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COMMISSION REGULATION (EU) No 142/2011

of 25 February 2011

implementing 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 implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive

(Text with EEA relevance)

(OJ L 54, 26.2.2011, p. 1)

Amended by:

<u>B</u>

Official Journal

		No	page	date
► <u>M1</u>	Commission Regulation (EU) No 749/2011 of 29 July 2011	L 198	3	30.7.2011
► <u>M2</u>	Commission Regulation (EU) No 1063/2012 of 13 November 2012	L 314	5	14.11.2012
► <u>M3</u>	Commission Implementing Regulation (EU) No 1097/2012 of 23 November 2012	L 326	3	24.11.2012
► <u>M4</u>	Commission Regulation (EU) No 294/2013 of 14 March 2013	L 98	1	6.4.2013
► <u>M5</u>	Commission Regulation (EU) No 555/2013 of 14 June 2013	L 164	11	18.6.2013
► <u>M6</u>	Commission Regulation (EU) No 717/2013 of 25 July 2013	L 201	31	26.7.2013
► <u>M7</u>	Commission Regulation (EU) No 185/2014 of 26 February 2014	L 57	21	27.2.2014
<u>M8</u>	Commission Regulation (EU) No 592/2014 of 3 June 2014	L 165	33	4.6.2014
► <u>M9</u>	Commission Regulation (EU) 2015/9 of 6 January 2015	L 3	10	7.1.2015
► <u>M10</u>	Commission Regulation (EU) 2017/172 of 1 February 2017	L 28	1	2.2.2017
► <u>M11</u>	Commission Regulation (EU) 2017/786 of 8 May 2017	L 119	1	9.5.2017
► <u>M12</u>	Commission Regulation (EU) 2017/893 of 24 May 2017	L 138	92	25.5.2017
► <u>M13</u>	Commission Regulation (EU) 2017/1261 of 12 July 2017	L 182	31	13.7.2017
► <u>M14</u>	Commission Regulation (EU) 2017/1262 of 12 July 2017	L 182	34	13.7.2017
► <u>M15</u>	Commission Regulation (EU) 2019/319 of 6 February 2019	L 61	1	28.2.2019
► <u>M16</u>	Commission Implementing Regulation (EU) 2019/1084 of 25 June 2019	L 171	100	26.6.2019

Corrected by:

►<u>C1</u> Corrigendum, OJ L 226, 24.8.2013, p. 44 (294/2013)

COMMISSION REGULATION (EU) No 142/2011

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implementing 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 implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive

(Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

This Regulation lays down implementing measures:

- (a) for the public and animal health rules for animal by-products and derived products laid down in Regulation (EC) No 1069/2009;
- (b) concerning certain samples and items exempt from veterinary checks at border inspection posts as provided for in Article 16(1)(e) and (f) of Directive 97/78/EC.

Article 2

Definitions

For the purposes of this Regulation, the definitions set out in Annex I apply.

Article 3

End point in the manufacturing chain for certain derived products

The following derived products may be placed on the market, other than imported, without restrictions, as provided in Article 5(2) of Regulation (EC) No 1069/2009:

- (a) biodiesel which fulfils the requirements for the disposal and use of derived products set out in point 2(b) of Section 3 of Chapter IV of Annex IV;
- (b) processed petfood which fulfil the specific requirements for processed petfood set out in point 7(a) of Chapter II of Annex XIII;
- (c) dogchews which fulfil the specific requirements for dogchews set out in point 7(b) of Chapter II of Annex XIII;
- (d) hides and skins of ungulates which fulfil the specific requirements for the end point for those products set out in point C of Chapter V of Annex XIII;

▼B

- (e) wool and hair, which fulfil the specific requirements for the end point for those products set out in point B of Chapter VII of Annex XIII;
- (f) feathers and down, which fulfil the specific requirements for the end point for those products set out in point C of Chapter VII of Annex XIII:

▼M1

- (g) fur which fulfils the special requirements for the end point for that product set out in Chapter VIII of Annex XIII;
- (h) fish oil for the production of medicinal products which fulfils the special requirements for the end point for that product set out in Chapter XIII of Annex XIII;

▼<u>M4</u>

- gasoline and fuels which fulfil the specific requirements for products from the multi-step catalytic process for the production of renewable fuels set out in point 2(c) of Section 3 of Chapter IV of Annex IV;
- (j) oleochemical products derived from rendered fats and which fulfil the requirements set out in Chapter XI of Annex XIII;

▼ <u>M13</u>

(k) renewable diesel, renewable jet fuel, renewable propane and renewable gasoline which fulfil the specific requirements for products from the multi-step catalytic hydro-treatment for the production of renewable fuels set out in point 2(f) of Section 3 of Chapter IV of Annex IV.

▼<u>B</u>

Article 4

Serious transmissible diseases

The diseases listed by the OIE in Article 1.2.3 of the Terrestrial Animal Health Code, 2010 edition, and in Chapter 1.3 of the Aquatic Animal Health Code, 2010 edition, shall be regarded as serious transmissible diseases for the purposes of general animal health restrictions, as provided for in Article 6(1)(b)(ii) of Regulation (EC) No 1069/2009.

CHAPTER II

DISPOSAL AND USE OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS

Article 5

Restrictions on the use of animal by-products and derived products

- 1. Operators in the Member States referred to in Chapter I of Annex II shall comply with the conditions for the feeding of fur animals with certain materials derived from bodies or parts of animals of the same species set out in the same Chapter.
- 2. Operators shall comply with the restrictions on the feeding of farmed animals with herbage from land to which certain organic fertilisers or soil improvers have been applied, as set out in Chapter II of Annex II.

▼<u>M8</u>

Article 6

Disposal by incineration, disposal or recovery by co-incineration and use as a fuel for combustion

▼B

- 1. The competent authority shall ensure that incineration and coincineration of animal by-products and derived products shall only take place:
- (a) in incineration plants and co-incineration plants which have been granted a permit in accordance with Directive 2000/76/EC; or
- (b) for plants not required to have a permit under Directive 2000/76/EC, in incineration and co-incineration plants which have been approved by the competent authority to carry out disposal by incineration, or disposal or recovery of animal by-products or derived products, if they are waste, by co-incineration, in accordance with Article 24(1)(b) or (c) of Regulation (EC) No 1069/2009.
- 2. The competent authority shall only approve incineration plants and co-incineration plants as referred to in point 1(b), in accordance with Article 24(1)(b) or (c) of Regulation (EC) No 1069/2009, if they comply with the requirements set out in Annex III hereto.
- 3. Operators of incineration plants and co-incineration plants shall comply with the general requirements for incineration and co-incineration set out in Chapter I of Annex III.
- 4. Operators of high-capacity incineration and co-incineration plants shall comply with the requirements of Chapter II of Annex III.
- 5. Operators of low-capacity incineration and co-incineration plants shall comply with the requirements of Chapter III of Annex III.

▼ M8

- 6. Operators shall ensure that combustion plants other than those referred to in Section 2 of Chapter IV of Annex IV, under their control in which animal by-products or derived products are used as a fuel, comply with the general conditions and specific requirements set out in Chapters IV and V of Annex III respectively and are approved by the competent authority in accordance with Article 24(1)(d) of Regulation (EC) No 1069/2009.
- 7. The competent authority shall only approve combustion plants referred to in paragraph 6 for the use of animal by-products and derived products as fuel for combustion, provided that:
- (a) the combustion plants fall within the scope of Chapter V of Annex III hereto;
- (b) the combustion plants comply with all the relevant general conditions and specific requirements set out in Chapters IV and V of Annex III hereto;
- (c) administrative procedures are in place to ensure that the requirements for the approval of the combustion plants are checked annually.

▼ M14

- 8. For the use of manure of farmed animals as a fuel for combustion as set out in Chapter V of Annex III, the following rules shall apply in addition to those referred to in paragraph 7 of this Article:
- (a) the application for approval that is submitted by the operator to the competent authority in accordance with Article 24(1)(d) of Regulation (EC) No 1069/2009 must contain evidence certified by the competent authority or by a professional organisation authorised by the competent authorities of the Member State, that the combustion plant in which the manure of farmed animals is used as a fuel fully meets the requirements laid down in points B(3), B(4) and B(5) of Chapter V of Annex III to this Regulation, without prejudice to the possibility for the competent authorities of the Member State to grant a derogation from compliance with certain provisions in accordance with point C(4) of Chapter V of Annex III;
- (b) the procedure for approval provided for in Article 44 of Regulation (EC) No 1069/2009 shall not be completed until at least two consecutive checks, one of them unannounced, have been carried out by the competent authority or by a professional organisation authorised by that authority, during the first six months of the operating of the combustion plant, including the necessary temperature and emission measurements. After the results of those checks showed compliance with the requirements set out in points B(3), B(4) and B(5) and, where applicable, with point C(4) of Chapter V of Annex III to this Regulation, full approval can be granted.

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Article 7

Landfilling of certain Category 1 and 3 materials

By way of derogation from Article 12 and Article 14(c) of Regulation (EC) No 1069/2009, the competent authority may authorise the disposal of the following Category 1 and 3 materials in an authorised landfill:

- (a) imported petfood or petfood produced from imported materials, from Category 1 material referred to in Article 8(c) of Regulation (EC) No 1069/2009;
- (b) Category 3 material referred to in Article 10(f) and (g) of Regulation (EC) No 1069/2009, provided that:
 - such materials have not been in contact with any of the animal by-products referred to in Articles 8 and 9 and Article 10(a) to
 (e) and (h) to (p) of that Regulation;
 - (ii) at the time when they are destined for disposal, the materials:
 - referred to in Article 10(f) of that Regulation have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004, and
 - referred to in Article 10(g) of that Regulation have been processed in accordance with Chapter II of Annex X hereto or in accordance with the specific requirements for petfood set out in Chapter II of Annex XIII hereto; and
 - (iii) the disposal of such materials does not pose a risk to public or animal health.

Article 8

Requirements for processing plants and other establishments

- 1. Operators shall ensure that processing plants and other establishments under their control comply with the following requirements set out in Chapter I of Annex IV:
- (a) the general conditions for processing set out in Section 1;
- (b) the requirements for wastewater treatment set out in Section 2;
- (c) the specific requirements for the processing of Category 1 and 2 materials set out in Section 3;
- (d) the specific requirements for the processing of Category 3 materials set out in Section 4.
- 2. The competent authority shall only approve processing plants and other establishments, if they comply with the conditions laid down in Chapter I of Annex IV.

Article 9

Hygiene and processing requirements for processing plants and other establishments

Operators shall ensure that establishments and plants under their control comply with the following requirements set out in Annex IV:

- (a) the hygiene and processing requirements set out in Chapter II;
- (b) the standard processing methods set out in Chapter III, provided such methods are used in the establishment or plant;
- (c) the alternative processing methods set out in Chapter IV, provided such methods are used in the establishment or plant.

Article 10

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

- 1. Operators shall ensure that establishments and plants under their control comply with the following requirements for the transformation of animal by-products and derived products into biogas or for composting set out in Annex V:
- (a) the requirements applicable to biogas and composting plants set out in Chapter I;
- (b) the hygiene requirements applicable to biogas and composting plants set out in Chapter II;
- (c) the standard transformation parameters set out in Section 1 of Chapter III;
- (d) the standards for digestion residues and compost set out in Section 3 of Chapter III.
- 2. The competent authority shall only approve biogas and composting plants, if they comply with the requirements laid down in Annex V.

3. The competent authority may authorise the use of alternative transformation parameters for biogas and composting plants subject to the requirements set out in Section 2 of Chapter III of Annex V.

CHAPTER III

DEROGATIONS FROM CERTAIN PROVISIONS OF REGULATION (EC) No 1069/2009

Article 11

Special rules on research and diagnostic samples

1. The competent authority may authorise the transport, use and disposal of research and diagnostic samples under conditions which ensure the control of the risks to public and animal health.

The competent authority shall in particular ensure that operators comply with the requirements of Chapter I of Annex VI.

- 2. Operators shall comply with the special rules on research and diagnostic samples set out in Chapter I of Annex VI.
- 3. Operators may dispatch research and diagnostic samples which consist of the following animal by-products and derived products to another Member State without informing the competent authority of the Member State of origin in accordance with Article 48(1) of Regulation (EC) No 1069/2009 and without the competent authority of the Member State of destination being informed by means of the TRACES system and agreeing to accept the consignment in accordance with Article 48(1) and (3) of that Regulation:
- (a) Category 1 and 2 materials and meat-and-bone meal or animal fat derived from Category 1 and 2 materials;
- (b) processed animal protein.

Article 12

Special rules on trade samples and display items

1. The competent authority may authorise the transport, use and disposal of trade samples and display items under conditions which ensure the control of the risks to public and animal health.

The competent authority shall in particular ensure that operators comply with the requirements of points 2, 3 and 4 of Section 1 of Chapter I of Annex VI.

2. Operators shall comply with the special rules on trade samples and display items set out in Section 2 of Chapter I of Annex VI.

- Operators may dispatch trade samples which consist of the following animal by-products and derived products to another Member State without informing the competent authority of the Member State of origin in accordance with Article 48(1) of Regulation (EC) No 1069/2009 and without the competent authority of the Member State of destination being informed by means of the TRACES system and agreeing to accept the consignment in accordance with Article 48(1) and (3) of that Regulation:
- (a) Category 1 and 2 materials and meat-and-bone meal or animal fat derived from Category 1 and 2 materials;
- (b) processed animal protein.

Article 13

Special feeding rules

- 1. Operators may feed Category 2 material to the following animals, provided that such material comes from animals which were not killed or did not die as a result of the presence or suspected presence of a disease communicable to humans or animals, subject to compliance with the general requirements laid down in Section 1 of Chapter II of Annex VI and any other conditions that may be laid down by the competent authority:
- (a) zoo animals;
- (b) fur animals;
- (c) dogs from recognised kennels or packs of hounds;
- (d) dogs and cats in shelters;

▼ M4

- (e) maggots and worms for fishing bait;
- (f) circus animals.

▼B

- Operators may feed Category 3 material to the following animals subject to compliance with the general requirements laid down in Section 1 of Chapter II of Annex VI and any other conditions that may be laid down by the competent authority:
- (a) zoo animals;
- (b) fur animals:
- (c) dogs from recognised kennels or packs of hounds;
- (d) dogs and cats in shelters;

▼ M4

- (e) maggots and worms for fishing bait;
- (f) circus animals.

▼B

Article 14

Feeding of certain species in and outside feeding stations and in ZOOS

- The competent authority may authorise the use of Category 1 material consisting of entire bodies or parts of dead animals containing specified risk material for the feeding:
- (a) in feeding stations, to endangered or protected species of necrophagous birds and other species living in their natural habitat, for the promotion of biodiversity, subject to compliance with the conditions set out in Section 2 of Chapter II of Annex VI;

▼<u>B</u>

▼<u>B</u>

- (b) outside feeding stations, if appropriate without prior collection of the dead animals, to wild animals referred to point 1(a) of Section 2 of Chapter II of Annex VI, subject to compliance with the conditions set out in Section 3 of that Chapter.
- 2. The competent authority may authorise the use of Category 1 material consisting of entire bodies or parts of dead animals containing specified risk materials and the use of material derived from zoo animals for the feeding of zoo animals subject to compliance with the conditions set out in Section 4 of Chapter II of Annex VI.

Article 15

Special rules on collection and disposal

▼ M4

If the competent authority authorises the disposal of animal by-products by way of the derogation provided for in Article 19(1)(a), (b), (c), (e) and (f) of Regulation (EC) No 1069/2009, the disposal shall comply with the following special rules set out in Chapter III of Annex VI:

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- (a) the special disposal rules for animal by-products set out in Section 1;
- (b) the rules for the burning and burial of animal by-products in remote areas set out in Section 2;
- (c) the rules for the burning and burial of bees and apiculture byproducts set out in Section 3.

▼ M9

By way of derogation from Article 14 of Regulation (EC) No 1069/2009, Member States may authorise the collection, transport and disposal of small quantities of Category 3 materials as referred to in Article 10(f) of that Regulation by means referred to in Article 19(1)(d) of that Regulation, subject to compliance with the requirements for disposal by other means set out in Chapter IV of Annex VI hereto.

▼B

CHAPTER IV

AUTHORISATIONS OF ALTERNATIVE METHODS

Article 16

Standard format for applications for authorisation of alternative methods

- 1. Applications for authorisation of alternative methods of use or disposal of animal by-products or derived products, as referred to in Article 20(1) of Regulation (EC) No 1069/2009, shall be submitted by Member States or interested parties in accordance with the requirements of the standard format for applications for alternative methods set out in Annex VII.
- 2. Member States shall designate national contact points to provide information on the competent authority responsible for evaluating applications for authorisation of alternative methods of use or disposal of animal by-products.

· <u>Б</u>

3. The Commission shall publish a list of national contact points on its website.

CHAPTER V

COLLECTION, TRANSPORT, IDENTIFICATION AND TRACEABILITY

Article 17

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

- 1. Operators shall ensure that animal by-products and derived products:
- (a) comply with the requirements for collection, transport and identification set out in Chapters I and II of Annex VIII;
- (b) are accompanied during transport by commercial documents or health certificates in accordance with the requirements set out in Chapter III of Annex VIII.
- 2. Operators consigning, transporting or receiving animal by-products or derived products shall keep records of consignments and related commercial documents or health certificates in accordance with the requirements set out in Chapter IV of Annex VIII.
- 3. Operators shall comply with the requirements for the marking of certain derived products set out in Chapter V of Annex VIII.

CHAPTER VI

REGISTRATION AND APPROVAL OF ESTABLISHMENTS AND PLANTS

Article 18

Requirements regarding the approval of one or more establishments and plants handling animal by-products on the same site

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

Article 19

Requirements concerning certain approved establishments and plants handling animal by-products and derived products

Operators shall ensure that establishments and plants under their control which have been approved by the competent authority, comply with the requirements set out in the following Chapters of Annex IX hereto where they carry out one or more of the following activities referred to Article 24(1) of Regulation (EC) No 1069/2009:

(a) Chapter I, where they manufacture petfood as referred to in Article 24(1)(e) of that Regulation;

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- (b) Chapter II, where they store animal by-products as referred to in Article 24(1)(i) of that Regulation and where they handle animal by-products after their collection, by way of the following operations referred to in Article 24(1)(h) of that Regulation:
 - (i) sorting;
 - (ii) cutting;
 - (iii) chilling;
 - (iv) freezing;
 - (v) salting;
 - (vi) preservation by other processes;
 - (vii) removal of hides and skins or removal of specified risk material;
 - (viii) operations involving the handling of animal by-products which are carried out in compliance with obligations under Union veterinary legislation;
 - hygienisation/pasteurisation of animal by-products destined for transformation into biogas/composting, prior to such transformation or composting in another establishment or plant in accordance with Annex V hereto;
 - (x) sieving;

▼ M9

- (c) Chapter III, where they store derived products for certain intended purposes as referred to in Article 24(1)(j) of that Regulation;
- (d) Chapter V, where they store on the farm animal by-products intended for subsequent disposal as referred to in Article 4 of that Regulation.

▼B

Article 20

Requirements concerning certain registered establishments and plants handling animal by-products and derived products

- 1. Operators of registered plants or establishments or other registered operators shall handle animal by-products and derived products under the conditions set out in Chapter IV of Annex IX.
- 2. Registered operators transporting animal by-products or derived products, other than between premises of the same operator, shall in particular comply with the conditions set out in point 2 of Chapter IV of Annex IX.
- 3. Paragraphs 1 and 2 shall not apply to:
- (a) approved operators who are transporting animal by-products or derived products as an ancillary activity;
- (b) operators who have been registered for transport activities in accordance with Regulation (EC) No 183/2005.

▼ M2

- 4. The competent authority may exempt the following operators from the obligation to notify, referred to in Article 23(1)(a) of Regulation (EC) No 1069/2009:
- (a) operators handling or generating game trophies or other preparations referred to in Chapter VI of Annex XIII hereto for private or noncommercial purposes;

▼<u>M2</u>

 (b) operators handling or disposing research and diagnostic samples for educational purposes;

▼<u>M3</u>

(c) operators transporting dry untreated wool and hair, provided they are securely enclosed in packaging, and directly dispatched to a plant producing derived products for uses outside the feed chain or to a plant carrying out intermediate operations, under conditions which prevent the spreading of pathogenic agents;

▼ M9

- (d) operators using small quantities of Categories 2 and 3 materials referred to in Articles 9 and 10 of Regulation (EC) No 1069/2009 or of products derived therefrom, for the purpose of direct supply of the products within the region to the final user, on the local market or to local retail establishments, if the competent authority does not consider such activity to present a risk of spreading any serious transmissible disease to humans or animals; this point shall not apply where those materials are used as feed for farmed animals other than fur animals;
- (e) users of organic fertilisers or soil improvers at premises where farmed animals are not kept;
- (f) operators handling and distributing organic fertilisers or soil improvers exclusively in ready-to-sell retail packaging of not more than 50 kg in weight for uses outside the feed and food chain.

▼M16

Article 20a

Lists of establishments, plants and operators in Member States

The competent authority of a Member State shall ensure that up-to-date lists of establishments, plants and operators, referred to in the first subparagraph of Article 47(1) of Regulation (EC) No 1069/2009 are:

- (a) drawn up in accordance with the technical specifications published on the Commission website (1);
- (b) either entered in TRACES or accessible by means of TRACES as of 31 October 2021 at the latest.

▼B

CHAPTER VII

PLACING ON THE MARKET

Article 21

Processing and placing on the market of animal by-products and derived products for feeding to farmed animals, excluding fur animals

- 1. Operators shall comply with the following requirements for the placing on the market, other than the import, of the animal by-products and derived products destined for feeding to farmed animals excluding fur animals, as provided for in Article 31(2) of Regulation (EC) No 1069/2009, set out in Annex X hereto:
- (a) the general requirements for the processing and the placing on the market set out in Chapter I;

https://ec.europa.eu/food/sites/food/files/safety/docs/ fs-animal-products-app-est-technical spec 04032012 en.pdf

▼<u>B</u>

- (b) the specific requirements for processed animal proteins and other derived products set out in Chapter II;
- (c) the requirements for certain fish feed and fishing baits set out in Chapter III.
- 2. The competent authority may authorise the placing on the market, other than the import, of milk, milk-based products and milk-derived products categorised as Category 3 material in accordance with Article 10(e), (f) and (h) of Regulation (EC) No 1069/2009 and which have not been processed in accordance with the general requirements set out in Part I of Section 4 of Chapter II of Annex X hereto, provided that those materials comply with the requirements for the derogation for the placing on the market of milk processed in accordance with national standards set out in Part II of that Section.

Article 22

Placing on the market and use of organic fertilisers and soil improvers

1. Operators shall comply with the requirements for the placing on the market, other than the import, of organic fertilisers and soil improvers, and the use of such products, in particular their application to land, as provided for in Articles 15(1)(i) and 32(1) of Regulation (EC) No 1069/2009, set out in Annex XI hereto.

