Part II: Certification

II. Declaration	II.a. Reference number	II.b.

I, the undersigned, declare that the intermediate product referred to above are intended to be imported by me into the Union and satisfy the definition provided for in Annex I no. 27 of Regulation (EU) No …/…, and in particular that:

(1) it is intended for the manufacture of medicinal products, veterinary medicinal products, medical devices, in vitro diagnostics or laboratory reagents;

(2) its design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as derived products and to qualify the material for that purpose, except for the fact that it requires some further handling or transformation such as mixing, coating, assembling, packaging or labelling to make it suitable for placing on the market or putting into service as medicinal products, veterinary medicinal products, medical devices or in vitro diagnostics in accordance with the Union legislation(1) applicable to those products or as laboratory reagents;

(3) it has been derived from the following material which may have originated from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC(2):

(a) carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons,

(b) carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation , but which did not show any signs of disease communicable to humans or animals;

(ii) heads of poultry;

(iii) hides and skins, including trimmings and splitting, thereof horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of animals other than ruminants;

(iv) pig bristles;

(v) feathers;]

(2) and/or [— blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation];

(2) and/or [— animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2) and/or [— products of animal origin, or foodstuffs containing products of animal origin, which are no longer intend for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]

(2) and/or [— petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2) and/or [— blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live

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animals that did not show signs of any disease communicable through that product to humans or animals;]

(2) and/or [— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2) and/or [— animal-by products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

(2) and/or [— the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;
(ii) the following originating from terrestrial animals:

— hatchery by-products,

— eggs,

— egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

(2) and/or [— animal-by products from aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]

(2) and/or [— animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]

(2) and/or [— products derived from or generated by:

— aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals,

— aquatic and terrestrial invertebrates other than species pathogenic to humans or animals,

— animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]

(2) and/or [— animal by-products other than Category 1 material or Category 3 material, as referred to in Article 9(g) of Regulation (EC) No 1069/2009, which:

— do not carry any risk of transmission of diseases communicable to humans or animals,

— are transported under conditions which exclude the transmission of such risks,;]

(4) their outer packaging is labelled 'FOR MEDICINAL PRODUCTS / VETERINARY MEDICINAL PRODUCTS / MEDICAL DEVICES / IN VITRO DIAGNOSTICS / LABORATORY REAGENTS ONLY' and they are not intended to be diverted at any stage within the Union for any other use;

(5) the consignment will be transported directly to the place of destination as indicated under point I.12. of this declaration that is

- an establishment or plant for the production of medicinal products, veterinary medicinal products, medical devices, in vitro diagnostics or laboratory reagents, which has been registered in accordance with Article 23 of Regulation (EC) No 1069/2009;

- an establishment or plant which has been approved in accordance with Article 24(1)(h), from

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where they shall only be dispatched to an establishment or plant referred to in the preceding subpoint of (5).

Notes

(1) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Union code relating to veterinary medicinal products, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Union code relating to medicinal products for human use, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices, as appropriate.

(2) Delete as appropriate

The importer

Name (in capital letters): Address:

Date: Signature:

ANNEX XIX

OFFICIAL CONTROLS

SECTION I

OFFICIAL CONTROLS REGARDING THE ANIMAL BY-PRODUCTS CHAIN

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

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

SECTION II

OFFICIAL CONTROLS IN PROCESSING PLANTS

CHAPTER I

Supervision of the production

1. The competent authority shall supervise processing plants to ensure compliance with the requirements of the Animal By-products Regulation and with this Regulation. It shall in particular:

   (a) check:

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

      (ii) the efficacy of the own checks carried out by the plant, in accordance with Article 28 of the Animal By-products Regulation, 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 Union 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 the Animal by-products Regulation and with this Regulation.

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

CHAPTER II

Validation procedures

1. The competent authority must *check that a validation of* the processing plant *has been carried out by the operator* in accordance with the following procedures and indicators:

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

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

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

   (d) achievement of the following requirements:

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

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

2. In the case of a batch pressure system:

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

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

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

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

3. In the case of a continuous pressure system:

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

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

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

(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:

(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 *checks on 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).