▼ M9

- 2. The placing on the market of the following is not subject to any animal health conditions:
- (a) guano from wild sea birds, collected in the Union or imported from third countries;
- (b) ready-to-sell growing media, other than that imported, with a content of less than:
 - (i) 5 % in volume of derived products of Category 3 material or of Category 2 material other than processed manure;
 - (ii) 50 % in volume of processed manure.

▼B

- 3. The competent authority of the Member State where an organic fertiliser or a soil improver, which has been produced from meat-and-bone meal derived from Category 2 material or from processed animal protein, is to be applied to land, shall authorise one or more components which are to be mixed with those materials, in accordance with Article 32(1)(d) of Regulation (EC) No 1069/2009, according to the criteria set out in point 3 of Section 1 of Chapter II of Annex XI hereto.
- 4. By way of derogation from Article 48(1) of Regulation (EC) No 1069/2009, the competent authorities of a Member State of origin and of a Member State of destination, which share a common border may authorise the dispatch of manure between farms located in border regions of those two Member States subject to appropriate conditions for the control of any possible risks to public or animal health, such as obligations for the operators concerned to keep appropriate records, which are laid down in a bilateral agreement.
- 5. As provided for in Article 30(1) of Regulation (EC) No 1069/2009, the competent authorities of the Member States shall encourage, where necessary, the development, dissemination and use of national guides for good agricultural practice for the application of organic fertilisers and soil improvers to land.

Article 23

Intermediate products

- 1. Intermediate products, imported into or in transit through the Union shall comply with the conditions controlling potential risks to public and animal health referred to in Annex XII hereto.
- 2. Intermediate products which have been transported to an establishment or plant referred to in point 3 of Annex XII hereto, may be handled without further restrictions under Regulation (EC) No 1069/2009 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 Regulation (EC) No 1069/2009.

▼<u>M9</u>

3. The operator or owner of the establishment or plant of destination of intermediate products or his representative shall use and/or dispatch the intermediate products exclusively for use in manufacturing according to the definition of intermediate products under Point 35 of Annex I.

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Article 24

Petfood and other derived products

- 1. The use of Category 1 material referred to in Article 8(a),(b), (d) and (e) of Regulation (EC) No 1069/2009 for the manufacture of derived products which are intended to be ingested by or applied to humans or animals, other than for derived products referred to in Articles 33 and 36 of that Regulation shall be prohibited.
- 2. Where an animal by-product or a derived product may be used for feeding to farmed animals or for other purposes referred to in Article 36(a) of Regulation (EC) No 1069/2009, they shall be placed on the market, other than imported, in accordance with the specific requirements for processed animal protein and other derived products set out in Chapter II of Annex X hereto, provided that Annex XIII hereto does not set out any specific requirements for such products.
- 3. Operators shall comply with the requirements for the placing on the market, other than the import, of petfood, as referred to in Article 40 of Regulation (EC) No 1069/2009, set out in Chapters I and II of Annex XIII hereto.
- 4. Operators shall comply with the requirements for the placing on the market, other than the import, of derived products, as referred to in Article 40 of Regulation (EC) No 1069/2009, set out in Chapter I and Chapters III to XII of Annex XIII hereto.

CHAPTER VIII

IMPORT, TRANSIT AND EXPORT

Article 25

Import, transit and export of animal by-products and of derived products

- 1. The importation into and the transit through the Union of the following animal by-products shall be prohibited:
- (a) unprocessed manure;
- (b) untreated feathers and parts of feathers and down;
- (c) beeswax in the form of honeycomb.

▼ M2

- 2. The importation into and the transit through the Union of the following shall not be subject to any animal health conditions:
- (a) wool and hair which has been factory-washed or which has been treated by another method which ensures that no unacceptable risks remain;
- (b) furs which have been dried at an ambient temperature of 18 °C for a period of at least two days at a humidity of 55 %;
- (c) wool and hair produced from animals other than those of the porcine species, which has been treated by factory-washing which consisting of the immersion of the wool and hair in series of baths of water, soap and sodium hydroxide or potassium hydroxide;
- (d) wool and hair produced from animals other than those of the porcine species, which is dispatched directly to a plant producing derived products from wool and hair for the textile industry and has been treated by at least one of the following methods:
 - chemical depilation by means of slaked lime or sodium sulphide,
 - fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours,
 - industrial scouring which consists of the immersion of wool and hair in a water-soluble detergent held at 60-70 °C,
 - storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days;
- (e) wool and hair that is dry and securely enclosed in packaging, produced from animals other than those of the porcine species, which is intended for dispatch to a plant producing derived products from wool and hair for the textile industry and meets all of the following requirements:
 - (i) it was produced at least 21 days before the date of entry into the Union kept in a third country or region thereof which is
 - listed in Part 1 of Annex II to Regulation (EU) No 206/2010 and authorised for imports into the Union of fresh meat of ruminants not subject to supplementary guarantees A and F mentioned therein,

▼ M2

- free of foot-and-mouth disease, and, in the case of wool and hair from sheep and goats, of sheep pox and goat pox in accordance with the basic general criteria listed in Annex II to Directive 2004/68/EC;
- (ii) it is accompanied by a importers' declaration as required in accordance with Chapter 21 of Annex XV;
- (iii) it was presented by the operator to one of the approved Union border inspection posts listed in Annex I to Decision 2009/821/EC where it passed with satisfactory result the documentary check carried out in accordance with Article 4(3) of Directive 97/78/EC.

▼<u>B</u>

- 3. Operators shall comply with the following specific requirements for the importation into and the transit through the Union of certain animal by-products and derived products, as referred to in Articles 41(3) and 42 of Regulation (EC) No 1069/2009, set out in Annex XIV hereto:
- (a) the specific requirements for the import and transit of Category 3 material and derived products for uses in the feed chain, other than for petfood or feed to fur animals, set out in Chapter I of that Annex;
- (b) the specific requirements for the import and transit of animal byproducts and derived products for uses outside the feed chain for farmed animals, set out in Chapter II of that Annex.

▼M10

4. The rules set out in Chapter V of Annex XIV shall apply to exports from the Union of the derived products specified therein.

▼B

Article 26

Placing on the market, including importation, and export of certain Category 1 materials

The competent authority may authorise the placing on the market, including the importation, and the export of hides and skins derived from animals which have been submitted to an illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or in Article 2(b) of Directive 96/23/EC, and of ruminant intestines with or without content and of bones and bone products containing vertebral column and skull, subject to compliance with the following requirements:

- (a) those materials must not be Category 1 materials derived from any of the following animals:
 - animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001;
 - (ii) animals in which the presence of a TSE has been officially confirmed;
 - (iii) animals killed in the context of TSE eradication measures;
- (b) those materials must not be intended for any of the following uses:
 - (i) feeding;
 - (ii) application to land from which farmed animals are fed;
 - (iii) the manufacture of:
 - cosmetic products as defined in Article 1(1) of Directive 76/768/EEC;

- active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC;
- medical devices as defined in Article 1(2)(a) of Directive 93/42/EEC;
- in vitro diagnostic medical devices as defined in Article 1(2)(b) of Directive 98/79/EC;
- veterinary medicinal products as defined in Article 1(2) of Directive 2001/82/EC;
- medicinal products as defined in Article 1(2) of Directive 2001/83/EC;
- (c) the materials must be imported with a label and must comply with the specific requirements for certain movements of animal byproducts set out in Section 1 of Chapter IV of Annex XIV hereto;
- (d) the materials must be imported in accordance with sanitary certification requirements laid down in national legislation.

Article 27

Importation and transit of research and diagnostic samples

1. The competent authority may authorise the importation and the transit of research and diagnostic samples, comprising derived products or animal by-products, including the animal by-products referred to in Article 25(1), in accordance with conditions which ensure the control of risks to public and animal health.

Such conditions shall include at least the following:

- (a) the introduction of the consignment must have been authorised in advance by the competent authority of the Member State of destination; and
- (b) the consignment must be sent directly from the point of entry into the Union to the authorised user.
- 2. Operators shall present research and diagnostic samples which are intended to be imported via a Member State, other than the Member State of destination, at an approved Union border inspection post listed in Annex I to Decision 2009/821/EC. At the border inspection post, those research and diagnostic samples shall not be subject to veterinary checks in accordance with Chapter I of Directive 97/78/EC. The competent authority of the border inspection post shall inform the competent authority of the Member State of destination of the introduction of the research and diagnostic samples by means of the TRACES system.
- 3. Operators handling research samples or diagnostic samples shall comply with the special requirements for disposal of research and diagnostic samples set out in Section 1 of Chapter III of Annex XIV hereto.

Article 28

Importation and transit of trade samples and display items

- 1. The competent authority may authorise the importation and the transit of trade samples in accordance with the special rules set out in point 1 of Section 2 of Chapter III of Annex XIV hereto.
- 2. Operators handling trade samples shall comply with the special rules for handling and disposal of trade samples set out in points 2 and 3 of Section 2 of Chapter III of Annex XIV hereto.
- 3. The competent authority may authorise the importation and the transit of display items in accordance with the special rules for display items set out in Section 3 of Chapter III of Annex XIV hereto.
- 4. Operators handling display items shall comply with the conditions for packaging, handling and disposal of display items set out in Section 3 of Chapter III of Annex XIV hereto.

Article 29

Specific requirements for certain movements of animal by-products between territories of the Russian Federation

- 1. The competent authority shall authorise specific movements of consignments of animal by-products coming from and destined to the Russian Federation directly or via another third country, by road or by rail through the Union, between approved Union border inspection posts listed in Annex I to Decision 2009/821/EC, 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 Union 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 EU' 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 provided for in Annex III to Regulation (EC) No 136/2004 by the official veterinarian of the border inspection post of introduction.
- 2. 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.
- 3. 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.

▼<u>M5</u>

Article 29a

Specific requirements for transit through Croatia of animal byproducts coming from Bosnia and Herzegovina and destined to third countries

- 1. The movements of consignments of animal by-products and derived products coming from Bosnia and Herzegovina and destined to third countries through the Union, by road, directly between the border inspection post of Nova Sela and the border inspection post of Ploče, shall be authorised provided that the following conditions are met:
- (a) the consignment is sealed with a serially numbered seal by the official veterinarian at the border inspection post of entry;
- (b) the documents accompanying the consignment and referred to in Article 7 of Directive 97/78/EC are stamped 'ONLY FOR TRANSIT TO THIRD COUNTRIES VIA THE EU' on each page by the official veterinarian at the border inspection post of entry;
- (c) the procedural requirements provided for in Article 11 of Directive 97/78/EC are complied with;
- (d) the consignment is certified as acceptable for transit on the Common Veterinary Entry Document referred to in Article 2(1) of Regulation (EC) No 136/2004 by the official veterinarian at the border inspection post of entry.
- 2. Unloading or storage, as defined in Article 12(4) or in Article 13 of Directive 97/78/EC, of such consignments in the Union shall not be allowed.
- 3. Regular audits shall be made by the competent authority to ensure that the number of consignments and the quantities of products leaving the Union matches the number and quantities entering the Union.

Article 30

Lists of establishments and plants in third countries

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.

Each list shall be kept up to date regularly.

▼M16

This Article does not apply to the specific movements of consignments of animal by-products coming from and destined to the Russian Federation as referred to in Article 29 and to the movements of consignments of animal by-products and derived products coming from Bosnia and Herzegovina and destined to third countries as referred to in Article 29a.

▼<u>B</u>

Article 31

Models of health certificates and declarations for importation and transit

Consignments of animal by-products and derived products for importation into or transit through the Union shall be accompanied by health certificates and declarations, in accordance with the models set out in Annex XV hereto, at the point of entry into the Union where the veterinary checks take place, as provided for in Directive 97/78/EC.

▼<u>B</u>

CHAPTER IX

OFFICIAL CONTROLS

Article 32

Official controls

1. The competent authority shall take the necessary measures to control the entire chain of collection, transport, use and disposal of animal by-products and derived products, as referred to in Article 4(2) of Regulation (EC) No 1069/2009.

Those measures shall be carried out in accordance with the principles for official controls laid down in Article 3 of Regulation (EC) No 882/2004.

- 2. The official controls referred to in paragraph 1 shall include checks on the keeping of records and other documents required by the rules laid down in this Regulation.
- 3. The competent authority shall carry out the following official controls, as referred to in Article 45(1) of Regulation (EC) No 1069/2009, in accordance with the requirements set out in Annex XVI hereto:
- (a) official controls in processing plants as set out in Chapter I;
- (b) official controls of other activities which involve the handling of animal by-products, and derived products as set out in Sections 1 to 9 of Chapter III.
- 4. The competent authority shall carry out checks on seals which are applied to consignments of animal by-products or derived products.

When the competent authority applies a seal to such consignment which is transported to a place of destination, it must inform the competent authority of the place of destination.

- 5. The competent authority shall draw up the lists of establishments, plants and operators referred to in Article 47(1) of Regulation (EC) No 1069/2009 in accordance with the format set out in Chapter II of Annex XVI hereto.
- 6. The competent authority of the Member State of destination shall decide upon the application by an operator concerning the acceptance or refusal of certain Category 1, Category 2 material and meat-and-bone meal or animal fat derived from Category 1 and Category 2 materials, within 20 calendar days from the date of receipt of such application provided that it has been submitted in one of the official languages of that Member State.

▼ M<u>16</u>

7. Operators shall submit applications for the authorisation referred to in paragraph 6 in accordance with the standard format set out in Section 10 of Chapter III of Annex XVI hereto by means of TRACES.

▼<u>B</u>

Article 33

Reapproval of plants and establishments after the grant of a temporary approval

1. Where a plant or establishment approved for the processing of Category 3 material is subsequently granted temporary approval for the processing of Category 1 or Category 2 material, in accordance with Article 24(2)(b)(ii) of Regulation (EC) No 1069/2009, it shall be prohibited from recommencing the processing of Category 3 material, without first obtaining the approval of the competent authority to recommence processing of Category 3 material in accordance with Article 44 of that Regulation.

2. Where a plant or establishment approved for the processing of Category 2 material is subsequently granted temporary approval for the processing of Category 1 material, in accordance with Article 24(2)(b)(ii) of Regulation (EC) No 1069/2009, it shall be prohibited from recommencing the processing of Category 2 material, without first obtaining the approval of the competent authority to recommence processing of Category 2 material in accordance with Article 44 of that Regulation.

CHAPTER X

FINAL PROVISIONS

Article 34

Restrictions on the placing on the market of certain animal byproducts and derived products for reasons of public and animal health

The competent authority shall not prohibit or restrict the placing on the market of the following animal by-products and derived products for public health or animal health reasons other than the rules laid down in Union legislation, and in particular those laid down in Regulation (EC) No 1069/2009 and in this Regulation:

- (a) processed animal protein and other derived products referred to in Chapter II of Annex X hereto;
- (b) petfood and certain other derived products referred to in Annex XIII hereto;
- (c) animal by-products and the derived products imported into or in transit through the Union as referred to in Annex XIV hereto.

Article 35

Repeal

- 1. The following acts are repealed:
- (a) Regulation (EC) No 811/2003;
- (b) Decision 2003/322/EC;
- (c) Decision 2003/324/EC;
- (d) Regulation (EC) No 878/2004;
- (e) Decision 2004/407/EC;
- (f) Regulation (EC) No 79/2005;
- (g) Regulation (EC) No 92/2005;
- (h) Regulation (EC) No 181/2006;
- (i) Regulation (EC) No 197/2006;
- (i) Regulation (EC) No 1192/2006;
- (k) Regulation (EC) No 2007/2006.
- 2. References to the repealed acts shall be construed as references to this Regulation.

Article 36

Transitional measures

- 1. For a transitional period until 31 December 2011, operators may place on the market organic fertilisers and soil improvers which were produced before 4 March 2011 in accordance with Regulations (EC) No 1774/2002 and (EC) No 181/2006:
- (a) provided that they have been produced from one of the following:
 - (i) meat-and-bone meal derived from Category 2 material;
 - (ii) processed animal protein;
- (b) even though they have not been mixed with a component to exclude the subsequent use of the mixture for feeding purposes.
- 2. For a transitional period until 31 January 2012, consignments of animal by-products and of derived products accompanied by a health certificate, declaration or commercial document, which has been completed and signed in accordance with the appropriate model set out in Annex X to Regulation (EC) No 1774/2002 shall continue to be accepted for importation into the Union, provided that such certificates, declarations or documents were completed and signed before 30 November 2011.

▼ <u>M9</u>			
▼ <u>B</u>			

Article 37

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

It shall apply from 4 March 2011.

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

ANNEX I

DEFINITIONS AS REFERRED TO IN ARTICLE 2

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

- 'fur animals' means animals kept or reared for the production of fur and not used for human consumption;
- 2. 'blood' means fresh whole blood;
- 3. '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, egg products, fish oil, fat derivatives, collagen, gelatine and hydrolysed proteins, dicalcium phosphate, tricalcium phosphate, milk, milk-based products, milk-derived products, colostrum, colostrum products and centrifuge or separator sludge;
- '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;
- 5. 'processed animal protein' means animal protein derived entirely from Category 3 material, which have been treated in accordance with Section 1 of Chapter II of Annex X (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, milk-derived products, colostrum, colostrum products, centrifuge or separator sludge, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, including eggshells, tricalcium phosphate and collagen;
- 'blood meal' means processed animal protein derived from the heat treatment of blood or fractions of blood in accordance with Section 1 of Chapter II of Annex X;

▼ M<u>11</u>

7. 'fishmeal' means processed animal protein derived from aquatic animals except sea mammals, including farmed aquatic invertebrates, including those covered by Article 3(1)(e) of Council Directive 2006/88/EC (¹), and starfish of the species Asterias rubens which are harvested in a mollusc production area;

▼B

- 8. 'rendered fats' means either fats derived from the processing of:
 - (a) animal by-products; or
 - (b) products for human consumption, which an operator has destined for purposes other than human consumption;

▼M11

 'fish oil' means oil derived from the processing of aquatic animals except sea mammals, including farmed aquatic invertebrates, including those covered by Article 3(1)(e) of Directive 2006/88/EC, and starfish of the

⁽¹) Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

▼M11

species Asterias rubens which are harvested in a mollusc production area, or oil from the processing of fish for human consumption, which an operator has destined for purposes other than human consumption;

▼B

- 'apiculture by-products' means honey, beeswax, royal jelly, propolis or pollen not intended for human consumption;
- 'collagen' means protein-based products derived from hides, skins, bones and tendons of animals;
- '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;
- 'greaves' means the protein-containing residue of rendering, after partial separation of fat and water;
- 'hydrolysed proteins' means polypeptides, peptides and aminoacids, and mixtures thereof, obtained by the hydrolysis of animal by-products;
- 15. 'white water' means a mixture of milk, milk-based products or products derived thereof with water which is collected during the rinsing of dairy equipment including containers used for dairy products, prior to their cleaning and disinfection;
- 'canned petfood' means heat-processed petfood contained within a hermetically sealed container;
- 'dogchews' means products for pet animals to chew, produced from untanned hides and skins of ungulates or from other material of animal origin;
- 'flavouring innards' means a liquid or dehydrated derived product of animal origin used to enhance the palatability values of petfood;

▼<u>M4</u>

- 19. 'petfood' means feed, other than material referred to in Article 24(2), for use as feed for pet animals, and dogchews consisting of animal by-products or derived products which:
 - (a) contain Category 3 material, other than material referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009; and
 - (b) may contain imported Category 1 material comprising of animal by-products 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;

▼B

- 20. 'processed petfood' means petfood, other than raw petfood, which has been processed in accordance with point 3 of Chapter II of Annex XIII;
- 21. 'raw petfood' means petfood containing certain Category 3 material which has not undergone any preserving process other than chilling or freezing;
- 'catering waste' means all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens;

▼<u>M4</u>

 'digestion residues' means residues, including the liquid fraction, resulting from the transformation of animal by-products in a biogas plant;

▼<u>B</u>

- 'digestive tract content' means the content of the digestive tract of mammals and ratites;
- 25. 'fat derivatives' means derived products from rendered fats, which, as regards rendered fats of Category 1 or Category 2 material, have been processed in accordance with Chapter XI of Annex XIII;
- 26. 'guano' means a natural product which has been collected from the excrements of bats or wild sea birds and which is not mineralised;
- 27. 'meat-and-bone meal' means animal protein derived from the processing of Category 1 or Category 2 materials in accordance with one of the processing methods set out in Chapter III of Annex IV;
- 28. 'treated hides and skins' means derived products from untreated hides and skins, other than dogchews, that have been:
 - (a) dried;
 - (b) dry-salted or wet-salted for a period of at least 14 days prior to dispatch;
 - (c) salted for a period of at least seven days in sea salt with the addition of 2 % of sodium carbonate;
 - (d) dried for a period of at least 42 days at a temperature of at least 20 °C;
 - (e) subject to a preservation process other than tanning;
- 'untreated hides and skins' means all cutaneous and subcutaneous tissues that have not undergone any treatment, other than cutting, chilling or freezing;
- 30. 'untreated feathers and parts of feathers' means feathers and parts of feathers, other than feathers or parts of feathers, which have been treated:
 - (a) with a steam current; or
 - (b) by another method that ensures that no unacceptable risks remain;

▼ M2

- 31. 'untreated wool' means wool, other than wool which has:
 - (a) undergone factory washing;
 - (b) been obtained from tanning;
 - (c) been treated by another method that ensures that no unacceptable risks remain:
 - (d) been produced from animals other than those of the porcine species, and has undergone factory-washing which consisting of the immersion of the wool in series of baths of water, soap and sodium hydroxide or potassium hydroxide; or
 - (e) been produced from animals other than those of the porcine species, is intended for being dispatched directly to a plant producing derived products from wool for the textile industry and has undergone at least one of the following treatments:
 - (i) chemical depilation by means of slaked lime or sodium sulphide;
 - (ii) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours;
 - (iii) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at $60-70~^{\circ}\text{C}$;
 - (iv) storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days;
- 32. 'untreated hair' means hair, other than hair which has:
 - (a) undergone factory washing;
 - (b) been obtained from tanning;

▼ M2

- (c) been treated by another method that ensures that no unacceptable risks remain;
- (d) been produced from animals other than those of the porcine species, and has undergone factory-washing which consisting of the immersion of the hair in series of baths of water, soap and sodium hydroxide or potassium hydroxide; or
- (e) been produced from animals other than those of the porcine species, is intended for being dispatched directly to a plant producing derived products from hair for the textile industry and has undergone at least one of the following treatments:
 - (i) chemical depilation by means of slaked lime or sodium sulphide;
 - (ii) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours;
 - (iii) industrial scouring which consists of the immersion of hair in a water-soluble detergent held at 60-70 °C;
 - (iv) storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days;

▼B

- 33. 'untreated pig bristles' means pig bristles, other than pig bristles which have:
 - (a) undergone factory washing;
 - (b) been obtained from tanning; or
 - (c) been treated by another method that ensures that no unacceptable risks remain;
- 'display item' means animal by-products or derived products intended for exhibitions or artistic activities;

▼ M9

- 35. 'intermediate product' means a derived product:
 - (a) which is intended for uses within the manufacturing of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products as follows:
 - as material in a manufacturing process or in the final production of a finished product;
 - (ii) in validation or verification during a manufacturing process; or
 - (iii) in quality control of a finished product;
 - (b) whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in point (a);
 - (c) which however requires some further manufacturing or transformation, such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, active implantable medical device, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagent or cosmetic products;

▼B

36. 'laboratory reagent' means a packaged product, ready for use, containing animal by-products or derived products and intended as such or in combination with substances of non-animal origin for specific laboratory use as a reagent or reagent product, calibrator or control material to detect, measure, examine or produce other substances;

▼B

- 37. 'product used for in vitro diagnosis' means a packaged product, ready for use, 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, 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; it does not include donated organs or blood;
- 38. 'research and diagnostic samples' means animal by-products and derived products intended for the following purposes: examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology, in the context of educational or research activities;

▼ M9

39. 'trade samples' means animal by-products or derived products intended for particular studies or analyses authorised by the competent authority in accordance with Article 17(1) of Regulation (EC) No 1069/2009 with a view to carrying out a production process, including the processing of animal by-products or derived products, the development of feedingstuff, pet food or derived products, or the testing of machinery or equipment;

▼<u>B</u>

- 40. 'co-incineration' means the recovery or disposal of animal by-products or derived products, if they are waste, in a co-incineration plant;
- 41. '**combustion**' means a process involving the oxidisation of fuel in order to use the energy value of the animal by-products or derived products, if they are not waste;
- 42. 'incineration' means the disposal of animal by-products or derived products as waste, in an incineration plant, as defined in point 4 of Article 3 of Directive 2000/76/EC;
- 43. 'incineration and co-incineration residues' means any residues as defined in point 13 of Article 3 of Directive 2000/76/EC, which are generated by incineration or co-incineration plants treating animal by-products or derived products;
- 44. 'colour-coding' means the systematic use of colours as set out in point 1(c) of Chapter II of Annex VIII for displaying information as provided for in this Regulation on the surface or on part of the surface of a packaging, container or vehicle, or on a label or symbol applied to them;
- 45. 'intermediate operations' means the operations, other than storage, referred to in Article 19(b);
- 46. '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;
- 47. 'taxidermy' means the art of preparing, stuffing and mounting the skins of animals with lifelike effect, so that no unacceptable risks to public and animal health may be transmitted through the mounted skin;
- 48. '**trade**' means trade in goods between Member States as referred to in Article 28 of the Treaty on the Functioning of the European Union;
- 'processing methods' means the methods listed in Chapters III and IV of Annex IV;

▼<u>B</u>

- 50. '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 as a shipping unit;
- 51. 'hermetically sealed container' means a container that is designed and intended to be secure against the entry of micro-organisms;
- 'biogas plant' means a plant in which animal by-products or derived products are at least part of the material which is submitted to biological degradation under anaerobic conditions;
- 53. 'collection centres' means premises other than processing plants in which the animal by-products referred to in Article 18(1) of Regulation (EC) No 1069/2009 are collected with the intention to be used for feeding to the animals referred to in the same Article;
- 54. 'composting plant' means a plant in which animal by-products or derived products are at least part of the material which is submitted to biological degradation under aerobic conditions;
- 55. 'co-incineration plant' means any stationary or mobile plant whose main purpose is the generation of energy or the production of material products as defined in point 5 of Article 3 of Directive 2000/76/EC;
- 56. 'incineration plant' means any stationary or mobile technical unit and equipment dedicated to the thermal treatment of waste as defined in point 4 of Article 3 of Directive 2000/76/EC;
- 57. 'petfood plant' means premises or facilities for the production of petfood or flavouring innards, as referred to in Article 24(1)(e) of Regulation (EC) No 1069/2009;

▼ M9

- 58. 'processing plant' means premises or facilities for the processing of animal by-products as referred to in Article 24(1)(a) of Regulation (EC) No 1069/2009, in which animal by-products are processed in accordance with Annex IV and/or Annex X;
- 59. 'growing media' means materials, including potting soil, other than soil in situ, in which plants are grown and which is used independently from soil in situ.

ANNEX II

RESTRICTIONS ON THE USE OF ANIMAL BY-PRODUCTS

CHAPTER I

Intra-species recycling of fur animals

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

▼<u>M1</u>

(a) foxes (Vulpes vulpes and Alopex lagopus);

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- (b) raccoon dogs (Nyctereutes procyonides).
- 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 the processing methods set out in Chapter III of Annex IV 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:
 - (i) which have been registered by the competent authority 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 transmissible spongiform encephalopathies (TSEs) in fur animals is in place on the farm and includes regular laboratory testing of samples for TSE;
 - (iii) which have provided appropriate guarantees that no animal by-product or meat-and-bone meal or other products which have been processed in accordance with Chapter III of Annex IV and which are derived from those animals or their offspring may enter the food or feed chain of other animals than fur animals;
 - (iv) which have 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 Chapter III of Annex IV 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 farm complies with the requirements set out in point 2 of Section 1 of Chapter II of Annex VI and point (2)(b)(ii) of Chapter II of Annex VIII.

- (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 Regulation (EC) No 1069/2009 and using only processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV 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;
 - (ii) cease the dispatch of fur animals to any destination without a written authorisation of the competent authority.

CHAPTER II

Feeding of farmed animals with herbage

The following conditions shall apply to the feeding of farmed animals with herbage from land, either by direct access of the animals to that land or by using cut herbage as feed, provided that organic fertilisers or soil improvers have been applied to that land:

- (a) The waiting period of at least 21 days referred to in Article 11(1)(c) of Regulation (EC) No 1069/2009 must have been observed,
- (b) Only organic fertilisers and soil improvers have been used which comply with Article 32(1) and (2) of Regulation (EC) No 1069/2009 and with Chapter II of Annex XI hereto.

However, those conditions shall not apply, provided only the following organic fertilisers or soil improvers have been applied to land:

- (a) manure and guano;
- (b) digestive tract content, milk, milk-based products, milk-derived products, colostrum and colostrum products, which the competent authority does not consider to present a risk for the spread of any serious animal disease.

ANNEX III

DISPOSAL, RECOVERY AND USE AS A FUEL

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CHAPTER I

GENERAL REQUIREMENTS FOR INCINERATION AND CO-INCINERATION

Section 1

General conditions

- Operators of incineration and co-incineration plants referred to in Article 6(1)(b) of this Regulation shall ensure that the following hygiene conditions are met in the plants under their control:
 - (a) Animal by-products and derived products must be disposed of as soon as possible after arrival, in accordance with conditions laid down by the competent authority. They shall be stored properly until disposal, in accordance with conditions laid down by the competent authority.
 - (b) Plants must have appropriate arrangements for the cleaning and disinfection of containers and vehicles in place, in particular in a designated area from which wastewater is disposed of in accordance with Union legislation, to avoid risks of contamination.
 - (c) Plants must be located on a well-drained hardstanding.
 - (d) Plants must have appropriate arrangements for protection against pests, such as insects, rodents and birds. A documented pest control programme must be used for that purpose.
 - (e) Staff must have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins, if necessary to prevent risks of contamination
 - (f) Cleaning procedures must be established and documented for all parts of the premises. Suitable equipment and cleaning agents must be provided for cleaning.
 - (g) Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and maintained for at least two years.
- The operator of an incineration or co-incineration plant shall take all
 necessary precautions concerning the reception of animal by-products or
 derived products to prevent, or limit as far as practicable, direct risks to
 human or animal health.
- Animals must not have access to the plants, animal by-products and derived products that are awaiting incineration or co-incineration or to 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;

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- (b) equipment must be dedicated entirely to the operation of the incinerator and not used elsewhere on the holding or, alternatively, cleaned and disinfected before such use;
- (c) personnel working in the plant must change their outer clothing and footwear before handling livestock or livestock feed.
- The storage of animal by-products and derived products that are awaiting incineration or co-incineration and of ashes must be in covered, correctly identified and, if appropriate, leak proof containers.
- Incompletely incinerated animal by-products must be reincinerated or disposed of by other means, other than by disposal in an authorised landfill, in accordance with Articles 12, 13 and 14, as applicable, of Regulation (EC) No 1069/2009.

Section 2

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 °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 chamber where the incineration or the co-incineration is carried out, as authorised by the competent authority.

Section 3

Incineration and co-incineration residues

- Incineration and co-incineration residues shall be minimised in their amount and harmfulness. Such residues must be recovered, where appropriate, directly in the plant or outside it in accordance with relevant Union legislation or disposed of in an authorised landfill.
- Transport and intermediate storage of dry residues, including dust, shall take place in such a way as to prevent dispersal in the environment, such as in closed containers.

Section 4

Measurement of temperature and of other parameters

- 1. Techniques shall be used to monitor the parameters and conditions relevant to the incineration or co-incineration process.
- 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.
- 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.

Section 5

Abnormal operating

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

CHAPTER II

HIGH-CAPACITY INCINERATION AND CO-INCINERATION PLANTS

Section 1

Specific operating conditions

Incineration or co-incineration plants treating only animal by-products and derived products with a capacity of more than 50 kg per hour (high-capacity plants) and which are not required to have a permit to operate in accordance with Directive 2000/76/EC shall comply with the following conditions:

- (a) The plants must be equipped 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 or 1100 °C, as applicable. It must also be used during plant start-up and shut-down operations to ensure that the temperature of 850 °C or of 1100 °C, as applicable, is maintained at all times during these operations and as long as unburned material is in the chamber where the incineration or co-incineration is carried out.
- (b) When animal by-products or derived products are introduced into the chamber where the incineration or co-incineration is carried out by a continuous process, the plant must operate an automatic system to prevent the introduction of animal by-products or derived products at start-up, until the temperature of 850 °C or of 1100 °C, as applicable, has been reached, and whenever the temperature is not maintained.
- (c) The operator must operate the incineration plant in such manner that a level of incineration is achieved such that the slag and bottom ashes total organic carbon content is less than 3 % or their loss on ignition is less than 5 % of the dry weight of the material. If necessary, appropriate techniques of pre-treatment shall be used.

Section 2

Water discharges

- 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.
- Storage capacity shall be provided for contaminated rainwater run-off from the plant site or for contaminated water arising from spillage or firefighting operations.

The operator shall, if necessary, ensure that such rainwater and such water can be tested and treated before discharge, when necessary.

CHAPTER III

LOW-CAPACITY INCINERATION AND CO-INCINERATION PLANTS

Incineration and co-incineration plants treating only animal by-products and derived products with a maximum capacity of less than 50 kg of animal by-products per hour or per batch (low-capacity plants) and which are not required to have a permit to operate in accordance with Directive 2000/76/EC shall:

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- (a) only be used for the disposal of:
 - (i) dead pet animals referred to in Article 8(a)(iii) of Regulation (EC) No 1069/2009;
 - (ii) Category 1 materials referred to in Article 8(b), (e) and (f), Category 2 materials referred to in Article 9 or Category 3 materials referred to in Article 10 of that Regulation; and
 - (iii) dead individually identified equine animals from holdings not subject to health restrictions in accordance with Article 4(5) or 5 of Directive 2009/156/EC, if authorised by the Member State;

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- (b) when Category 1 materials referred to in Article 8(b) of Regulation (EC) No 1069/2009 are introduced into the low-capacity plant, be equipped with an auxiliary burner;
- (c) operate in such way that the animal by-products are completely reduced to

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CHAPTER IV

GENERAL REQUIREMENTS FOR THE USE OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS AS A FUEL

Section 1

General requirements regarding the combustion of animal by-products and derived products as a fuel

- 1. Operators of combustion plants referred to in Article 6(6) shall ensure that the following conditions are met in the combustion plants under their control:
 - (a) Animal by-products and derived products intended to be used as a fuel must be utilised for that purpose as soon as possible or safely stored until used.
 - (b) The combustion plants must have in place appropriate measures to ensure that cleaning and disinfection of containers and vehicles are carried out in a designated area of their premises from which the wastewater can be collected and disposed of in accordance with Union legislation, to avoid risks of contamination of the environment.

By way of derogation from the requirements set out in the first subparagraph, containers and vehicles used for the transport of rendered fats may be cleaned and disinfected at the plant of loading or at any other plant approved or registered under Regulation (EC) No 1069/2009.

(c) The combustion plants must be located on a well-drained hard standing.

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- (d) The combustion plants must have appropriate measures in place for the protection against pests. A documented pest control programme must be used for that purpose.
- (e) Staff must have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins, if necessary, to prevent risks of contamination of equipment for handling of farmed animals or their feedstuffs.
- (f) Cleaning and disinfection procedures, must be established and documented for all parts of the combustion plant. Suitable equipment and cleaning agents must be provided for cleaning.
- (g) Hygiene control must include regular inspections of the environment and equipment. Inspection schedules and results must be documented and retained for a period of at least two years.
- (h) Where rendered fats are used as a fuel for combustion in stationary internal combustion engines located within approved or registered food or feed processing plants, the processing of food or feed on the same site must take place under strict conditions of separation.
- Operators of the combustion plants shall take all necessary precautions concerning the reception of animal by-products or derived products to prevent or limit as far as practicable, risks to human or animal health and the environment.
- Animals must not have access to the combustion plant or to the animal by-products and derived products awaiting combustion or the ash resulting from the combustion
- 4. Where the combustion plant is located on a holding keeping animals of food producing species:
 - (a) there must be total physical separation between the combustion equipment and the animals including their feed and bedding;
 - (b) equipment must be dedicated entirely to the operation of the combustion plant and not used elsewhere on the holding unless it had been effectively cleaned and disinfected before such use;
 - (c) personnel working in the combustion plant must change their outer clothing and footwear and take personal hygiene measures before handling animals on this or any other holding or their feed or bedding material.
- The animal by-products and derived products that are awaiting combustion as a fuel and the combustion residues must be stored in a closed and covered dedicated area, or in covered and leak-proof containers.
- The combustion of animal by-products or derived products shall be carried out under conditions which prevent cross-contamination of feed for animals.

Section 2

Operating conditions of combustion plants

- Combustion plants must be designed, built, equipped and operated in such a
 way that even under the most unfavourable conditions the animal by-products
 and derived products are treated for at least for 2 seconds at a temperature of
 850 °C or for at least 0,2 seconds at a temperature of 1 100 °C.
- The gas resulting from the process is raised in a controlled and homogeneous fashion for 2 seconds to a temperature of 850 °C or for 0,2 seconds to a temperature of 1 100 °C.

The temperature must be measured near the inner wall or at another representative point of the combustion chamber, as authorised by the competent authority.

- Automated techniques shall be used to monitor the parameters and conditions relevant to the combustion process.
- 4. Temperature measurement results shall be recorded automatically and presented in an appropriate fashion to enable the competent authority to verify compliance with the permitted operating conditions referred to in points 1 and 2 in accordance with procedures to be decided upon by the relevant authority.
- 5. The operator of a combustion plant shall ensure that the fuel is combusted in such a way that the total organic carbon content of the slags and bottom ashes is less than 3 % or their loss on ignition is less than 5 % of the dry weight of the material.

Section 3

Combustion residues

- Combustion residues shall be minimised in their amount and harmfulness. Such residues must be recovered, or where it is not appropriate, disposed of or used in accordance with relevant Union legislation.
- The transport and intermediate storage of dry residues, including dust, shall take place in closed containers or in another way which prevents dispersal into the environment.

Section 4

Breakdown or abnormal operating conditions

- The combustion plant shall be equipped with facilities which automatically shut down operations in the case of a breakdown or abnormal operating conditions until normal operations can be resumed.
- Incompletely combusted animal by-products and derived products must be combusted again or disposed of by means referred to in Articles 12, 13 and 14 of Regulation (EC) No 1069/2009 other than disposal in an authorised landfill.

CHAPTER V

TYPES OF PLANTS AND FUELS THAT MAY BE USED FOR COMBUSTION AND SPECIFIC REQUIREMENTS FOR PARTICULAR TYPES OF PLANTS

- A. Stationary internal combustion engines
 - 1. Starting material:

For this process, a fat fraction derived from animal by-products of all categories may be used provided it meets the following conditions:

- (a) unless fish oil or rendered fat is used which has been produced in accordance with Section VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively, the fat fraction derived from animal by-products must first be processed using:
 - (i) in the case of a fat fraction of Category 1 and 2 materials, any of the processing methods 1 to 5 as set out in Chapter III of Annex IV.

Where this fat is 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 immediate direct combustion the permanent marking with glyceroltriheptanoate (GTH) referred to in point 1 of Chapter V of Annex VIII shall not be required;

- (ii) in the case of a fat fraction of Category 3 material, any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV;
- (iii) in the case of the materials derived from fish, any of the processing methods 1 to 7 as set out in Chapter III of Annex IV;
- (b) the fat fraction must be separated from the protein and in the case of fat from ruminant origin which is intended to be combusted in another plant, insoluble impurities in excess of 0,15 % by weight must be removed.

2. Methodology:

Combustion of animal fat as a fuel in a stationary internal combustion engine shall be carried out as follows:

- (a) the fat fractions referred to in points 1(a) and (b) must be combusted:
 - (i) under the conditions laid down in Section 2(1) of Chapter IV; or
 - (ii) using process parameters achieving an equivalent outcome as the conditions under (i) and which are authorised by the competent authority;
- (b) the combustion of material of animal origin other than animal fat must not be permitted;

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- (c) the animal fat derived from Category 1 or Category 2 combusted in premises approved or registered in accordance with Regulations (EC) No 852/2004, (EC) No 853/2004, 183/2005, or in public places must have been processed with processing method 1 as set out in Chapter III of Annex IV;
- (d) the combustion of animal fat must be carried out in accordance with Union legislation for the protection of the environment, in particular, with reference to the standards and requirements of that legislation and the requirements regarding best available techniques for the control and monitoring of emissions.

3. Operating conditions:

By way of derogation from the requirements set out in the first paragraph of point 2 of Section 2 of Chapter IV, requirements based on other process parameters, which ensure an equivalent environmental outcome may be authorised by the competent authority responsible for environmental issues.

- B. On-farm combustion plants in which poultry manure is used as a fuel
 - 1. Type of plant:

On-farm combustion plant with a total rated thermal input not exceeding 5 MW

2. Starting material and scope:

Exclusively unprocessed poultry manure, as referred to in Article 9(a) of Regulation (EC) No 1069/2009, to be used as a fuel for combustion in accordance with the requirements set out in point 3 to 5.

The combustion of other animal by-products or derived products and of manure of other species or generated outside the holding shall not be allowed for use as a fuel in on-farm combustion plants referred to in point 1.

- 3. Specific requirements for poultry manure used as a fuel for combustion:
 - (a) The manure shall be stored securely in a closed storage area to minimise the need for further handling and to prevent cross contamination with other areas on a holding keeping animals of food producing species.
 - (b) The on-farm combustion plant must be equipped with:
 - (i) an automatic fuel management system to place the fuel directly in the combustion chamber without further handling;
 - (ii) an auxiliary burner which must be used during start-up and shut-down operations to ensure that the temperature requirements set out in Section 2(2) of Chapter IV are met at all times during those operations and as long as unburned material is in the combustion chamber.

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- 4. Emission limit values and monitoring requirements:
 - (a) The emissions of sulphur dioxide, nitrogen oxides (namely the sum of nitrogen monoxide and nitrogen dioxide, expressed as nitrogen dioxide) and particulate matter shall not exceed the following emission limit values, expressed in mg/Nm³ at a temperature of 273,15 K, a pressure of 101,3 kPa and an oxygen content of 11 per cent, after correction for the water vapour content of the waste gases:

Pollutant	Emission limit value in mg/Nm ³
Sulphur dioxide	50
Nitrogen oxides (as NO ₂)	200
Particulate matter	10

(b) The operator of the on-farm combustion plant shall carry out at least annual measurements of sulphur dioxide, nitrogen oxides and particulate matter.

As an alternative to the measurements referred to in the first subparagraph, other procedures, verified and approved by the competent authority, may be used to determine the emissions of sulphur dioxide.

Monitoring shall be carried out by or on behalf of the operator in accordance with CEN standards. Where CEN standards are not available, ISO, national or other international standards which ensure the provision of data of an equivalent scientific quality shall apply.

- (c) All results shall be recorded, processed and presented in such a way as to enable the competent authority to verify compliance with the emission limit values.
- (d) For on-farm combustion plants applying secondary abatement equipment in order to meet the emission limit values, the effective operation of that equipment shall be monitored continuously and the results thereof recorded.
- (e) In the event of non-compliance with the emission limit values referred to in point (a) or where an on-farm combustion plant does not meet the requirements of point 1 of Section 2 of Chapter IV, operators shall immediately inform the competent authority and take the measures necessary to ensure that compliance is restored within the shortest possible time. Where compliance cannot be restored, the competent authority shall suspend the operation of the plant and withdraw its approval.
- 5. Changes of operation and breakdowns:
 - (a) The operator shall notify the competent authority of any planned change of the on-farm combustion plant which would affect its emissions at least one month before the date on which the change takes place.
 - (b) The operator shall take the necessary measures to ensure that the periods of start-up and shut-down of the on-farm combustion plant and of any malfunctions are kept as short as possible. In the case of a malfunction or a breakdown of secondary abatement equipment, the operator shall immediately inform the competent authority.

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- C. Combustion plants in which manure of farmed animals other than poultry manure set out in point B is used as a fuel for combustion
 - 1. Type of plant:

Combustion plants with a total rated thermal input not exceeding 50 MW.

2. Starting material:

Exclusively manure of farmed animals other than poultry manure set out in point B, to be used as a fuel for combustion in accordance with the requirements set out in point 3.

The combustion of other animal by-products or derived products shall not be allowed for use as a fuel in combustion plants referred to in point 1. Manure of farmed animals other than poultry manure set out in point B generated outside the holding should not come in contact with farmed animals.

3. Methodology:

Combustion plants in which manure of farmed animals other than poultry manure set out in point B is used as a fuel shall comply with requirements set out in points B(3), B(4) and B(5).

4. Derogation and transitional period:

The Member State competent authority responsible for environmental issues may:

- (a) by way of derogation from point B(3)(b)(ii), grant combustion plants operating on 2 August 2017 an additional time period of maximum 6 years to comply with the first paragraph of point 2 of Section 2 of Chapter IV of Annex III to this Regulation;
- (b) by way of derogation from point B(4), authorise emissions of particulate matter not exceeding 50 mg/m³, provided the total rated thermal input of the combustion plants does not exceed 5 MW;
- (c) by way of derogation from point B(3)(b)(i), authorise manual placement of horse manure as fuel in the combustion chamber when a total rated thermal input not exceeding 0,5 MW.