CHAPTER III

Lists of registered and approved establishments, plants and operators

1. Access to lists of registered and approved establishments, plants and operators

In order to assist Member States in making up-to-date lists of registered and approved establishments, plants and operators available to other Member States and to the public, the Commission shall provide a website which shall contain links to the national websites provided by each Member State, as referred to in paragraph 2(a).

2. Format for national websites

(a) Each Member State shall provide the Commission with a linking address to a single national website containing the master list of lists of all registered and approved establishments, plants in its territory (‘master list’).

(b) Each master list shall consist of one sheet and shall be completed in one or more official languages of the Union.

SECTION III

SPECIFIC REQUIREMENTS

CHAPTER I

Official controls regarding marking of derived products

The competent authority shall carry out a performance check of the monitoring and recording system referred to in point 2 of Section V of Annex X to ascertain compliance with this Regulation and may, where necessary, request the testing of additional samples in accordance with the method referred to in the second paragraph of the same point.

CHAPTER II

Official controls in low-capacity incineration plants

The competent authority must inspect the low-capacity incineration plant for incineration of the Category 1 materials referred to Article 8(b)(i) of the Animal By-products Regulation before approval, and at least once a year to monitor compliance with the Animal By-products Regulation and with this Regulation.

CHAPTER III

Official controls in remote areas

In the case of disposal of animal by-products in remote areas in accordance with Article 19(1)(b) of the Animal By-products Regulation, the competent authority shall monitor regularly the areas categorised as remote areas to ensure that those areas and the disposal operations are properly controlled.

CHAPTER IV

Official controls in registered farms for the feeding of fur animals

1. The competent authority shall take the necessary measures to control:

(a) the appropriate composition, processing and use of the feed containing processed animal protein derived from the bodies or parts of bodies of animals of the same species; and

(b) that the animals that are fed with the feed referred to in point (a), including:

(i) strict supervision of the health status of those animals;

(ii) appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.

2. The samples referred to in point 1(b)(ii) shall include samples taken from animals showing neurological symptoms and from older breeding animals.

CHAPTER V

Official controls regarding collection centres

1. The competent authority shall

(a) include collection centres into the list drawn up in accordance with Article 47 of the Animal By-products Regulation;

(b) assign an official number to each collection centre;

(c) update the list and make it available together with the list drawn up in accordance with Article 47 of the Animal By-products Regulation; and

2. The competent authority shall carry out official controls at collection centres in order to verify compliance with this Regulation.

CHAPTER VI

Official controls regarding the feeding of necrophagous birds with Category 1 material

The competent authority shall supervise the health status of the *farmed* animals in the region where the feeding takes place, and shall carry out an appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs. The samples shall include samples taken from animals showing neurological symptoms and from older breeding animals.

CHAPTER VII

Official controls regarding the application of organic fertilisers and soil improvers, other than manure

1. The competent authority shall carry out controls at regular intervals on *farms* where organic fertilisers and soil improvers other than manure are applied to land to which

farmed animals have access. Those controls shall include checks on the stocks of such products kept on farm and the records kept in accordance with the Animal By-products Regulation and with this Regulation.

2. The competent authority shall take appropriate action in case the requirements of the Animal By-products Regulation or of this Regulation are not complied with.

CHAPTER VIII

Official controls regarding approved photographic factories

The competent authority shall carry out documentary checks in approved photographic factories referred to in Annex XVII Section II Chapter II point 1 at least twice a year on the channelling chain from the border inspection posts of first entry to the approved photographic factories for the purpose of reconciliation of the quantities of products imported, used and disposed of.

CHAPTER IX

Time period for the decision on certain consignments dispatched to other Member States

The competent authority shall take its decision on certain consignments dispatched from another Member State, as referred to in Article 48(1) of the Animal By-products Regulation, within 14 calendar days.