ANNEX IV

PROCESSING

CHAPTER I

REQUIREMENTS FOR PROCESSING PLANTS AND CERTAIN OTHER PLANTS AND ESTABLISHMENTS

Section 1

General conditions

- Processing plants shall meet the following requirements, for processing by pressure sterilisation or in accordance with the processing methods referred to in Article 15(1)(b) of Regulation (EC) No 1069/2009:
 - (a) Processing plants must not be situated on the same site as slaughter-houses 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:
 - 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 in the processing plant:
 - 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 processing plants processing Category 3 material, 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 or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004.

Member States shall inform the Commission and the other Member States in the framework of the Standing Committee on the Food Chain and Animal Health referred to in Article 52(1) of Regulation (EC) No 1069/2009 of the use made of this derogation by their competent authorities;

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- (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:
 - 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;
 - (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.
- The processing plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the means of transport, 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.
- 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 must have its own laboratory or make use of the services of an external laboratory. The laboratory must be equipped to carry out necessary analyses and be approved by the competent authority on the basis of an assessment of the capacity of the laboratory to carry out those analyses, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority, to assess the capacity of the laboratory to carry out those analyses.

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

Section 2

Wastewater treatment

 Processing plants processing Category 1 material and other premises where specified risk material is removed, slaughterhouses and processing plants processing Category 2 material shall have a pre-treatment process for the retention and collection of animal material as an initial step in the treatment of wastewater.

The equipment used in the pre-treatment process shall consist of drain traps or screens 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 ensure that the solid particles in the wastewater passing through them are no more than 6 mm

- 2. Wastewater from the premises as referred to in point 1 must enter a pre-treatment process which shall ensure that all wastewater has been filtered through the process before being drained off the premises. No grinding, maceration or any other processing or application of pressure shall be carried out which could facilitate the passage of solid animal material through the pre-treatment process.
- All animal material retained in the pre-treatment process in premises as referred to in point 1 shall be collected and transported as Category 1 or Category 2 material, as appropriate, and disposed of in accordance with Regulation (EC) No 1069/2009.
- 4. Wastewater having passed the pre-treatment process in premises referred to in point 1 and wastewater from other premises handling or processing animal by-products shall be treated in accordance with Union legislation, without restrictions in accordance with this Regulation.
- 5. In addition to the requirements laid down in point 4, the competent authority may oblige operators to treat wastewater originating in the unclean sector of processing plants and in plants or establishments carrying out intermediate operations with Category 1 material or Category 2 material or storing Category 1 material or Category 2 material, in accordance with conditions which ensure that risks from pathogens are mitigated.
- Without prejudice to points 1 to 5, the disposal of animal by-products, including blood and milk, or derived products through the wastewater stream shall be prohibited.

However, Category 3 material comprising of centrifuge or separator sludge may be disposed of through the wastewater stream, provided that it has been subject to one of the treatments for centrifuge or separator sludge set out in Part III of Section 4 of Chapter II of Annex X hereto.

Section 3

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

The layout of processing plants processing Category 1 and Category 2 materials 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.

Section 4

Specific requirements for the processing of Category 3 materials

The following requirements shall apply in addition to the general conditions set out in Section 1:

- 1. Processing plants processing Category 3 materials shall not be located at the same site as processing plants processing Category 1 or Category 2 materials, unless located in a completely separate building.
- 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 due to:
 - (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. Processing plants processing Category 3 material shall have in place an installation to check the presence of foreign bodies, such as packaging material or metallic pieces, in the animal by-products or derived products, if they are processing materials which are destined for feeding. Such foreign bodies shall be removed before or during processing.

CHAPTER II

HYGIENE AND PROCESSING REQUIREMENTS

Section 1

General hygiene requirements

In addition to the general hygiene requirements provided for in Article 25 of Regulation (EC) No 1069/2009, processing plants shall have a documented pest control programme in place for the implementation of the arrangements for protection against pests, such as insects, rodents and birds, referred to in Article 25(1)(c) of that Regulation.

Section 2

General processing requirements

- 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.
- Material that may not have received the specified heat treatment, such as material discharged at start up or leakage from cookers, must be recirculated through the heat treatment or collected and reprocessed or disposed of in accordance with Regulation (EC) No 1069/2009.

Section 3

Processing methods for Category 1 and Category 2 material

Unless the competent authority requires the application of pressure sterilisation (method 1), Category 1 and Category 2 material shall be processed in accordance with processing methods 2, 3, 4 or 5 as referred to in Chapter III.

Section 4

Processing of Category 3 material

- The critical control points that determine the extent of the heat treatments applied in processing shall include for each processing method as specified in Chapter III:
 - (a) raw material particle size;
 - (b) temperature achieved in the heat treatment process;
 - (c) pressure, if applied to the raw material;
 - (d) duration of the heat treatment process or feed rate to a continuous system. Minimum processing standards must be specified for each applicable critical control point.
- 2. In the case of chemical treatments which have been authorised by the competent authority as processing method 7 in accordance with point G of Chapter III, the critical control points that determine the extent of the chemical treatments applied shall include the pH adjustment achieved.
- Records shall be maintained for at least two years to show that the minimum process values for each critical control point are applied.
- 4. Category 3 material shall be processed in accordance with any of the processing methods 1 to 5 or processing method 7, or, in the case of material originating from aquatic animals, with any of the processing methods 1 to 7, as referred to in Chapter III.

CHAPTER III

STANDARD PROCESSING METHODS

A. Processing method 1 (pressure sterilisation)

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. Processing 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.

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

C. Processing 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.

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

D. Processing 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.

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

E. Processing 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.

- 3. The processing may be carried out in batch or continuous systems.
- F. Processing method 6 (for Category 3 animal by-products originating from aquatic animal or aquatic invertebrates only)

Reduction

- The animal by-products must be reduced to a particle size which is no greater than:
 - (a) 50 mm, in case of heat treatment in accordance with point 2(a); or
 - (b) 30 mm, in case of heat treatment in accordance with point 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.

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. Processing method 7

- 1. Any processing method authorised by the competent authority where the following have been demonstrated by the operator to that authority:
 - (a) the identification of relevant hazards in the starting material, in view of the origin of the material, and of the potential risks in view of the animal health status of the Member State or the area or zone where the method is to be used;
 - (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, and, as appropriate, the critical temperature, the absolute time, pressure profile, raw material feed rate and fat recycling rate.

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- By way of derogation from point 1, the competent authority may authorise the use of processing methods which have been approved prior to the date of entry into application of this Regulation, in accordance with Chapter III of Annex V to Regulation (EC) No 1774/2002.
- 4. The competent authority shall permanently or temporarily suspend the application of processing methods referred to in points 1 and 3, if it obtains evidence that any of the circumstances specified in point 1(a) or (b) have substantially changed.
- 5. 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 processing method.

CHAPTER IV

ALTERNATIVE PROCESSING METHODS

Section 1

General provisions

▼ M1

 Materials resulting from the processing of Category 1 and 2 materials shall be permanently marked in accordance with the requirements for the marking of certain derived products set out in Chapter V of Annex VIII.

However, such marking shall not be required for the following materials referred to in Section 2:

- (a) biodiesel produced in accordance with point D;
- (b) hydrolysed materials referred to in point H;
- (c) mixtures of pig and poultry manure with quick lime produced in accordance with point I;

▼M13

(d) renewable fuels produced from rendered fats, which are derived from Category 1 and Category 2 materials, in accordance with point J and L.

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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.

Section 2

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) must be 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 must be adjusted so that the molar equivalency referred to is achieved.

- (b) Animal by-products must be placed in a steel alloy container. The measured amount of alkali must be added either in solid form or as a solution as referred to in point (a).
- (c) The container must be closed and the animal by-products and alkali mixture must be 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 Regulation (EC) No 1069/2009.

However, materials derived from Category 1 materials comprising of animals killed in the context of TSE eradication measures 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) of this Section; or

- (iii) one hour without interruption in the case of animal by-products consisting of fish or of poultry materials.
- (d) The process must be carried out in a batch system and the material in the vessel must be 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 must be 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 must be 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 must be carried out in a batch and the material in the vessel must be constantly mixed; and
- (c) The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure 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 must be first processed using processing method 1 (pressure sterilisation) as set out in Chapter III in an approved processing plant;
- (b) Following the process referred to in point (a), the defatted materials must be 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 must be carried out in a batch or continuous system and the material is constantly mixed;
- (d) The animal by-products must be treated in such a manner that the requirements regarding time, temperature and pressure are achieved at the same time;
- (e) The resulting material must then be mixed with water and anaerobically fermented (biogas transformation) in a biogas reactor;
- (f) In the case of starting material of Category 1, the entire process must take place on the same site and in a closed system and the biogas produced during the process must 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 derived from 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 are 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 derived from animal by-products must be first processed using:
 - (i) in the case of Category 1 or 2 materials, processing method 1 (pressure sterilisation) as set out in Chapter III; and

- (ii) in the case of Category 3 materials, any of the processing methods 1 to 5 or processing method 7 or, in the case of material derived from fish, processing methods 1 to 7 as set out in Chapter III;
- (b) The processed fat must then be processed further using one of the following methods:
 - (i) a process whereby the processed fat must be separated from the protein and in the case of fat from ruminant origin, insoluble impurities in excess of 0,15 % by weight must be removed, and the processed fat must be subsequently submitted to esterfication and transesterfication.

However, esterfication is not required for processed fat derived from Category 3 material. For esterfication the pH must be reduced to less than 1 by adding sulphuric acid (H₂SO₄) or an equivalent acid and the mixture must be heated to 72 °C for at least two hours during which it must be intensely mixed.

Transesterfication must 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 must be 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 must be warmed up using natural gas;
- (b) The animal by-products must be loaded into the primary chamber of the gasificator and the door must be closed. The primary chamber must have no burners and must be heated instead by the transfer of heat by conduction from the afterburner, which must be underneath the primary chamber. The only air admitted to the primary chamber must be via three inlet valves mounted on the main door to enhance the efficiency of the process;
- (c) The animal by-products must be volatilised into complex hydrocarbons and the resultant gases must pass from the primary chamber via a narrow opening at the top of the back wall to the mixing and cracking zones, where they must be broken down into their constituent elements. Finally the gases must pass into the afterburner chamber where they must be burned in the flame of a natural gas fired burner in the presence of excess air;

- (d) Each process unit must have two burners and two secondary air fans for back-up in case of burner or fan failure. The secondary chamber must be designed to give a minimum residence time of two seconds at a temperature of at least 950 °C under all conditions of combustion;
- (e) On leaving the secondary chamber the exhaust gases must 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 must be 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 must be 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 must not be 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 are 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 must first be 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 ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001 and from the processing of animals, other than ruminants which require TSE testing, any of the processing methods 1 to 5 as set out in Chapter III of this Annex.
 - for the fat fraction from the processing of other ruminants, processing method 1 as referred in Chapter III; 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 processing method 7; in the case the materials are derived from fish, processing methods 1 to 7 as set out in Chapter III;
- (b) The fat fraction must be separated from the protein and in the case of fat from ruminant origin which is intended to be combusted in another plant, insoluble impurities in excess of 0,15 % by weight must be removed;

- (c) Following the process referred to in points (a) and (b), the fat must be:
 - (i) vaporised in a steam-raising boiler and combusted at a temperature of at least 1100 °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 must not be 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) the processing of food or feed in an approved plant on the same premises takes place under strict conditions of separation;
- (f) The combustion must be 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. Thermomechanical biofuel production process
 - 1. Starting material

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

2. Processing method

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

- (a) The animal by-products must be loaded into a converter and subsequently treated at a temperature of 80 °C for a period of eight hours. During this period, the material must be constantly reduced in size using appropriate mechanical abrasion equipment.
- (b) The material must be subsequently treated at a temperature of $100\ ^{\circ}\mathrm{C}$ 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 must be treated in such a manner that the requirements regarding time, temperature and pressure set out in points (a) and (b) are achieved at the same time;
- (e) During the heat treatment of the material, evaporated water must be continually extracted from the air-space above the biofuel and must be passed through a stainless steel condenser. The condensate must be kept at a temperature of at least 70 °C for at least one hour before being discharged as wastewater;

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- (f) After the heat treatment of the material, the resulting biofuel from the converter must then be discharged and automatically conveyed by a fully covered and interlocked conveyor to incineration or co-incineration on the same site;
- (g) The process must be carried out in a batch mode.

▼<u>M9</u>

▼M1

- I. Lime treatment for pig and poultry manure
 - 1. Starting materials

For this process, manure, as referred to in Article 9(a) of Regulation (EC) No 1069/2009, of pig and poultry origin may be used.

- 2. Processing method
 - (a) The dry matter content of the manure must be determined by using the CEN EN 12880:2000 (¹) method 'Characterization of sludges. Determination of dry residue and water content'.

For this process, the dry matter content must be between 15 % and 70 %.

- (b) The amount of lime which has to be added must be determined in such way that one of the combinations of time and temperature set out in point (f) is achieved.
- (c) The particle size of the animal by-products to be processed must be no greater than 12 mm.

If necessary, the particles of the manure must be reduced in size in such a way that that maximum particle size is achieved.

(d) The manure must be mixed with quick lime (CaO) which has a medium to high reactivity of less than six minutes to achieve a 40 °C rise in temperature as per the criteria in the reactivity test 5.10 in the CEN EN 459-2:2002 method (²).

The mixing must be carried out with two mixers which are operating in line, with two screws per mixer.

Both mixers must:

- (i) have a screw diameter of 0,55 m and a screw length of 3,5 m;
- (ii) operate with a power of 30 kW and a rotation speed of the screw of 156 rpm;
- (iii) have a treatment capacity of 10 tonnes per hour.

The mean blending duration must be approximately two minutes.

(e) The mixture must be mixed for a period of at least six hours into a stockpile with a minimum size of two tonnes.

BS EN 12880:2000, Characterization of sludges. Determination of dry residue and water content. European Committee for Standardisation,

⁽²⁾ CEN EN 459-2;2002 method CEN/TC 51 - Cement and building limes. European Committee for Standardisation,

▼M1

- (f) At monitoring points which must be introduced into the stockpile, continuous measurements must be carried out to demonstrate that the mixture in the stockpile reaches a pH of at least 12 during one of the following periods of time, during which period one of the corresponding following temperatures must be achieved:
 - (i) 60 °C for 60 minutes: or
 - (ii) 70 °C for 30 minutes.
- (g) The process must be carried out in a batch mode.
- (h) A permanent written procedure based on the HACCP principles must be put in place.
- (i) Operators may demonstrate to the competent authority, by way of a validation according to the following requirements, that a process using a mixing device which is different from the mixing device referred to in point (d) or using dolime (CaOMgO) instead of quick lime is at least as efficient as the process set out in points (a) to (h):

That validation must:

- demonstrate that by using the different mixing device to that referred to in point (d) or the dolime, as applicable, a mixture with manure can be produced which achieves the parameters for pH, time and temperature referred to in point (f);
- be based on monitoring of time and temperature at the base, the middle and at the top of the stockpile, with a representative number of monitoring points (at least four monitoring points in the basal zone, which are located at a maximum of 10 cm above the base and at a maximum of 10 cm below the top, one monitoring point in the middle half way between base and the top of stockpile, and four monitoring points in the marginal zone at the top of the pile, which are located at a maximum of 10 cm below the surface and at a maximum of 10 cm below the top of the stockpile);
- be carried out during two periods of at least 30 days, of which one must be in the cold season of the year at the geographical place where the mixing device is to be used.
- J. Multi-step catalytic process for the production of renewable fuels
 - 1. Starting materials
 - (a) For this process, the following materials may be used:
 - rendered fats derived from Category 2 material, which have been processed using processing method 1 (pressure sterilisation);
 - (ii) fish oil or rendered fats derived from Category 3 material, which have been processed using:
 - any of the processing methods 1 to 5 or processing method
 7; or
 - in the case of material derived from fish oil, any of the processing methods 1 to 7;
 - (iii) fish oil or rendered fat which have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004, respectively.

▼<u>M1</u>

(b) The use of rendered fats derived from Category 1 material for this process shall be prohibited.

2. Processing method

- (a) The rendered fat must be submitted to a pre-treatment which consists of:
 - the bleaching of the centrifuged materials by passing them through a clay filter;
 - (ii) the removal of remaining insoluble impurities by filtration.
- (b) The pre-treated materials must be submitted to a multi-step catalytic process which consists of a hydro-deoxygenisation step, followed by an isomerisation step.

The materials must be submitted to a pressure of at least 20 bars at a temperature of at least 250 °C for at least 20 minutes.

▼ M9

- K. Ensilage of fish material
 - 1. Starting materials

For this process, only the following by-products obtained from aquatic animals may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) and (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials.
- 2. Processing method
- 2.1. The materials to be treated shall be collected at aquaculture farms and food processing establishments on a daily basis and without undue delays, ground or chopped, and thereafter subjected to ensiling at a pH of 4 or below, with formic acid or other organic acid authorised in accordance with the feed legislation. The resulting fish silage must be a suspension of parts of aquatic animals liquefied by the action of endogenous enzymes in the presence of the added acid. The proteins of aquatic animals must be reduced into smaller soluble units, by the enzymes and the acid, in order to prevent microbial spoilage. The ensiled material is transported to the processing plant.
- 2.2. At the processing plant the ensiled material of aquatic animals must be piped into closed storage tanks. The incubation time must be at least 24 hours at a pH of 4 or below before heat treatment can be conducted. Before the heat treatment the ensilage of aquatic animals must have a pH of 4 or below and have a particle size of less than 10 mm following a filtration or maceration at the plant. During processing it must be subjected to preheating to a temperature above 85 °C, followed by incubation in an insulated container to obtain 85 °C throughout the fish material for 25 minutes. The process must take place in a closed production line with tanks and pipelines.
- 2.3. Before authorisation is given, the operator's permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be assessed by the competent authority.

▼M13

- Multiple-step catalytic hydro-treatment for the production of renewable fuels
 - 1. Starting materials

For this process, the following materials may be used:

- (a) rendered fats derived from Category 1 material, which have been processed using processing method 1 (pressure sterilisation);
- (b) rendered fats and fish oil complying with point J(1)(a) of this Section.
- 2. Processing method
 - (a) The rendered fat must be submitted to a pre-treatment which consists at least of bleaching of the starting material, including rendered fats, with acid in the presence of bleaching clay and subsequent removal of the used bleaching clay and insoluble impurities by filtration.

Prior to this treatment rendered fat may be degummed with acid and/or caustic solution in order to remove impurities from the rendered fat by forming gums and subsequently separating those gums by centrifugation.

(b) The pre-treated materials must be submitted to a hydro-treatment process which consists of a catalytic hydro-treatment step, a stripping step followed by an isomerisation step.

The materials must be submitted to a pressure of at least 30 bars at a temperature of at least 265 °C for at least 20 minutes.

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Section 3

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(a) or (b) of Regulation (EC) No 1069/2009;
 - (ii) disposed of by burial in an authorised landfill;

▼ M4

(iii) transformed into biogas. In such case the digestion residues must be disposed of in accordance with point (i) or (ii), except where the material results from processing in accordance with point 2(a) or (b) where the residues can be used in accordance with the conditions set out in point 2(a) or point 2(b)(iii) as appropriate; or

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- (iv) further processed into fat derivatives for uses other than feeding.
- (b) Category 2 or Category 3 material shall be:

▼ M4

 (i) disposed of as provided for in point 1(a)(i) or (ii), with or without prior processing as provided for in Article 13(a) and (b) and Article 14(a) and (b) of Regulation (EC) No 1069/2009;

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

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- (iii) used as an organic fertiliser or soil improver; or
- (iv) composted or transformed into biogas.
- 2. Materials resulting from processing in accordance with:
 - (a) the alkaline hydrolysis process defined in point A of Section 2 may be transformed in a biogas plant and subsequently combusted rapidly at a minimum of 900°C, followed by rapid chilling ('quenching'); where material referred to in Article 8(a) and (b) of Regulation (EC) No 1069/2009 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:
 - in the case of biodiesel and of residues from the distillation of biodiesel, used as a fuel without restrictions under this Regulation (end point);

▼<u>M4</u>

- (ii) in the case of potassium sulphate, used for direct application to land or for the production of derived products for application to land;
- (iii) in the case of glycerine derived from Categories 1 and 2 material which has been processed in accordance with processing method 1 as set out in Chapter III:
 - used for technical purposes,
 - transformed into biogas, in which case the digestion residues may be applied to land within the national territory of the producing Member State, subject to the decision of the competent authority, or
 - used for denitrification in a waste water treatment plant, in which case the residues of the denitrification may be applied to land in accordance with Council Directive 91/271/EEC (¹);
- (iv) in the case of glycerine derived from Category 3 material:
 - used for technical purposes,
 - transformed into biogas, in which case the digestion residues may be applied to land, or
 - used for feeding, provided that the glycerine is not derived from Category 3 material referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009;

▼<u>M1</u>

- (c) the multi-step catalytic process for the production of renewable fuels may be:
 - in the case of gasoline and the other fuels resulting from the process, used as a fuel without restrictions under this Regulation (end point);
 - (ii) in the case of used clay from bleaching and sludge from the pre-treatment process referred to in point J(2)(a) of Section 2:
 - disposed of by incineration or co-incineration,
 - transformed into biogas,
 - composted or used for the manufacture of derived products referred to in Article 36(a)(i) of Regulation (EC) No 1069/2009;

▼<u>M9</u>

- (d) the lime-treated mixture of pig and poultry manure may be applied to land as processed manure;
- (e) The final product derived from the ensilaging of fish material may:
 - (i) for Category 2 materials, be used for purposes referred to in Article 13(a) to (d) and (g) to (i) of Regulation (EC) No 1069/2009 without further processing or as feed for animals referred to in Article 18 or Article 36(a)(ii) of that Regulation; or
 - (ii) for Category 3 materials, be used for purposes referred to in Article 14 of Regulation (EC) No 1069/2009;

▼<u>M13</u>

- (f) the multiple-step catalytic hydro-treatment for the production of renewable fuels may be:
 - (i) in the case of renewable diesel, renewable jet fuel, renewable propane and renewable gasoline resulting from the process, used as a fuel without restrictions under this Regulation (end point);
 - (ii) in the case of gum sludge and used bleaching clay from the pre-treatment process referred to in point L(2)(a) of Section 2:
 - disposed of in accordance with Article 12(a) or (b) of Regulation (EC) No 1069/2009,
 - disposed of by burial in an authorised landfill,
 - transformed into biogas, provided the digestion residues from the biogas transformation are disposed of by incineration, co-incineration or burial in an authorised landfill,
 - used for technical purposes referred to in Article 36(a)(i) of Regulation (EC) No 1069/2009.

▼<u>M4</u>

3. Any waste other than animal by-products and derived products provided for in point 2, resulting 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 Regulation (EC) No 1069/2009 and with this Regulation.

ANNEX V

TRANSFORMATION OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS INTO BIOGAS, COMPOSTING

CHAPTER I

REQUIREMENTS APPLICABLE TO PLANTS

Section 1

Biogas plants

- A biogas plant must be equipped with a pasteurisation/hygienisation unit, which cannot be by-passed for the animal by-products or derived products introduced with a maximum particle size of 12 mm before entering the unit, with:
 - (a) installations for monitoring that the temperature of 70 °C is reached during the time of one hour;
 - (b) recording devices to record continuously the results of the monitoring measurements referred to in point (a); and
 - (c) an adequate system to prevent insufficient heating.
- 2. By way of derogation from point 1, a pasteurisation /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 set out in Chapter III of Annex IV;
 - (b) Category 3 material that has been processed in accordance with any of the processing methods 1 to 5 or processing method 7, or in the case of material originating from aquatic animals, any of the processing methods 1 to 7, as set out in Chapter III of Annex IV;
 - (c) Category 3 material that has undergone pasteurisation/hygienisation in another approved plant;

▼ M4

(d) animal by-products which may be applied to land without processing in accordance with Article 13(f) of Regulation (EC) No 1069/2009 and with this Regulation, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease to humans or animals;

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- (e) animal by-products which have been subject to the alkaline hydrolysis process set out in point A of Section 2 of Chapter IV of Annex IV;
- (f) the following animal by-products, if authorised by the competent authority:
 - (i) the animal by-products referred to in Article 10(f) of Regulation (EC) No 1069/2009, which have undergone processing 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;
 - (ii) the animal by-products referred to in Article 10(g) of Regulation (EC) No 1069/2009; or
 - (iii) animal by-products which are transformed into biogas, where the digestion residues are subsequently composted or processed or disposed of in accordance with this Regulation.

3. If the biogas plant is located on or next to premises where farmed animals are kept and the biogas plant does not only use manure, milk or colostrum which accrues from those animals, the plant shall be located at a distance from the area where such animals are kept.

That distance shall be determined in a manner which ensures that there is no unacceptable risk for the transmission of a disease communicable to humans or animals from the biogas plant.

In all cases, there must be total physical separation between that biogas plant and the 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 by the competent authority, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority.

Section 2

Composting plants

- A composting plant must be equipped with a closed composting reactor or closed area, which cannot be by-passed for the animal by-products or derived products introduced into the plant, and it must be equipped with the following:
 - (a) installations for monitoring temperature against time;
 - (b) recording devices to record, where appropriate continuously, the results of the monitoring measurements referred to in point (a);
 - (c) an adequate safety system to prevent insufficient heating.
- 2. By way of derogation from point 1, 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 point 2 of Section 1; 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 the composting plant does not only use manure, milk or colostrum which accrues from those animals, the composting plant shall be located at a distance from the area where animals are kept.

That distance shall be determined in a manner which ensures that there is no unacceptable risk for the transmission of a disease communicable to humans or animals from the composting plant.

In all cases, there must be total physical separation between that composting plant and the animals and their feed and bedding, with fencing where necessary.

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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 by the competent authority, be accredited according to internationally recognised standards or be subject to regular controls by the competent authority.

CHAPTER II

HYGIENE REQUIREMENTS APPLICABLE TO BIOGAS AND COMPOSTING PLANTS

- 1. Animal by-products must be transformed as soon as possible after arrival at the biogas or composting plant. They must be stored properly until treated.
- Containers, receptacles and vehicles used for transporting untreated material must be cleaned and disinfected in a designated area.

That area must be situated or designed so as 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.
- 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.
- Digestion residues and compost must be handled and stored at the biogas or composting plant in such way as to prevent recontamination.

CHAPTER III

TRANSFORMATION PARAMETERS

Section 1

Standard transformation parameters

- Category 3 material which is 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, milk-based products, milk-derived products, colostrum and colostrum products may be used without pasteurisation/hygienisation as raw material in a biogas plant, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease to humans or animals.

The minimum requirements set out in points (b) and (c) of this point shall also apply to Category 2 material which is introduced into a biogas plant without prior processing in accordance with Article 13(e)(ii) of Regulation (EC) No 1069/2009.

- 2. Category 3 material which is 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.

The minimum requirements set out in points (b) and (c) of this point shall also apply to Category 2 material which is composted without prior processing in accordance with Article 13(e)(ii) of Regulation (EC) No 1069/2009.

Section 2

Alternative transformation parameters for biogas and composting plant

- 1. The competent authority may authorise the use of parameters other than the parameters set out in point 1 of Section 1 of Chapter I and other than the standard transformation parameters, provided that the applicant for such use demonstrates that such parameters ensure adequate reduction of biological risks. That demonstration shall include a validation, which shall be carried out in accordance with the following requirements:
 - (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 point (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 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 point (c) must demonstrate that the process achieves the following overall risk reduction:
 - (i) for thermal and chemical processes by:
 - a reduction of 5 log10 of Enterococcus faecalis or Salmonella Senftenberg (775W, H2S negative),
 - reduction of infectivity titre of thermoresistant 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:
 - a 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 point (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 by the operator 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. By way of derogation from point 1, pending the adoption of rules as referred to in Article 15(2)(a)(ii) of Regulation (EC) No 1069/2009, the competent authority may 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, for:
 - (a) catering waste used as the only animal by-product in a biogas or composting plant; and
 - (b) mixtures of catering waste with the following materials:
 - (i) manure;
 - (ii) digestive tract content separated from the digestive tract;
 - (iii) milk;
 - (iv) milk-based products;
 - (v) milk-derived products;
 - (vi) colostrum;
 - (vii) colostrum products;

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- (viii) eggs;
- (ix) egg products;

▼<u>M9</u>

- (x) animal by-products referred to in Article 10(f) of Regulation (EC) No 1069/2009, which have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004;
- (xi) mixture of animal by-products referred to in point 2(b) with non-animal by-product materials.

▼<u>B</u>

- 3. Where the materials referred to in point 2(b) or derived products referred to in Article 10(g) of Regulation (EC) No 1069/2009 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 materials present a risk of spreading any serious transmissible disease to humans or animals;

▼ M9

(b) considers that the digestion residues or compost are unprocessed material and obliges operators to handle them in accordance with Regulation (EC) No 1069/2009, with this Regulation or, in the case of compost or digestion residues derived from catering waste, to recover or dispose of in accordance with the environmental legislation.

▼B

- 4. Operators may place on the market digestion residues and compost, which have been produced according to parameters which have been authorised by the competent authority:
 - (a) in accordance with point 1;
 - (b) in accordance with points 2 and 3, only within the Member State where those parameters have been authorised.

Section 3

Standards for digestion residues and compost

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

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Escherichia coli: n = 5, c = 1, m = 1000, M = 5000 in 1 g;
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or

Enterococcaceae: n = 5, c = 1, m = 1000, M = 5000 in 1 g;

and

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

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Salmonella: absence in 25 g: n = 5; c = 0; m = 0; M = 0
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Where in the case of point (a) or (b):

- 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;

▼<u>B</u>

- 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.

▼ <u>M10</u>

2. Digestion residues or compost other than those referred to in point 3(b) of Section 2, which do not comply with the requirements set out in this Section, shall be resubmitted to transformation or composting, and in the case of Salmonella handled or disposed of in accordance with the instructions of the competent authority.

▼<u>M1</u>

3. When animal by-products are transformed into biogas or composted together with materials which are not of animal origin, the competent authority may authorise operators to take representative samples after the pasteurisation referred to in point 1(a) of Section 1 of Chapter I or after composting referred to in point 1 of Section 2, as applicable, and before the mixing with materials which are not of animal origin takes place, in order to monitor the efficiency of the transformation or composting of the animal by-products, as applicable.

ANNEX VI

SPECIAL RULES ON RESEARCH, FEEDING AND COLLECTION AND DISPOSAL

CHAPTER I

SPECIAL RULES ON SAMPLES FOR RESEARCH AND OTHER PURPOSES

Section 1

Research and diagnostic samples

- 1. Operators shall ensure that consignments of research and diagnostic samples are accompanied by a commercial document, which must specify:
 - (a) the description of the material and the animal species of origin;
 - (b) the category of the material;
 - (c) the quantity of the material;
 - (d) the place of origin and the place of dispatch of the material;
 - (e) the name and the address of the consignor;
 - (f) the name and the address of the consignee and/or user.
- 2. Users that handle research and diagnostic samples shall take all necessary measures to avoid the spreading of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.
- 3. Any subsequent use of research and diagnostic samples for purposes other than those referred to in point 38 of Annex I shall be prohibited.
- 4. Unless they are kept for reference purposes, research and diagnostic samples and any products derived from the use of those samples shall be disposed of:
 - (a) as waste by incineration or co-incineration;
 - (b) in case of the animal by-products or derived products referred to in Article 8 (a)(iv), Article 8(c) and (d) and Article 9 and Article 10 of Regulation (EC) No 1069/2009 which are part of cell cultures, laboratory kits or laboratory samples, by a treatment under conditions which are at least equivalent to the validated method for steam autoclaves (¹) and subsequent disposal as waste or wastewater in accordance with relevant Union legislation;
 - (c) by pressure sterilisation and subsequent disposal or use in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.
- Users that handle research and diagnostic samples shall keep a register of consignments of such samples.

⁽¹) CEN TC/102 – Sterilisers for medical purposes – EN 285:2006 + A2:2009 – Sterilization - Steam Sterilisers - Large Sterilisers, reference published in OJ C 293, 2.12.2009, p. 39.

▼<u>B</u>

The register shall include the information referred to in point 1 and the date and method of disposal of the samples and of any derived products.

6. By way of derogation from points 1, 4 and 5, the competent authority may accept the handling and disposal of research and diagnostic samples for educational purposes under other conditions which ensure that no unacceptable risks for public or animal health arise.

Section 2

Trade samples and display items

- 1. Trade samples and display items may only be transported, used and disposed of in accordance with points 1 to 4 and 6 of Section 1.
- 2. Unless trade samples are kept for reference purposes, they shall be, after the particular studies or analyses have been concluded:
 - (a) redispatched to the Member State of origin;
 - (b) dispatched to another Member State or third country, if such dispatch has been authorised by the competent authority of the Member State or third country of destination in advance; or
 - (c) disposed of or used in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.
- 3. After the exhibition or after the artistic activity has been concluded, display items shall be redispatched to the Member State of origin, dispatched or disposed of, in accordance with point 2.

CHAPTER II

SPECIAL FEEDING RULES

Section 1

General requirements

▼ M4

Categories 2 and 3 materials as referred to in Article 18(1) of Regulation (EC) No 1069/2009 may be fed to the animals referred to in paragraph (1)(a), (b), (d), (f), (g) and (h) of that Article subject to compliance with at least the following conditions, in addition to any conditions laid down by the competent authority in accordance with Article 18(1) of that Regulation:

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- 1. The animal by-products shall be transported to the users or to collection centres in accordance with Sections 1 and 3 of Chapter I of Annex VIII.
- Collection centres shall be registered by the competent authority, provided that:
 - (a) they comply with the requirements for plants carrying out the intermediate operations set out in Chapter II of Annex IX; 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.

▼<u>B</u>

- 4. Operators of collection centres supplying material, other than animal by-products originating from aquatic animals and from aquatic invertebrates, to final users must ensure that it undergoes one of the following treatments:
 - (a) denaturing with a solution of a colouring agent; the solution must be of such a strength that the colouring on the stained material is clearly visible and does not disappear when the coloured materials are subject to freezing or chilling, and the whole surface of all pieces of material must have been covered with such solution 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 handling or treatment authorised by the competent authority responsible for the operator.

Section 2

Feeding of certain species in feeding stations

- The competent authority may authorise the use of Category 1 material referred to in Article 18(2)(b) of Regulation (EC) No 1069/2009 for the feeding of the following endangered and protected species in feeding stations under the following conditions:
 - (a) The material must be fed to:

▼ M9

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

Country code Me	Member State	Animal species	
		Local name	Latin name
BG	Bulgaria	bearded vulture	Gypaetus barbatus
		black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
		golden eagle	Aquila chrysaetos
		imperial eagle	Aquila helíaca
		white-tailed eagle	Haliaeetus albicilla
		black kite	Milvus migrans
		red kite	Milvus milvus
EL	Greece	bearded vulture	Gypaetus barbatus
		black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
		golden eagle	Aquila chrysaetos
		imperial eagle	Aquila heliaca
		white-tailed eagle	Haliaeetus albicilla
		black kite	Milvus migrans

▼ <u>M9</u>

Country	Member State	Animal species		
code		Local name	Latin name	
ES	Spain	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle Spanish imperial eagle black kite red kite	Gypaetus barbatus Aegypius monachus Neophron percnopterus Gyps fulvus Aquila chrysaetos Aquila adalberti Milvus migrans Milvus milvus	
FR	France	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle white-tailed eagle black kite red kite	Gypaetus barbatus Aegypius monachus Neophron percnopterus Gyps fulvus Aquila chrysaetos Haliaeetus albicilla Milvus migrans Milvus milvus	
HR	Croatia	bearded vulture black vulture Egyptian vulture griffon vulture	Gypaetus barbatus Aegypius monachus Neophron percnopterus Gyps fulvus	
IT	Italy	bearded vulture black vulture Egyptian vulture griffon vulture golden eagle black kite red kite	Gypaetus barbatus Aegypius monachus Neophron percnopterus Gyps fulvus Aquila chrysaetos Milvus migrans Milvus milvus	
CY	Cyprus	black vulture griffon vulture	Aegypius monachus Gyps fulvus	
PT	Portugal	black vulture Egyptian vulture griffon vulture golden eagle	Aegypius monachus Neophron percnopterus Gyps fulvus Aquila chrysaetos	
SK	Slovakia	golden eagle imperial eagle white-tailed eagle black kite red kite	Aquila chrysaetos Aquila heliaca Haliaeetus albicilla Milvus migrans Milvus milvus	

⁽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; or

- (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 operator responsible for the feeding station.

The competent authority shall grant such authorisations provided that:

- the feeding is not used as an alternative way of disposal of specified risk materials or the disposal of fallen ruminant stock containing such material 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 must ensure coordination with any other competent authorities responsible for the supervision of the requirements laid down in the authorisation;
- (d) The competent authority must be 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 must:
 - (i) refer to and name the species actually concerned;
 - (ii) describe in detail the location of the feeding station in the geographical area where feeding shall take place; and
 - (iii) be immediately suspended in the 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 operator responsible for the feeding shall:
 - 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 eligible bodies of bovine animals and at least 4 % of eligible bodies 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, if applicable, in accordance with a Decision adopted in accordance with the second subparagraph of Article 6(1b) of that Regulation; and
 - (iii) keep records at least of the number, nature, estimated 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. When a Member State applies to the Commission to be included into the list set out under point 1(a), it shall submit:
 - (a) a detailed justification for the extension of the list to include certain species of necrophagous birds in that 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;
 - (b) an explanation of the measures which will be taken in order to ensure compliance with point 1.

Feeding of wild animals outside feeding stations

The competent authority may authorise the use of Category 1 material comprising of entire bodies or parts of dead animals containing specified risk materials outside feeding stations, if appropriate without prior collection of the dead animals, for feeding to wild animals referred to in point 1(a) of Section 2 under the following conditions:

- The competent authority must be 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;
- The competent authority must identify in the authorisation, holdings or herds within a geographically defined feeding zone under the following conditions:
 - (a) The feeding zone must not extend to areas where intensive farming of animals takes place;
 - (b) Farmed animals in holdings or herds in the feeding zone must be under the regular surveillance of an official veterinarian regarding the prevalence of TSE and of diseases transmissible to humans or animals;
 - (c) Feeding must be immediately suspended in the case of:
 - (i) a suspected or confirmed link to the spread of TSE in a holding or herd, until the risk can be excluded;
 - (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
 - (iii) non-compliance with any of the rules provided for in this Regulation;
 - (d) The competent authority must specify in the authorisation:
 - (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 Regulation (EC) No 1069/2009 which are applicable to infringements of measures referred to under point (i) by the persons or entities referred to under point (ii) of this point (d);
 - (e) Where the feeding is carried out without the prior collection of the dead animals, an estimate of the likely mortality rate of farmed animals in the feeding zone and of the likely feeding requirements of the wild animals must be carried out, as a basis for the assessment of the potential risks of disease transmission.

Feeding of zoo animals with Category 1 material

The competent authority may authorise the use of Category 1 material comprising of entire bodies or parts of dead animals containing specified risk materials and the use of material derived from zoo animals, for the feeding of zoo animals under the following conditions:

- (a) The competent authority must have granted an authorisation to the operator responsible for the feeding. The competent authority shall grant such authorisations provided that:
 - the feeding is not used as an alternative way of disposal of specified risk materials or disposal of fallen ruminant stock containing such material posing a TSE risk;
 - (ii) when Category 1 material comprising of entire bodies or parts of dead animals containing specified risk material, 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 TSEs;
- (b) The authorisation granted by the competent authority must be immediately suspended in the case of:
 - a suspected or confirmed link to the spread of TSEs until the risk can be excluded; or
 - (ii) non-compliance with any of the rules provided for in this Regulation;
- (c) The operator responsible for the feeding shall:
 - 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, if applicable, in accordance with a Decision adopted in accordance with the second subparagraph of Article 6(1b) of that Regulation;
 - (iii) keep records at least of the number, nature, estimated weight and origin of the bodies of the animals used for feeding, the results of the TSE tests and the date of the feeding.

CHAPTER III

SPECIAL RULES ON COLLECTION AND DISPOSAL

Section 1

Special disposal rules for animal by-products

- 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 Regulation (EC) No 1069/2009, 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; 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.
- The burning of animal by-products on the sites referred to in Article 19(1)(b),
 (c) and (e) of Regulation (EC) No 1069/2009 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 when they could result in 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 authorised landfill.
- The burial of animal by-products on the sites referred to in Article 19(1)(a), (b), (c) and (e) of Regulation (EC) No 1069/2009 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:
 - (b) in an authorised landfill or in another site without endangering human health and using processes or methods which do not harm the environment, in particular when they could result in 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)(a), (b), (c) and (e) of Regulation (EC) No 1069/2009, the movement of the animal by-products from the place of origin to the place of disposal must be carried out under the following conditions:
 - (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.

Burning and burial of animal by-products in remote areas

The maximum percentage as referred to in Article 19(2) of Regulation (EC) No 1069/2009 shall not exceed the following:

- (a) 10 % of the bovine population of the Member State concerned;
- (b) 25 % of the ovine and caprine population of the Member State concerned;

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- (c) 10 % of the porcine population of the Member State concerned; and
- (d) a percentage of the population of other species which is determined by the competent authority, on the basis of an assessment of the possible risks for public and animal health which arise from the disposal of animals of those species by burning or burial on site.

Section 3

Burning and burial of bees and apiculture by-products

In the case of bees and apiculture by-products, the competent authority may authorise the disposal by burning or burial on site, as referred to in Article 19(1)(f) of Regulation (EC) No 1069/2009, provided that all necessary measures are taken to ensure that the burning or burial does not endanger animal or human health or the environment.

CHAPTER IV

DISPOSAL BY OTHER MEANS

By way of derogation from Article 14 of Regulation (EC) No 1069/2009, Member States may authorise the collection, transport and disposal of the Category 3 materials referred to in Article 10(f) of that Regulation by means other than burning or burial on site provided that:

- (a) the materials do not exceed a volume of 20 kg per week from the establishment or plant where the materials are collected, regardless of the species of origin of the materials;
- (b) the materials are collected, transported and disposed of by means which prevent the transmission of unacceptable risks to public and animal health;
- (c) the competent authority carries out regular checks, including checks on the records kept by operators, in the establishments or plants where the materials are collected, to ensure compliance with the provisions of this Section.

ANNEX VII

STANDARD FORMAT FOR APPLICATIONS FOR ALTERNATIVE METHODS

CHAPTER I

Language regime

- Applications for authorisation of an alternative method of use or disposal of animal by-products or derived products as referred to in Article 20 of Regulation (EC) No 1069/2009 (applications) shall be submitted in one of the official languages of the European Union as referred to in Article 1 of Regulation No 1 of 1958.
- Interested parties that submit such applications in a language other than English shall validate the official translation of their application, which EFSA shall provide, prior to the assessment.

The period referred to in Article 20(5) of Regulation (EC) No 1069/2009 shall only start once the interested party has validated the official translation of the application.

CHAPTER II

Content of applications

▼ M1

- Applications shall contain all the necessary information to allow EFSA to assess the safety of the proposed alternative method, and in particular describe:
 - the categories of animal by-products intended to be submitted to the method,
 - the entire process,
 - the biological hazards for human and animal health involved, and
 - the degree of risk reduction to be achieved by the process.
- 2. The application referred to in paragraph 1 shall moreover:
 - (a) indicate the applicable points in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009 including the physical status of those materials and, if applicable, any pre-treatment to which those materials have been submitted and indicating any materials other than animal by-products which are to be used in the process.
 - (b) include a HACCP protocol and a flow diagram which clearly indicates the individual steps of the process, identifies the parameters critical for the inactivation of relevant pathogens such as temperature, pressure, exposure time, adjustment of the pH value and particle size and is complemented by technical data sheets of the equipment used during the process;
 - (c) identify and characterize biological hazards for human and animal health represented by the categories of animal by-products intended to be submitted to the method;
 - (d) show that the most resistant biological hazards associated with the category of materials to be processed are reduced in any products generated during the process, including the waste water, at least to the degree achieved by the processing standards laid down in this Regulation for the same category of animal by-products. The degree of risk reduction must be determined with validated direct measurements, unless modelling or comparisons with other processes are acceptable.

- Validated direct measurements as referred to in paragraph 2(d) above shall mean:
 - (a) 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 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, to identify and to confirm; or
 - (b) using a well-characterised test organism or virus introduced in a suitable test body into the starting material.

If several treatment steps are involved, an assessment must be performed on the degree to which individual titre reduction steps are additive, or whether early steps in the process may compromise the efficacy of subsequent steps;

- (c) reporting complete results by
 - (i) describing in detail the used methodology;
 - (ii) describing the nature of samples which have been analysed;
 - (iii) showing that the number of samples analysed is representative;
 - (iv) justifying the number of tests performed and the selection of measuring points;
 - (v) indicating the sensitivity and the specificity of the detection methods used;
 - (vi) providing data on the repeatability and statistical variability of the measurements obtained during the experiments;
 - (vii) justifying, if used the significance of prion surrogates;
 - (viii) showing, where in absence of direct measurements, models or comparisons with other processes are used, that the factors leading to risk reduction are well known and the model of risk reduction is well established;
 - (ix) providing data for the entire process on direct measurements of all factors leading to the risk reduction which demonstrate that these factors are homogenously applied throughout the treated batch.

4.	The HACCP plan referred to in paragraph 2(b) must be based on the critical
	parameters which are used to obtain the risk reduction, in particular:

_	pressure,

temperature,

- time, and

microbiological criteria.

▼M1

The critical limits retained in the HACCP plan must be defined, based on the results of the experimental validation and/ or of the model provided.

If the successful functioning of the process can only be demonstrated with reference to technical parameters which are specifically related to the equipment used in the process, the HACCP plan must also include the technical limits which must be met, in particular energy uptake, number of pump strokes or dosage of chemicals.

Information must be given on the critical and technical parameters that are to be monitored and recorded in a continuous manner or after defined intervals and on the methods used for measuring and monitoring.

The variability of parameters under typical production conditions must be taken into account.

The HACCP plan must reflect normal and abnormal/ emergency operating conditions including a breakdown of the process and it must specify possible corrective actions which are to be applied in the case of abnormal/emergency operating conditions.

- 5. The applications shall also contain sufficient information on:
 - (a) the risks associated with interdependent processes, and in particular on the outcome of an evaluation of possible indirect impacts, which may:
 - (i) influence the level of risk reduction of a particular process;
 - (ii) arise from transport or storage of any products generated during the process and from the safe disposal of such products, including waste water
 - (b) the risks associated with the intended end use of the products, in particular:
 - the intended end use of any products generated during the process must be specified;
 - (ii) the likely risks for human health and animal health and possible impacts on the environment must be assessed on the basis of the risk reduction estimated in accordance with point 2(d).
- 6. Applications shall be submitted with documentary evidence, in particular:
 - (a) a flow diagram showing the functioning of the process;
 - (b) the evidence referred to in point 2(d), as well as other evidence aiming to substantiate the information provided in the framework of the application as set out in point 2.
- 7. Applications shall include a contact address for the interested party, which shall include the name and full address, telephone and/or fax number and/or the electronic mail address of a particular person that is responsible as or on behalf of the interested party.

ANNEX VIII

COLLECTION, TRANSPORT AND TRACEABILITY

CHAPTER I

COLLECTION AND TRANSPORT

Section 1

Vehicles and containers

- As from the starting point in the manufacturing chain referred to in Article 4(1) of Regulation (EC) No 1069/2009, 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 in accordance with Regulation (EC) No 767/2009 and which are stored and transported in accordance with Annex II to Regulation (EC) No 183/2005, must be maintained in a clean condition.

In particular, unless they are dedicated to the carriage of particular animal by-products or derived products in a way which avoids cross-contamination, they must be:

- (a) clean and dry before use; and
- (b) cleaned, washed and/or disinfected after each use to the extent necessary to avoid cross-contamination.
- 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, provided the competent authority has authorised such use:

- (a) for the carriage of different animal by-products or derived products provided that they are cleaned and disinfected between the different uses in a manner which prevents cross-contamination;
- (b) for the carriage of animal by-products or derived products referred to in Article 10(f) of Regulation (EC) No 1069/2009, following their use for the carriage of products intended for human consumption, under conditions which prevent cross-contamination.
- Packaging material must be disposed of, by incineration or by other means in accordance with Union legislation.

Section 2

Temperature conditions

1. The transport of animal by-products destined for the production of feed material or raw petfood must take place at an appropriate temperature, in the case of animal by-products from meat and meat products which have been destined for purposes other than human consumption, at a maximum of 7 °C, unless they are used for feeding purposes in accordance with Chapter I of Annex II, in order to avoid any risk to animal or public health.

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- 2. Unprocessed Category 3 material destined for the production of feed material or petfood must be stored and transported chilled, frozen or ensiled, unless:
 - (a) it is processed within 24 hours after collection or after the end of storage in chilled or frozen form, if the subsequent transport takes place in means of transport in which the storage temperature is maintained;
 - (b) in the case of milk, milk-based products or milk-derived products which have not been subject to any of the treatments referred to in Part I of Section 4 of Chapter II of Annex X, it is transported chilled and in insulated containers, unless risks can be mitigated by other measures, due to the characteristics of the material.
- 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.

Section 3

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

Section 1 shall not apply to the collection and transportation of Category 3 material comprising of milk, milk-based products and milk derived products by operators of milk-processing establishments which have been approved in accordance with Article 4 of Regulation (EC) No 853/2004, where they are receiving products which they have previously delivered and which are returned to them, in particular from their customers.

Section 4

Derogation for collection and transport of manure

By way of derogation from Section 1, the competent authority may accept the collection and transport of manure transported between two points located on the same farm or between farmers and users in the same Member State under other conditions which provide for the prevention of unacceptable risks to public and animal health.

CHAPTER II

IDENTIFICATION

- 1. All necessary measures must be taken to ensure that:
 - (a) consignments of 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;
 - (c) consignments of 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), (ii) and (iii), as from the time when the consignment has passed the border inspection post of first entry into the Union.
- During transport and storage, 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) of Regulation (EC) No 1069/2009 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 where they are destined for
 - disposal, 'for disposal only';
 - the manufacture of petfood, 'for manufacture of pet food only';
 - 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 milk, milk-based products, milk-derived products, colostrum and colostrum products, 'not for human consumption';
 - (v) in the case of gelatine produced from Category 3 material, 'gelatine suitable for animal consumption';

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- (vi) in the case of collagen produced from Category 3 material, 'collagen suitable for animal consumption';
- (vii) in the case of raw petfood, 'as pet food only';
- (viii) in the case of fish and derived products from fish intended for feed for fish, and treated and packaged before distribution, the name and address of the feed manufacturing establishment of origin, marked clearly and legibly, and
 - in the case of fishmeal from wild fish, bearing the words 'contains fishmeal from wild fish only – may be used for the feeding of farmed fish of all species';
 - in the case of fishmeal from farmed fish, bearing the words 'contains fishmeal from farmed fish of the [...] species only – may only be used for the feeding of farmed fish of other fish species';
 - in the case of fishmeal from wild fish and from farmed fish, bearing the words 'contains fishmeal from wild fish and farmed fish of the [...] species – may only be used for the feeding of farmed fish of other fish species';
- (ix) in the case of blood products from equidae for purposes other than in feed, 'blood and blood products from equidae. Not for human or animal consumption';
- in the case of horns, hooves and other materials for the production of organic fertilisers and soil improvers referred to in Section 12 of Chapter II of Annex XIV, 'not for human or animal consumption';
- (xi) in the case of organic fertilisers and soil improvers, 'organic fertilisers or soil improvers/no grazing of farmed animals or use of crops as herbage during at least 21 days following application';
- (xii) in the case of material used for feeding in accordance with Section 1 of Chapter II of Annex VI, the name and the address of the collection centre, and the indication 'not for human consumption';
- (xiii) in the case of manure and digestive tract content, 'manure';
- (xiv) in the case of intermediate products, on the outer packaging, bearing the words 'for medicinal products/veterinary medicinal products/medical devices/active implantable medical devices/in vitro diagnostic medical devices/laboratory reagents only';
- (xv) in the case of research and diagnostic samples, the words 'for research and diagnostic purposes', instead of the label text laid down in point (a);
- (xvi) in the case of trade samples, the words 'trade sample not for human consumption', instead of the label text laid down in point (a);

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(xvii) in the case of display items, the words 'display item not for human consumption', instead of the label text laid down in point (a);

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(xviii) in the case of fish oil for the production of medicinal products referred to in Chapter XIII of Annex XIII, the words 'fish oil for the production of medicinal products', instead of the label text laid down in point (a);

▼ M4

- (xix) in the case of manure which has been subject to the lime treatment set out in point I of Section 2 of Chapter IV of Annex IV, the words 'manure-lime-mixture';
- (xx) in the case of processed manure which has been subject to the treatment set out in point (b) and (c) of Section 2 of Chapter I of Annex XI, the words 'processed manure'.

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- (c) However, the label referred to in point (b)(xi) shall not be required for the following organic fertilisers and soil improvers:
 - in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer; or
 - (ii) in big bags of not more than 1 000 kg in weight, provided that:
 - they are authorised by the competent authority of the Member State where the organic fertiliser or soil improver is to be applied to land,
 - it is indicated on those bags that they are not destined for application to land to which farmed animals have access.
- 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. 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 set out for derived products in Chapter 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 and 2 of this Chapter shall not apply to the identification of Category 3 material comprising of milk, milk-based products and milk-derived products, by operators of milk-processing establishments which have been approved in accordance with Article 4 of Regulation (EC) No 853/2004, where they are receiving products which they have previously delivered and which are returned to them, in particular from their customers;
- (b) the competent authority may accept the identification of manure which is transported between two points located on the same farm or between farms and users located in the same Member State by other means, by way of derogation from points 1 and 2;
- (c) compound feeds as defined in Article 3(2)(h) of Regulation (EC) No 767/2009 which have been manufactured from animal by-products or from derived products and which are packaged and placed on the market as feed in accordance with Article 4 of Regulation (EC) No 767/2009 do not have to be identified in accordance with point 1 and they do not have to be labelled in accordance with point 2.

CHAPTER III

COMMERCIAL DOCUMENTS AND HEALTH CERTIFICATES

 During transportation, a commercial document in accordance with the model set out in this Chapter, 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 that:

- (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;
- (b) milk, milk-based products and milk-derived products which are Category 3 materials are collected and returned to operators of milk-processing establishments, which have been approved in accordance with Article 4 of Regulation (EC) No 853/2004, if those operators are receiving products, in particular from their customers, which they have previously delivered:
- (c) compound feeds as defined in Article 3(2)(h) of Regulation (EC) No 767/2009 which have been manufactured from animal by-products or from derived products, are placed on the market packaged and labelled in accordance with Article 4 of Regulation (EC) No 767/2009.
- 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.

- 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 6 shall accompany animal by-products and derived products as from the starting point in the manufacturing chain referred to in Article 4(1) of Regulation (EC) No 1069/2009, during transportation within the Union.

However, in addition to the authorisation to transmit information by way of an alternative system as referred to in the second subparagraph of Article 21(3) of Regulation (EC) No 1069/2009, the competent authority may authorise that animal by-products and derived products which are transported on its territory are accompanied by:

- (a) 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 Chapter;
- (b) a commercial document in which the quantity of the material is expressed in weight or volume of the material or in the number of packages.
- 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 Chapter.

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 point (d), comprises more than one page, each page shall be numbered – (page number) of (total number of pages) – at the bottom of the page and shall bear the code number of the document that has been designated by the responsible person at the top of the page.
- (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 according to one of the categories referred to in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009,
 - the animal species and the specific reference to the applicable point in Article 10 of Regulation (EC) No 1069/2009 for Category 3 material and products derived therefrom which are destined for feeding and,
 - if applicable, the ear-tag number of the animal;
- (iii) the quantity of the material, in volume, weight or number of packages;

▼M16

(iv) the name and address of the establishment or plant of origin of the material and its approval or registration number assigned in accordance with Regulation (EC) No 1069/2009 or, where applicable, in accordance with Regulations (EC) No 852/2004 (¹), (EC) No 853/2004 (²) or (EC) No 183/2005 of the European Parliament and of the Council (³), and the nature and the method of the treatment, as applicable;

⁽¹) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

⁽²⁾ 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 (OJ L 139, 30.4.2004, p. 55)

⁽³⁾ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

▼M16

- (v) the name, the address and the registration number of the transporter of the material;
- (vi) the name and address of the establishment or plant of destination and the registration or approval number assigned in accordance with Regulation (EC) No 1069/2009 or, where applicable, in accordance with Regulations (EC) No 852/2004 or (EC) No 183/2005;
- (vii) in case of transport in containers, the complete container identification number ('BIC code') issued in accordance with the requirements of the Bureau International des Containers et du Transport Intermodal (¹);
- (viii) in case of export of processed animal protein and products containing processed animal proteins as referred to in Annex IV to Regulation (EC) No 999/2001, the Member State of exit and border inspection post referred to in Commission Decision 2009/821/EC (²) of exit.

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- (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.

▼M16

(i) The competent authority responsible for the place of destination referred to in the second subparagraph of Article 48(3) of Regulation (EC) No 1069/2009 shall, within 15 working days of the receipt of the information referred to in the first subparagraph of Article 48(3) of that Regulation, inform the competent authority of the Member State of origin of the arrival of the consignment by means of TRACES.

⁽¹⁾ https://www.bic-code.org/identification-number/

⁽²⁾ Commission Decision 2009/821/EC of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces (OJ L 296, 12.11.2009, p. 1).

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Commercial document

For the transport within the European Union of animal by-products and derived products not intended for human consumption in accordance with Regulation (EC) No 1069/2009

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	l.1.	Consignor					1.2.	Do	ocument referen	ice No	I.2.a Local re	ference	No No		
		Address							I.3. Central competent authority						
									<u> </u>						
		Approval or registrat	ion num	hor		I.4. Local competent authority									
	Approval or registration number Postcode														
	1.5.	Consignee			I.6. Registered trader										
		Name Address						Name							
men		Address							egistration numb ddress	Jei					
ign		Postcode						A	uuless						
Sons		Approval or registrat	ion num	ber				Po	ostcode						
ed		Tel.							ember State						
atch															
disp							1.7								
Part I: Details of dispatched consignment	1.8.	Country of origin	ISO	I.9. Re	gion of origin	Code	I.10.		ountry of	ISO	I.11. Region		Code		
etail			code			1		ue	estination	code	destinat	1011	I		
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Part	1.12	Place of origin					I.13.	PI	ace of destination	on					
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		Name	Appro	val or reg	istration num	ber		Na	ame	App	proval or registra	tion nui	mber		
		Address						Ac	ddress						
								_							
		Postcode						Po	ostcode						
	I.14.	Place of loading					I.15.	Da	ate of departure						
	I.16.	Means of transport					l.17.	Tr	ansporter						
		Aeroplane	Ship	。 口	Railway wa	agon 🔲		Na	ame	Apı	oroval or Registra	ation nu	ımber		
			011	er 🗖				۸.	44						
		Road vehicle	Oth	er ப				AC	ddress						
		Identification:						Р	ostcode	Me	mber State				
	I.18.	Description of comm	odity						I.19. Commod	ity cod	e (CN code)				
		,	,					Į		-	I.20. Total Quai	ntity			
											i.Zu. Tulai Quai	шц			

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I.21. Temperature of products I.22. Number of							ımber of packages				
Ambient		Chilled		Frozen			Controlled te	mperature			
I.23. Seal number if a	seal i	imposed by	comp	etent autl	hority a	and th	he Container	BIC ID nun	nber	I.24. Ty	pe of packaging
I.25. Commodities ce	rtified	for:									
Animal feedingstuff Technical use			ре	tfood use				Organio	fertilise	ers/soil in	nprovers
,	Consignment is subject to requirements laid down in Regulation (EC) No 999/2001. Category 3 fish oil/fishmeal with excessive level(s) of dioxins and/or PCBs intended for detoxification according to Regulation (EU) 2015/786.										
1.26.			_				I.27. Transit	_	ember S		
	_							er State			O code
								er State er State			O code O code
I.28. Export							1.29.				
Third country	IS	O code									
Exit point	C	ode									
1.30.											
I.31. Identification of	I.31. Identification of the commodities Approval number of establishments										
Species Nature	e of co	mmodity	Cat	egory	Trea	tmen	nt type	Manufactu	ring plaı	nt	Batch number

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COUNTRY

Animal by-products/derived products not intended for human consumption

П Health information II.a. Certificate reference No II.b. 11.1 Declaration by the consignor I, the undersigned, declare that: II.1.1. the information in Part I is factually correct; II.1.2. 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 II: Declaration Part I: Box reference I.1: The legal or physical person ordering the transport indicated in the document required by the Convention relative au Contract de Transport International de Marchandises par Route (CMR). Box reference I.5: The legal or physical person for which the consignment is destined. Box reference I.6[optional, if appropriate]: Registered trader name, address, registration number. Box reference I.9 and I.11: if appropriate. Box reference I.12, I.13: approval number or registration number. In case of: products subject to Article 48(3) of Regulation (EC) No 1069/2009 only a storage plant, incineration or co-incineration plant registered in accordance with Article 23(1)(a); an establishment or plant approved in accordance with Article 24 of Regulation (EC) No 1069/2009 or in case of manure the authorised farm of destination: fish oil or fishmeal of Category 3 intended for detoxification according to Regulation (EU) 2015/786 indicate the approval number of the plant of destination according to Regulation (EC) No 183/2005 or Regulation (EU) 2015/786. Box reference I.14: complete if different from I.1. and I.12. Box reference I.17: registration or approval number of the actual transporter. If this is the same information as in Box I.6. use only box I.17. Box reference I.23: in case of transport in container, the complete container identification number ("BIC code") is obligatory. Box reference I.25: technical use: any use other than for animal consumption or organic fertilisers or soil improvers OF/SI. Technical products cannot be used in feed, petfood or OF/SI. Box reference I.31: Animal species: For Category 3 material and products derived therefrom destined for use as feed material. Select from the following: Aves, Ruminants, Suidae, other Mammalia, Pesca, Mollusca, Crustacea, Insecta (species, if appropriate), other Invertebrates, Mixed non-ruminant species, Mixed species containing ruminants. Nature of commodity: Enter a commodity chosen from the following list: "apiculture by-products", "blood products", "blood" Enter a commodity chosen from the following list: "apiculture by-products", "blood products", "blood", "bloodmeal", "digestion residues", "digestive tract content", "dog-chews", "fishmeal", "flavouring innards", "gelatine", "greaves", "hides and skins", "hydrolysed proteins", "organic fertilisers/soil improvers", "pet food", "processed animal protein", "animal by-products for the production of pet food", "raw pet food", "rendered fats", "compost", "processed manure", "fish oil", "milk products", "colostrum products" "centrifuge or separator sludge from milk processing", "dicalciumphosphate", "tricalciumphosphate", "collagen", "egg products", "serum of equidae", "game trophies", "wool", "hair", "fish brist, "fish oil", "fish brist, "serum of equidae", "game trophies", "wool", "hair", "serum of equidae", "game trophie "pig bristles", "feathers", "animal by-products for processing", "derived products", "meat-and-bone meal", "cadavers", "manure", "fat derivatives", "glycerine", "former food stuffs", "catering waste", "used cooking oil", "treated hides and skins", "growing media", "dead pet animals", "dead equidae", "former feed stuffs", "[nature of ABP or DP] mixed with non hazardous waste [EURAL code]", "eggs", "hatchery by products", "embryos in eggs or not".

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COUNTRY

Animal by-products/derived products not intended for human consumption

II.	Health information	l	II.a.	Certificate reference No	II.b.							
Catego	ry:	Specify Categories 1, 2 or 3 r	nate	rials.								
		In case of Category 3 material intended for use as feedstuff, indicate the point of Article 10 or Regulation (EC) No 1069/2009 that refers to the animal by-product concerned (e.g. Article 10(a) Article 10(b) etc).										
		In the case of Category 3 material for use in raw petfood indicate "3a", "3b(i)" or "3b(ii)" depending or whether the animal by-products are referred to in Article 10(a) or in Article 10(b)(i) or (ii) of Regulation (EC) No 1069/2009.										
		In the case of hides and skins and products derived therefrom, indicate "3b(iii)" or "3(n)" depending or whether the animal by-products or derived products are referred to in Article 10(b)(iii) or in Article 10(n) of Regulation (EC) No 1069/2009.										
		Treatment type: For treated hides and skins indicate the treatment:										
		"(a)" for dried;										
		"(b)" for dry-salted or wet-sa	Ited	for at least 14 days prior to dispate	ch;							
		"(c)" for salted for seven day	s in	sea salt with the addition of 2 $\%$ s	odium carbonate.							
		For Category 1 and 2 materials, describe the method of processing or transformation. Indicate the relevant processing method (choose a method from 1 to 5 referred to in Chapter III or an alternative method referred to Chapter IV of Annex IV to Regulation (EU) No 142/2011) or processing method for processed manure referred to in Annex XI thereof and indicate date of GTH marking as applicable.										
		For Category 3 materials destined for use in feed refer to the appropriate Section of Annex X to Regulation (EU) No 142/2011.										
		processing method (choose a (EU) No 142/2011 in case	a me of pr se o	othod from 1 to 7 referred to in Ch rocessed animal protein (PAP)), f ensilage, or describe the nature	eed, indicate the relevant standard apter III of Annex IV to Regulation an alternative method referred to and the methods of treatment se							
					fishmeal with excessive level(s) o 32/EC destined for detoxification in							
Batch r	number:	Enter batch number or ear ta	g nu	mber, if applicable.								
Manufa	ecturing plant:	in the case of PAP and other	feed	materials indicate the processing	plant							
Part II:												
_	The signature mus	st be in a different colour to tha	it of t	the printing.								
Signatu	ure											
Done a	t		on .									
		(place)		(dat	re)							
•••••		(signature of the re	spor	nsible person of place of origin)								
		(nai	me, i	n capital letters)								

CHAPTER IV

RECORDS

Section 1

General provisions

- The records as referred to in Article 22(1) of Regulation (EC) No 1069/2009 for animal by-products and derived products, other than compound feeds as defined in Article 3(2)(h) of Regulation (EC) No 767/2009, which have been manufactured from animal by-products or from derived products and which are placed on the market 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 carcases 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 or registration 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 or registration 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 name and address of the transporter.
- 2. By way of derogation from point 1 of this Section, operators do not have to keep the information referred to in point 1(a) and points (b)(i), (c)(i) and (iii) and d(ii) and (iii) separately, if they keep a copy of the commercial document laid down in Chapter III for each consignment and make such information available in conjunction with the other information required under point 1 of this Section
- Operators of incineration plants and co-incineration plants shall keep records of the quantities and category of the animal by-products and derived products incinerated or co-incinerated, as applicable, and the date at which those operations were carried out.

Additional requirements in case of use for special feeding purposes

In addition to the records required in accordance with Section 1, operators shall keep the following records in relation to relevant material if animal by-products are used for special feeding purposes in accordance with Chapter II of Annex VI:

- 1. in the case of final users, the quantity used, the animals that it is intended to be fed to and the date of use;
- 2. in the case of collection centres:
 - the quantity handled or treated in accordance with point 4 of Section 1 of Chapter I of Annex VI;
 - (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.

Section 3

Requirements in case of certain fur animals

The operator of the farm referred to in Chapter I of Annex II shall keep records at least of:

- (a) the number of furs and carcases of animals fed with materials originating of their own species; and
- (b) each consignment in order to ensure the traceability of the material.

Section 4

Requirements for the application of certain organic fertilisers and soil improvers to land

The person responsible for land to which organic fertilisers and soil improvers, other than the materials referred to in the second paragraph of Chapter II of Annex II are applied and to which farmed animals have access or from which herbage is cut for feeding to farmed animals, shall keep records of the following for a period of at least two years:

- 1. the quantities of organic fertilisers and soil improvers applied;
- 2. the date on which the organic fertilisers and soil improvers were applied to land and the places of such application;
- 3. the dates, following the application of the organic fertiliser or soil improver, on which livestock has been allowed to graze on the land or on which the land has been cut for herbage to be used for feeding.

Section 5

Requirements for animal by-products derived from aquatic animals and feeding of fish

Processing plants producing fishmeal or other feed originating from aquatic animals shall keep records of the following:

- (a) the quantities produced each day;
- (b) the species of origin, including an indication of whether the aquatic animals were caught in the wild or produced in aquaculture;

(c) in the case of fishmeal from farmed fish which is intended for feeding to farmed fish of another species, the scientific name of the species of origin.

Section 6

Requirements for the burning and burial of animal by-products

In the case of burning or burial of animal by-products as provided for in Article 19(1) of Regulation (EC) No 1069/2009, the person responsible for such burning or burial shall keep records of the following:

- (a) the quantities, categories and species of animal by-products burned or buried;
- (b) the date and place of burning and burial.

Section 7

Requirements for photogelatine

Operators of approved photographic factories referred to in Section 11 of Chapter II of Annex XIV shall keep records detailing the purchases and uses of photogelatine, as well as the disposal of residues and surplus material.

CHAPTER V

MARKING OF CERTAIN DERIVED PRODUCTS

- In processing plants for the processing of Category 1 or Category 2 material, derived products 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;
 - (b) all derived products contain homogenously throughout the substance a minimum concentration of at least 250 mg GTH per kg fat.
- 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:
 - (a) liquid derived products destined for biogas or composting plants;
 - (b) derived products used for feeding to fur animals in accordance with Chapter I of Annex II;
 - (c) biodiesel produced in accordance with point D of Section 2 of Chapter IV of Annex IV;

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- (d) derived products obtained in accordance with Article 12(a)(ii) and (b)(ii) and Article 13(a)(ii) and (b)(ii) and Article 16(e) of Regulation (EC) No 1069/2009, where such products are:
 - 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:
 - immediate direct incineration or co-incineration,
 - immediate use in accordance with a method approved for animal by-products of Category 1 and Category 2 in accordance with Chapter IV of Annex IV; or

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 (ii) intended for research and other specific purposes as referred to in Article 17 of Regulation (EC) No 1069/2009 which have been authorised by the competent authority;

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(e) renewable fuels produced from rendered fats, which are derived from Category 1 and Category 2 materials, in accordance with points J and L of Section 2 of Chapter IV of Annex IV.

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CHAPTER VI

TRANSPORT OF DEAD PET ANIMALS

The conditions in points 1 to 3 of Article 48 of Regulation (EC) No 1069/2009 regarding the advance authorisation by the competent authority in the Member States of destination and the use of TRACES shall not be required in the case of the transport of a dead pet animal for incineration in an establishment or plant located in the border region of another Member State sharing a common border when the Member States conclude a bilateral agreement on the condition of the transport.

ANNEX IX

REQUIREMENTS APPLICABLE TO CERTAIN APPROVED AND REGISTERED ESTABLISHMENTS AND PLANTS

CHAPTER I

MANUFACTURING OF PETFOOD

Establishments or plants manufacturing petfood as referred to in Article 24(1)(e) of Regulation (EC) No 1069/2009 shall have adequate facilities for:

- (a) storing and treating incoming material in complete safety; and
- (b) disposing of unused animal by-products remaining after the production of the products in accordance with this Regulation, or such material must be sent to an incineration plant, a co-incineration plant, a processing plant or, in the case of Category 3 material, to a biogas or composting plant in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009 and with this Regulation.

CHAPTER II

HANDLING OF ANIMAL BY-PRODUCTS AFTER THEIR COLLECTION

The requirements of this Chapter shall apply to the storage of animal by-products, as referred to in Article 24(1)(i) of Regulation (EC) No 1069/2009 and to the following operations involving the handling of animal by-products after their collection, as referred to in Article 24(1)(h) of that Regulation:

tiita	. Augulation.
(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, prior to such transformation or composting in another establishment or plant in accordance with Annex V

(j) sieving.

hereto;

General requirements

- Premises and facilities where intermediate operations are carried out shall meet at least the following requirements:
 - (a) They must be adequately separated from thoroughfares through which contamination may be spread and 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 must 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 must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid down in such a way as to facilitate the draining of liquids.
 - (d) The plant must have adequate 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 must 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 must have suitable temperature-controlled storage facilities of sufficient capacity for maintaining animal by-products at appropriate temperatures and designed to allow the monitoring and recording of those temperatures.
- 2. The plant shall be equipped with adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and for the vehicles, other than ships, in which they are transported. Adequate facilities shall be available for the disinfecting of vehicle wheels.

Section 2

Hygiene requirements

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

Section 3

Processing standards for hygienisation/pasteurisation

Hygienisation/pasteurisation as referred to in point (i) of the initial paragraph of this Chapter shall be carried out in accordance with the processing standards referred to in point 1 of Section 1 of Chapter I of Annex V or in accordance with alternative transformation parameters which have been authorised in accordance with point 1 of Section 2 of Chapter III of the same Annex.

CHAPTER III

REQUIREMENTS FOR STORAGE OF DERIVED PRODUCTS

Section 1

General requirements

Premises and facilities storing derived products shall meet at least the following requirements:

- Premises and facilities storing derived products from Category 3 material must not be at the same site as premises storing derived products from Category 1 or Category 2 material, unless cross-contamination is prevented due to the layout and management of the premises, such as by means of storage in completely separate buildings.
- 2. The plant must:
 - (a) have a covered space to receive and dispatch the derived products, unless the derived products are:
 - 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 or means of transport;
 - (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;
 - (d) have appropriate arrangements for protection against pests, such as insects, rodents and birds.
- The plant must 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 products must be stored properly until redispatched.

Section 2

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

- The storage of the products referred to in Part II of Section 4 of Chapter II of Annex X shall take place at an appropriate temperature to avoid any risk to public or animal health in a dedicated approved or registered storage establishment or plant or in a dedicated, separate storage area within an approved or registered storage establishment or plant.
- 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 Chapter I of Annex X.

CHAPTER IV

REGISTERED OPERATORS

- Operators of registered plants or establishments or other registered operators shall handle animal by-products and derived products under the following conditions:
 - (a) premises must be constructed in a way permitting their effective cleaning and disinfection, where appropriate;
 - (b) premises must have appropriate arrangements for protection against pests, such as insects, rodents and birds;
 - (c) installations and equipment must be kept in hygienic condition, where necessary;
 - (d) animal by-products and derived products must be stored under conditions preventing contamination.
- Operators shall keep records in a form which is accessible to the competent authority.
- 3. Registered operators transporting animal by-products or derived products, other than between premises of the same operator, 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.

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CHAPTER V

CONTAINMENT METHODS

Section 1

General provisions

- Materials resulting from a containment method may be used or disposed of only within the Member State where that containment method is authorised by the competent authority.
- 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, where a containment method is used for the first time in that Member State, in order to facilitate the introduction of the new containment method.

Section 2

Methodology

- A. Aerobic maturation and storage of dead-on-farm pigs and certain other porcine material with subsequent incineration or co-incineration.
 - 1. Member States concerned

The process of aerobic maturation and storage of dead-on-farm pigs and certain other porcine material with subsequent incineration or co-incineration may be used in France, Ireland, Latvia, Portugal and the United Kingdom.

Following aerobic maturation and storage of material, the competent authority of the Member State concerned must ensure that the materials are collected and disposed of within the territory of that Member State.

2. Starting materials

For this process, only the following materials of animals of the porcine species may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) to (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials referred to in Article 10(h) of Regulation (EC) No 1069/2009.

This method is only applicable to the disposal of animals of the porcine species originating in the same holding, provided this holding is not subject to restrictions due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine species. This method may not be used for animals which have died due to those diseases or have been killed for diseases control purposes, or parts of those animals.

3. Methodology

3.1. General principles

The method is a process authorised by the competent authority.

The site must be constructed and laid out in accordance with Union legislation for the protection of the environment, in order to prevent odours and risks to soil and groundwater.

The operator must:

- (a) take preventive measures against access of animals and put in place a documented pest control programme;
- (b) put in place procedures to prevent the spreading of diseases;
- (c) put in place procedures to prevent the spreading of used sawdust outside the closed system.

The process must be carried out in a closed system which consist of several cells, with a waterproof floor and delimited by solid walls. Any waste water must be collected; the cells must be connected with a drainpipe fitted with a 6 mm grid to capture solids.

Size and number of the cells must be adapted to the mortality level defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 with sufficient capacity for farm mortalities occurring during an eight-month period at least.

3.2. Phases

3.2.1. Filling and storage phase

The fallen pigs and other porcine material must be individually covered in sawdust and piled up until the cell is full. First a layer of at least 30 centimetres of sawdust must be placed on the ground. The carcasses and other porcine material must then be placed on this first layer of sawdust and each layer of carcasses and other porcine material must be covered with a layer of sawdust at least 30 cm thick.

Personnel must not walk on the stored material.

3.2.2. Maturing phase

When the cell is full and a rise in temperature allows the degradation of all the soft tissues, the maturation period starts and must last at least 3 months

At the end of the filling and storage phase and during all of the maturation phase, the operator must monitor the temperature in each cell with a temperature sensor placed between 40 cm and 60 cm beneath the pile surface of the latest built layer.

The electronic reading and monitoring of the temperature must be recorded by the operator.

At the end of the filling and storage phase, the temperature monitoring is an indicator of a satisfactory pile layout. The temperature must be measured by an automatic recording device. The aim is to reach 55 °C during 3 consecutive days, revealing that the maturing process is active and that the pile layout is effective and that the maturing phase has started.

The operator must monitor the temperature once a day and the following measures shall be taken depending on the outcome of these measurements:

- (a) where the temperature of 55 °C or more is maintained during 3 consecutive days, the pile may be removed after a 3 consecutive months maturing phase, or may remain stored on the premises awaiting a later removal;
- (b) where the temperature of 55 °C is not reached during 3 consecutive days, measures defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be set by the operator; if needed, the competent authority may stop the processing method and the material must be disposed of in compliance with Article 13 of the aforementioned Regulation.

A time limit for the storage phase may be determined by the competent authority.

3.2.3. Transport and incineration or co-incineration

The transport of the resulted material after the maturation phase to the approved incineration or co-incineration plant is subject to controls referred to in Regulation (EC) No 1069/2009 or Directive 2008/98/EC.

B. Hydrolysis with subsequent disposal

1. Member States concerned

The process of hydrolysis with subsequent disposal may be used in Ireland, Spain, Latvia, Portugal and the United Kingdom.

Following hydrolysis, the authorising competent authority must ensure that the materials are collected and disposed of within the same Member State referred to above.

2. Starting materials

For this process, only the following materials of porcine origin may be used:

- (a) Category 2 materials referred to in Article 9(f)(i) to (iii) of Regulation (EC) No 1069/2009;
- (b) Category 3 materials referred to in Article 10(h) of that Regulation.

This method is only applicable to the disposal of animals of the porcine species originating in the same holding and provided this holding is not subject to prohibition due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine species, or animals that have been killed for disease control purposes.

3. Methodology

Hydrolysis with subsequent disposal is a temporary storage on the spot. It shall be carried out according to the following standards:

- (a) Following their collection on a holding for which the competent authority has authorised the use of the processing method, based on an assessment of the animal density of the holding, the likely mortality rate and the potential risks for public and animal health which may arise, the animal by-products must be placed into a container which has been constructed in accordance with point (b) ('the container') and which has been placed at a dedicated site in accordance with points (c) and (d) ('the dedicated site').
- (b) The container must:
 - (i) have a device to close it;
 - (ii) be waterproof, leak-proof and hermetically sealed;
 - (iii) be coated in a way which prevents corrosion;
 - (iv) be equipped with a device for controlling emissions in accordance with point (e).
- (c) The container must be placed in a dedicated site which is physically separate from the holding.

That site must have dedicated access routes for the movement of materials and for collection vehicles.

- (d) The container and the site must be constructed and laid out in accordance with Union legislation for the protection of the environment, in order to prevent odours and risks to soil and groundwater.
- (e) The container must be linked to a pipe for gaseous emissions, which must be equipped with appropriate filters to prevent the transmission of diseases communicable to humans and animals.
- (f) The container must be closed for the process of hydrolysis for a period of at least three months, in such a way that any unauthorised opening is prevented.
- (g) The operator must put in place procedures to prevent the transmission of diseases communicable to humans or animals by movements of personnel.
- (h) The operator must:
 - (i) take preventive measures against birds, rodents, insects and other vermin:
 - (ii) put in place a documented pest control programme.
- (i) The operator must keep records of:
 - (i) any placing of material into the container;
 - (ii) any collection of hydrolysed material from the container.

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- (j) The operator must empty the container at regular intervals for a check:
 - (i) for the absence of corrosion;
 - (ii) to detect and prevent possible leakage of liquid materials into the ground.
- (k) Following hydrolysis, the materials must be collected, used and disposed of in accordance with Article 13(a), (b), (c) or Article 13(e)(i) of Regulation (EC) No 1069/2009 or Article 14 of that Regulation for Category 3 materials.
- (1) The process must be carried out in a batch mode.
- (m) Any other handling or use of the hydrolysed materials, including their application to land, shall be prohibited.

ANNEX X

FEED MATERIALS

CHAPTER I

GENERAL REQUIREMENTS FOR THE PROCESSING AND PLACING ON THE MARKET

Microbiological standards for derived products

The following microbiological standards shall apply to derived products:

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.

However, the microbiological standards set out in this Chapter shall not apply to rendered fats and fish oil from the processing of animal by-products, when the processed animal protein, which is obtained during the same processing, is subject to sampling to ensure compliance with those standards.

CHAPTER II

SPECIFIC REQUIREMENTS FOR PROCESSED ANIMAL PROTEIN AND OTHER DERIVED PRODUCTS

Section 1

Specific requirements for processed animal protein

▼M12

A. Raw materials

- Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than the Category 3 materials referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009, may be used for the production of processed animal protein.
- 2. Processed animal protein derived from farmed insects, intended for the production of feed for farmed animals other than fur animals, may only be obtained from the following insect species:
 - Black Soldier Fly (Hermetia illucens) and Common Housefly (Musca domestica);
 - (ii) Yellow Mealworm (*Tenebrio molitor*) and Lesser Mealworm (*Alphitobius diaperinus*);
 - (iii) House cricket (Acheta domesticus), Banded cricket (Gryllodes sigillatus) and Field Cricket (Gryllus assimilis).

B. Processing standards

 Processed animal protein of mammalian origin must have been submitted to processing method 1 (pressure sterilisation) as set out in Chapter III of Annex IV

However,

- (a) porcine blood or fractions of porcine blood for the production of bloodmeal may have been submitted instead to any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV, 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
 - may have been submitted to any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV, provided that it is subsequently disposed of or used as a fuel for combustion;
 - (ii) where it is exclusively destined for use in petfood, it may have been submitted to any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV, 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
 - consigned directly from a processing plant for Category 3 material to the petfood plant or to an approved storage plant, from where it is directly consigned to a petfood plant.
- Non-mammalian processed animal protein, with the exception of fishmeal, must have been submitted to any of processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV.
- 3. Fishmeal must have been submitted to:
 - (a) any of the processing methods set out in Chapter III of Annex IV; or
 - (b) another method which ensures that the product complies with the microbiological standards for derived products set in Chapter I of this Annex.

C. Storage

 Processed animal protein must be packed and stored in new or sterilised bags or stored in properly constructed bulk bins or in storage sheds.

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

- Products in conveyors, elevators and bins must be protected from casual contamination.
- Equipment for handling processed animal protein must be maintained in a clean and dry condition and must 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.

▼<u>B</u>

4. Processed animal protein must be kept dry.

Leakages and condensation in the storage area must be prevented.

Section 2

Specific requirements for blood products

A. Raw material

Only blood referred to in Article 10(a) and Article 10(b)(i) of Regulation (EC) No 1069/2009 may be used for the production of blood products.

B. Processing standards

Blood products must have been submitted to:

- (a) any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV; or
- (b) another method which ensures that the blood product complies with the microbiological standards for derived products set out in Chapter I of this Annex.

Section 3

Specific requirements for rendered fats, fish oil and fat derivatives from Category 3 material

A. Raw materials

▼ M9

1. Rendered fats

Only Category 3 material, other than Category 3 materials referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009, may be used for the production of rendered fat.

▼M11

2. Fish oil

Only Category 3 material referred to in Article 10(i), (j) and (l) of Regulation (EC) No 1069/2009 and Category 3 material of aquatic animal origin referred to in Article 10(e) and (f) of that Regulation may be used for the production of fish oil.

▼B

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 processing method 7, and fish oils may be produced:

- (a) using processing methods 1 to 7, as set out in Chapter III of Annex IV;
- (b) in accordance with another method which ensures that the product complies with the microbiological standards for derived products set out in Chapter I of this Annex.

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.

Fat derivatives from Category 3 rendered fats or fish oil shall be produced in accordance with one of the processing methods referred to in Chapter III of Annex IV.

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 those 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 directly to plants must be clean before use.

Section 4

Specific requirements for milk, colostrum and certain other products derived from milk or colostrum

Part I

General requirements

A. Raw material

Only milk referred to in Article 10(e) of Regulation (EC) No 1069/2009, other than centrifuge or separator sludge, and milk referred to in Article 10(f) and (h) of Regulation (EC) No 1069/2009 may be used for the production of milk, milk-based products and milk-derived products.

Colostrum may only be used provided that it originates from live animals that did not show any signs of disease communicable through the colostrum 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, milk-based product or milk-derived 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;

^(*) F₀ 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.

- 1.4. HTST in combination with one of the following:
 - (a) a subsequent physical treatment, by:
 - 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 6,0 for at least 1 hour;
 - (b) the condition that the milk, milk-based product or milk-derived 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.
- Milk-based products and milk-derived products must either be subjected to at least one of the treatments provided for in point 1 or be produced from milk treated in accordance with point 1.
- Whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with point 1 must:
 - (a) either be collected at least 16 hours following milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings; or
 - (b) have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin.
- 4. In addition to the requirements set out in points 1, 2 and 3, milk, milk-based products and milk-derived products must meet the following requirements:
- 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 it must be:
 - (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.
- Raw milk must be produced under conditions offering adequate guarantees as regards animal health.
- 6. Colostrum and colostrum products must:
- 6.1. be obtained from bovine animals kept on a holding on which all bovine herds are recognised as officially tuberculosis-free, officially brucellosis-free and officially enzootic-bovine-leukosis-free as defined in Article 2(2)(d), (f) and (j) of Directive 64/432/EEC;
- 6.2. have been produced at least 21 days before shipping and during that period no case of foot-and-mouth disease has been detected in the Member State of origin;

- 6.3. have undergone a single HTST treatment (*);
- 6.4. comply with the requirements set out in point 4 of this Part.

Part II

Derogation for the placing on the market of milk processed in accordance with national standards

▼ M4

1. The requirements laid down in points 2 and 3 of this Part shall apply to the processing, use and storage of milk, milk-based products and milk-derived products which are Category 3 material, as referred to in Article 10(e) of Regulation (EC) No 1069/2009, other than centrifuge or separator sludge, and milk, milk-based products and milk-derived products referred to in Article 10(f) and (h) of that Regulation, that have not been processed in accordance with Part I of this Section.

▼<u>B</u>

- 2. The competent authority shall authorise milk processing establishments approved or registered in accordance with Article 4 of Regulation (EC) No 853/2004 to supply milk, milk-based products and milk-derived products for the purposes referred to in point 3 of this Part provided the establishment concerned ensures the traceability of the products.
- 3. Milk, milk-based products 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 the requirements for heat treatment set out in point II.1(a) or (b) of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004, if those derived products have been subject to one of the following treatments:
 - (i) UHT;
 - (ii) sterilisation whereby either an Fc value equal or greater than 3 is achieved, or which was carried out at a temperature of at least 115 °C for 15 minutes or an equivalent combination of temperature and time;
 - (iii) pasteurisation or sterilisation, other than that referred to in point (ii), followed by:
 - in the case of dried milk or dried milk-based products or milk-derived products, a drying process;
 - in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6;
 - (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 the requirements for heat treatment set out in point II.1 (a) of Chapter II of Section IX of Annex III 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;</p>

^(*) 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.

- (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 point (a) and point (b)(i) cannot be ensured, provided that they are sent to a limited number of authorised animal holdings, fixed on the basis of a 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-andmouth 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.
- 4. The competent authority may authorise the supply of colostrum which does not comply with the conditions set out in point B.6 of Part I from one farmer to another farmer within the same Member State for feeding purposes, under conditions which prevent the transmission of health risks.

Part III

Special requirements for centrifuge or separator sludge

Category 3 material comprising of centrifuge or separator sludge 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 to farmed animals.

▼ M9

By way of derogation from the first paragraph, the competent authority may authorise alternative parameters for the heat treatment of centrifuge or separator sludge destined for uses within Member States which have authorised those alternative parameters, provided operators can demonstrate that the heat treatment according to the alternative parameters guarantees at least the same risk reduction as the treatment carried out according to the parameters set out in the first paragraph.

▼<u>B</u>

Section 5

Specific requirements for gelatine and hydrolysed protein

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of gelatine and hydrolysed protein.

B. Processing standards for gelatine

 Unless the gelatine has been produced in accordance with Section XIV of Annex III to Regulation (EC) No 853/2004, it 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.

- After having been subjected to the processes referred to in point 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
- The use of preservatives, other than sulphur dioxide and hydrogen peroxide, shall be 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 derived from ruminants shall have a molecular weight below 10 000 Dalton.

In addition to the requirements of the first paragraph, 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 exposure of the material to:

- (a) 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) 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.

Section 6

Specific requirements for dicalcium phosphate

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of dicalcium phosphate.

B. Processing standards

- Dicalcium phosphate must be produced by a process that comprises the three following stages:
 - (a) firstly, ensures that all bone that is Category 3 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) secondly, following the part of the process referred to in point (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7;
- (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.
- Where dicalcium phosphate is derived from defatted bones, it shall be derived from bones referred to in Article 10(a) of Regulation (EC) No 1069/2009.

Section 7

Specific requirements for tricalcium phosphate

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of tricalcium phosphate.

B. Processing standards

Tricalcium phosphate must be produced by a process that ensures:

- (a) that all bone that is Category 3 material is finely crushed and degreased in counterflow with hot water (bone chips must be 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;
- (d) granulation of the tricalcium phosphate after drying in a fluidised bed with air at 200 $^{\circ}$ C.

Section 8

Specific requirements for collagen

A. Raw materials

Only animal by-products which are Category 3 material or products which are derived from such animal by-products, other than materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009 may be used for the production of collagen.

B. Processing standards

 Unless the collagen has been produced in accordance with the requirements for collagen set out in Section XV of Annex III to Regulation (EC) No 853/2004, it 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.

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.

Section 9

Specific requirements for egg products

A. Raw materials

Only animal by-products referred to in Article 10(e) and (f) and Article 10(k)(ii) of Regulation (EC) No 1069/2009 may be used for the production of egg products.

B. Processing standards

Egg products must have been:

- (a) submitted to any of the processing methods 1 to 5 or processing method 7 set out in Chapter III of Annex IV;
- (b) submitted to another method and parameters which ensure that the products comply with the microbiological standards for derived products set out in Chapter I; or
- (c) treated in accordance with the requirements for eggs and egg products set out in Chapters I, II and III of Section X of Annex III to Regulation (EC) No 853/2004.

▼<u>M4</u>

Section 10

Specific requirements for feeding to farmed animals, other than fur animals, of certain Category 3 material referred to Article 10(f) of Regulation (EC) No 1069/2009

Category 3 material comprising of foodstuffs containing products of animal origin originating from Member States which are no longer intended 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, referred to in Article 10(f) of Regulation (EC) No 1069/2009, may be placed on the market for feeding to farmed animals, other than fur animals, without further treatment, provided that the material:

- (i) has undergone processing as defined in Article 2(1)(m) of Regulation (EC)
 No 852/2004 or in accordance with this Regulation;
- (ii) is composed of or contain one or more of the following Category 3 materials referred to in Article 10(f) of Regulation (EC) No 1069/2009:
 - milk,
 - milk-based products,
 - milk-derived products,
 - eggs,

▼<u>M4</u>

- egg products,
- honey,
- rendered fats,
- collagen,
- gelatine;
- (iii) has not been in contact with any other Category 3 materials; and
- (iv) all necessary precautions have been taken to prevent the contamination of the material.

▼<u>B</u>

CHAPTER III

REQUIREMENTS FOR CERTAIN FISH FEED AND FISHING BAITS

- Animal by-products from fish or aquatic invertebrates and derived products therefrom that are intended as feed for farmed fish or for other aquaculture species 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, 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;
 - (c) be processed in a processing plant in accordance with a method which ensures a microbiologically safe product, including with regard to fish pathogens.
- The competent authority may lay down conditions, aimed at preventing unacceptable risks for the transmission of diseases communicable to humans or animals, for the use of aquatic animals and of aquatic and terrestrial invertebrates:
 - (a) as feed for farmed fish or for aquatic invertebrates, when the animal by-products have not been processed in accordance with point 1(c);
 - (b) as fishing bait, including bait for aquatic invertebrates.

ANNEX XI

ORGANIC FERTILISERS AND SOIL IMPROVERS

CHAPTER I

REQUIREMENTS FOR UNPROCESSED MANURE, PROCESSED MANURE AND DERIVED PRODUCTS FROM PROCESSED MANURE

Section 1

Unprocessed manure

- Trade in unprocessed manure of species other than poultry or equidae between Member States shall be subject to the following conditions, in addition to the consent of the Member State of destination referred to in Article 48(1) of Regulation (EC) No 1069/2009:
 - (a) Trade in unprocessed manure of species other than poultry or equidae shall be prohibited, except for manure:
 - 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 of the Member State of destination may, having regard to the origin of the manure, its destination and health considerations, grant specific authorisation 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
 - transformation into biogas or composting in accordance with Regulation (EC) No 1069/2009 and with Annex V to this Regulation with a view to the manufacture of the products referred to in Section 2 of this Chapter.

In those cases, the competent authority shall take account of the origin of the manure when authorising the introduction to 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 attestation in accordance with the model set out in point 3 shall be added to the commercial document which accompanies the consignment of manure.
- Trade in unprocessed poultry manure between Member States shall be subject to the following conditions, in addition to the consent of the Member State of destination referred to in Article 48(1) of Regulation (EC) No 1069/2009:
 - (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 attestation in accordance with the model set out in point 3 shall be added to the commercial document which accompanies the consignment of manure.

3. Model health attestation to be added to the commercial document:

JRC	PEA	N UNION		Commercial do	cume		
	l.1.	Consignor	I.2. Document reference No I.2.a. Local reference N	lo			
		Name Address Postcode		I.3. Central competent authority			
				I.4. Local competent authority			
	I.5.	Consignee		1.6.			
		Name					
		Address	1.7.				
9		Postcode	1.7.				
atten		Tel.					
of dispatched consignment	I.8.	Country of origin ISO code I.9. Region of origin	Code	I.10. Country of	Code		
ran I: Details	l.12.	Place of origin		I.13. Place of destination			
<u></u>		Establishment	Establishment Other				
מַב		Name Approval number	Name Approval number				
		Address		Address			
		Postcode		Postcode			
Ì	I.14.	Place of loading	I.15. Date of departure				
	I.16. Means of transport			I.17. Transporter			
		Aeroplane ☐ Ship ☐ Railway wag	Name Approval number	er			
		Road vehicle Other O		Address			
		Identification		Postcode Member State			
	l.18.	Description of commodity		I.19. Commodity code (HS code)			
				I.20. Quantity			
ľ	I.21.	Temperature of products		I.22. Number of packages			
		Ambient ☐ Chilled ☐		Frozen 🗆			
Ī	1.23.	Seal/Container No		I.24. Type of packaging			
ł	1.25.	Commodities certified for:					
		Technical use					
Ī	1.26.	Transit through third country		I.27. Transit through Member States			
		Third country ISO code		Member State ISO code			
		Exit point Code		Member State ISO code			
		Entry point BIP unit No		Member State ISO code			
	1.28.	Export	1.29.				
		Third country ISO code Exit point Code					
ŀ	1.30.	Lak point Gode					
	I.31.	Identification of the commodities					
				Approval number of establishments			
		Species Nature of commodity Cate (scientific name)	egory	Treatment type Manufacturing plant Batch num	nber		

COUNTRY

Animal by-products/derived products not intended for human consumption

	II.	Health information	II.a. Certificate reference No	II.b.				
	III.	Health attestation						
		I, the undersigned official veterinarian, declare that I understand that the competent authority of the place of destination has given its consent to the introduction of the unprocessed manure on its territory and that the unprocessed manure referred to in box reference I.18 complies with the following conditions:						
اے		(a) in case of unprocessed poultry manure (1):						
ication		[The manure originates from an area which is not subject to restrictions by virtue of Newcastle disease or avian influenza.]						
Part II: Certification		and [In the case of unprocessed manure from poultry flocks vaccinated against Newcastle disease, the manure is not dispatched to a region which has obtained Newcastle disease non-vaccinating status pursuant to Article 15(2) of Directive 2009/158/EC.]						
Part		(b) in case of unprocessed manure of species other than poultry or equidae (1):						
		[The manure originates from an area which is not subject to restrictions by virtue of a serious transmissible disease.]						
		and						
		either [The manure is 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 Regulation (EC) No 1069/2009 with a view to the manufacture of processed manure or processed manure products.]						
		or [The manure is intended for applying to land on a	a holding.]					
	Notes							
	Part I:							
	— Во	x reference I.9 and I.11: if appropriate.						
	— Во	x reference I.12, I.13 and I.17: approval number or registration number	mber.					
	— Во	x reference I.14: complete if different from 'I.1. Consignor'.						
	— Во	x reference I.25: technical use: any use other than for animal cons	sumption.					
	— Во	x reference I.31:						
	Nat	ture of commodity: 'manure'.						
	Part II	l:						
	(¹) De	lete as appropriate.						
	Official veterinarian/Official inspector							
Name (in capital letters): Qualification and title:								
	Da	ite:	Signature:					
	Sta	amp:						

- 4. Unprocessed manure of equidae may be traded between Member States, provided that the Member State of destination has given its consent to the trade as referred to in Article 48(1) of Regulation (EC) No 1069/2009, and 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 2009/156/EC.
- 5. In accordance with Article 48(1)(c)(ii) of Regulation (EC) No 1069/2009, the competent authority of the Member State of destination may require operators dispatching unprocessed manure from another Member State:
 - (a) to transmit further information in relation to an intended dispatch, such as precise geographical indications regarding the place where the manure is to be unloaded; and
 - (b) to store the manure before application to land.
- 6. The competent authority may authorise the dispatch of manure transported between two points located on the same farm subject to conditions for the control of possible health risks, such as obligations for the operators concerned to keep appropriate records.

Section 2

Guano from bats, processed manure and derived products from processed manure

▼M1

The placing on the market of processed manure, derived products from processed manure and guano from bats shall be subject to the following conditions. In addition, in the case of guano from bats the consent of the Member State of destination is required as referred to in Article 48(1) of Regulation (EC) No 1069/2009:

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- (a) They must come from a plant for derived products for uses outside the feed chain or from a biogas or a composting plant or from a plant for the manufacturing of organic fertilisers or soil improvers.
- (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 referred to in point (b), provided an applicant demonstrates that such parameters ensure minimising of biological risks.

That 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 thermoresistant 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;

(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:

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Escherichia coli: n = 5, c = 5, m = 0, M = 1000 in 1 g;
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or

Enterococcaceae: n = 5, c = 5, m = 0, M = 1000 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:

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

Processed manure or processed manure products not complying with the standards in this point 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'.

CHAPTER II

REQUIREMENTS FOR CERTAIN ORGANIC FERTILISERS AND SOIL IMPROVERS

Section 1

Conditions for the production

- Organic fertilisers and soil improvers, other than manure, digestive tract content, compost, milk, milk-based products, milk-derived products, colostrum, colostrum products and digestion residues from the transformation of animal by-products or derived products into biogas, shall be produced by:
 - (a) applying processing method 1 (pressure sterilisation), when Category 2 material is used as starting material;

▼ M4

(b) using processed animal protein, including processed animal protein produced in accordance with point B.1(b)(ii) of Section 1 of Chapter II of Annex X, which has been produced from Category 3 material in accordance with Section 1 of Chapter II of Annex X, or materials which have been subject to another treatment, where such materials may be used for organic fertilisers and soil improvers in accordance with this Regulation; or

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- (c) by applying any of the processing methods 1 to 7, as set out in Chapter III of Annex IV, when Category 3 material is used as starting material which is not used for the production of processed animal protein.
- 2. Organic fertilisers and soil improvers which consist of or which have been produced from meat-and-bone meal derived from Category 2 material or from processed animal protein, shall be mixed, in a registered establishment or plant, with a sufficient minimum proportion of a component which is authorised by the competent authority of the Member State where the product is to be applied to land, in order to exclude the subsequent use of the mixture for feeding purposes.
- 3. The competent authority shall authorise the component referred to in point 2 according to the following:
 - (a) the component shall consist 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 shall be determined based on an assessment of the climatic and soil conditions for the use of the mixture as a fertiliser, on indications that the component renders the mixture unpalatable to animals or it is otherwise effective in preventing misuse of the mixture for feeding purposes and in accordance with 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.

The competent authority shall make the list of the authorised components available to the Commission and to other Member States upon request.

- 4. However, the requirements referred to in point 2 shall not apply:
 - (a) to organic fertilisers and soil improvers which are in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer; or
 - (b) to organic fertilisers and soil improvers in big bags of not more than 1 000 kg in weight, on the packages of which it is indicated that the organic fertilisers are not destined to land to which farmed animals have access, provided that the competent authority of the Member State where the organic fertiliser or soil improver is to be applied to land, has authorised the use of such big bags on the basis of an assessment of the likelihood of a potential diversion of the materials to farms keeping animals or to land to which farmed animals have access.
- 5. Producers of organic fertilisers and soil improvers must ensure that decontamination of pathogens is carried out prior to their placing on the market, in accordance with:
 - Chapter I of Annex X, in the case of processed animal protein or derived products from Category 2 or Category 3 material,
 - Section 3 of Chapter III of Annex V in the case of compost and digestion residues from the transformation of animal by-products or derived products into biogas.

Section 2

Storage and transport

After processing or transformation, organic fertilisers and soil improvers shall be properly stored and transported:

- (a) in bulk, under appropriate conditions that prevent contamination;
- (b) packaged or in big bags, in the case of organic fertilisers or soil improvers destined for sale to final users; or
- (c) in the case of storage on farm, in an adequate storage space to which no farmed animals have access.

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Section 3

Requirements for approval of establishments or plants

In order to be approved in accordance with Article 24(1)(f) of Regulation (EC) No 1069/2009, operators shall ensure that establishments or plants carrying out the activities referred to in point 1 of Section 1 meet the requirements laid down in Article 8 of this Regulation and:

- (a) have adequate facilities for storage of incoming ingredients to prevent cross-contamination and avoid contamination during storage;
- (b) dispose of unused animal by-products or derived products in accordance with Articles 13 and 14 of Regulation (EC) No 1069/2009.

ANNEX XII

INTERMEDIATE PRODUCTS

In accordance with Article 34(2) of Regulation (EC) No 1069/2009, the following conditions shall apply to the importation and transit through the Union of intermediate products:

- The import and transit of intermediate products shall be authorised, provided that:
 - (a) they are derived from the following materials:
 - (i) Category 3 material, other than materials referred to in Article 10(c),(n), (o) and (p) of Regulation (EC) No 1069/2009;
 - (ii) products generated by the animals referred to in Article 10(i), (l) and (m) of Regulation (EC) No 1069/2009; or
 - (iii) mixtures of the materials referred to in points (i) and (ii);
 - (b) in the case of intermediate products destined for the production of medical devices, in vitro diagnostic medical devices and laboratory reagents, they are derived from:
 - (i) materials which fulfil the criteria referred to in point (a), except that they 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;
 - (ii) Category 2 material referred to in Article 9(f) and (h) of Regulation (EC) No 1069/2009; or
 - (iii) mixtures of the materials referred to in points (i) and (ii);
 - (c) in the case of intermediate products destined for the production of active implantable medical devices, medicinal products and veterinary medicinal products, they are derived from the materials referred to in point (b), where 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 (d), in accordance with the conditions set out in point 2;
 - (f) each consignment is accompanied by a declaration of the importer in accordance with the model declaration set out in Chapter 20 of Annex XV, which must be at least in one of the official languages of the Member State in which the inspection at the border inspection post must be carried out and of the Member State of destination; these Member States may allow the use of other languages and request official translations for declarations in such other languages;
 - (g) in the case of materials referred to in point (b), the importer demonstrates to the competent authority that the materials:
 - (i) do not carry any risk of transmission of a disease communicable to humans or animals; or
 - (ii) are transported under conditions which prevent the transmission of any diseases communicable to humans or animals.

- 2. An establishment or plant may be registered or approved by the competent authority of a third country, as referred to in point 1(e), provided that:
 - (a) the operator or owner of the plant or his representative:
 - demonstrates that the plant has adequate facilities for the transformation of the materials referred to in point 1(a), (b) or (c), as applicable, 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 two 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 conditions:
 - (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 hazard analysis and critical control
 points (HACCP) principles;
 - (ii) 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;
 - (iii) the competent authority shall draw up a list of establishments or plants approved or registered in accordance with this Annex and shall assign an official number to each plant, which identifies the establishment or plant with respect to the nature of its activities; that list and subsequent amendments to it shall be submitted to the Member State where the inspection at the border inspection post must be carried out and to the Member State of destination.

▼ M9

- 3. The intermediate products imported into the Union shall be checked at the border inspection post in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post either to:
 - (a) a registered establishment or plant for the production of laboratory reagents, medical devices and in vitro diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Regulation (EC) No 1069/2009, where the intermediate products must be further mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the Union legislation applicable to the derived product;

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- (b) an establishment or plant which has been approved for the storage of animal by-products in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they must only be dispatched to an establishment or plant referred to in (a) of this point for the uses referred to in (a).
- Intermediate products in transit through the Union shall be transported in accordance with Article 11 of Directive 97/78/EC.

- 5. 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.
- 6. The operator or owner of the establishment or plant of destination or his representative shall keep records in accordance with Article 22 of Regulation (EC) No 1069/2009 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.
- 7. The competent authority shall ensure, in accordance with Directive 97/78/EC, that the consignments of intermediate products are sent from the Member State where the inspection at the border inspection post must be carried out to the plant of destination, as referred to in point 3 or, in the case of transit, to the border inspection post of exit.
- 8. 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.
- 9. 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 XIII

PETFOOD AND CERTAIN OTHER DERIVED PRODUCTS

CHAPTER I

General requirements

Petfood plants and establishments or plants producing derived products referred to in this Annex shall have adequate facilities for:

- (a) storing and treating incoming material under conditions which prevent the introduction of risks to public and animal health;
- (b) 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

Specific requirements for petfood, including dogchews

1. Raw petfood

Operators may only manufacture raw petfood from Category 3 material referred to in Article 10(a) and Article 10(b)(i) and (ii) of Regulation (EC) No 1069/2009.

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

Operators may manufacture processed petfood and dogchews only from:

- (a) Category 3 material, other than material referred to in Article 10(n), (o) and (p) of Regulation (EC) No 1069/2009; and
- (b) in the case of imported petfood or petfood produced from imported materials, from Category 1 material comprising of animal by-products 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.

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:
 - 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 material of animal origin exclusively using:
 - animal by-products or derived products from 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 referred to in Section 2 of Chapter II of Annex X, 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 animal by-products referred to in Article 10(1) and (m) of Regulation (EC) No 1069/2009 and in the case of animal by-products generated by aquatic animals, aquatic and terrestrial invertebrates, 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.

 Dogchews must be subjected to a treatment that is 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 dogchews and from processed petfood, other than from canned petfood and other than from such processed petfood which has been treated in accordance in point 3(b)(v), 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 shall be considered satisfactory if the number of bacteria in all samples does not exceed m;

- M = maximum value for the number of bacteria; the result shall be 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 shall still be 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 shall be considered satisfactory if the number of bacteria in all samples does not exceed m;
- M = maximum value for the number of bacteria; the result shall be considered unsatisfactory if the number of bacteria in one or more samples is M or more; and
- number of samples the bacterial count of which may be between m
 and M, the sample shall still be considered acceptable if the bacterial
 count of the other samples is m or less.
- 7. End point for processed petfood and dogchews

The following may be placed on the market without restrictions in accordance with this Regulation:

- (a) processed petfood
 - (i) which has been manufactured and packaged in the Union in accordance with point 3 and which has been tested in accordance with point 5; or
 - (ii) which has been subject to veterinary checks in accordance with Directive 97/78/EC at a border inspection post.
- (b) dogchews
 - (i) which have been manufactured and packaged in the Union in accordance with point 4 and which has been tested in accordance with point 5; or
 - (ii) which have been subject to veterinary checks in accordance with Directive 97/78/EC at a border inspection post.

CHAPTER III

Specific requirements for flavouring innards for the manufacture of petfood

 Operators may only use animal by-products which may be used as raw material for processed petfood and dogchews in accordance with point 2 of Chapter II for the production of liquid or dehydrated derived products used to enhance the palatability values of petfood.

- Flavouring innards must have been submitted to a treatment method and parameters, which ensure that the product complies with the microbiological standards set out in point 5 of Chapter II of this Annex. After treatment, every precaution must be taken to ensure that the product is not exposed to contamination.
- 3. The end product must be:
 - (a) 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

Specific 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 shall be subject to the following conditions:

- Blood may be placed on the market for such purposes provided that it has been collected:
 - (a) 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 I to Directive 2009/156/EC 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 OIE, 2010 edition;
 - (ii) have been kept for a period of 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 2009/156/EC or restrictions pursuant to Article 5 of that Directive;
 - (iii) for the periods laid down in Article 4(5) of Directive 2009/156/EC had no contact with equidae from holdings which were subject to a prohibition order for animal health reasons pursuant to that Article and for a period of 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 points (a) and (b) of the first subparagraph of Article 5(2) of that Directive;
 - (b) under veterinary supervision either:
 - (i) in slaughterhouses registered or 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.
- 2. Blood products may be placed on the market for such purposes 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 point 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, in the case of blood from equidae, bear the approval number of the slaughterhouse or facilities of collection referred to in point 1(b).

CHAPTER V

Specific requirements for hides and skins of ungulates and products derived therefrom

A. Establishments and plants

The competent authority may authorise plants handling hides and skins, including limed hides, to supply trimmings and splittings of these hides and skins for the production of gelatine for animal consumption, organic fertilisers or soil improvers, provided that:

- (a) the plant has storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities;
- (b) the storage rooms are kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials:
- (c) if raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch;
- (d) in the 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 before being used for the production of:
 - (i) gelatine for animal consumption; or
 - (ii) organic fertilisers or soil improvers.
- B. Placing on the market of animal by-products and of derived products
 - Untreated hides and skins may be placed on the market subject to the health conditions applicable to fresh meat pursuant to Directive 2002/99/EC.

- 2. Treated hides and skins 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;
 - (b) the commercial document laid down in Chapter III of Annex VIII contains a statement indicating that all precautions have been taken to avoid contamination with pathogenic agents.

C. End point for hides and skins

- Hides and skins of ungulates which pursuant to the decision of an operator are destined for purposes other than human consumption, and which comply with the requirements of Regulation (EC) No 853/2004 for raw materials for gelatine or collagen intended for use in food may be placed on the market without restrictions in accordance with this Regulation.
- 2. The following treated hides and skins may be placed on the market without restrictions in accordance with this Regulation:
 - (a) hides and skins having undergone the complete process of tanning;
 - (b) 'wet blue';
 - (c) 'pickled pelts';
 - (d) limed hides (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).
- 3. By way of derogation from point C.2, the competent authority may require that consignments of treated hides and skins referred to in point 2(c) and (d) are accompanied by a commercial document in accordance with the model set out under point 6 of Chapter III of Annex VIII, when they are supplied to establishments or plants producing petfood, organic fertilisers or soil improvers or transforming those materials into biogas.

CHAPTER VI

Specific requirements for game trophies and other preparations from animals

- A. The provisions of this Chapter are without prejudice to the measures for the protection of wild fauna, adopted pursuant to Regulation (EC) No 338/97.
- B. Safe sourcing

Game trophies and other preparations from animals, where for the preparation the animal by-products have been submitted to a treatment or are presented in a state which does not pose any health risks, may be placed on the market, provided they originate from:

- (a) species other than ungulates, birds and animals of the biological class Insecta or Arachnida; and
- (b) 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

- Game trophies or other preparations from animals, where for the preparation the animal by-products have been submitted to a treatment or are presented in a state which does not pose any health risks, may be placed on the market, provided they:
 - (a) originate from ungulates or birds which have undergone a complete taxidermy treatment ensuring their preservation at ambient temperatures;
 - (b) are mounted ungulates or birds or mounted parts of such animals;

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- (c) have been subject to an anatomical preparation such as by plastination;
- (d) are animals of the biological class Insecta or Arachnida which have been subject to a treatment, such as drying, to prevent any transmission of diseases communicable to humans or animals; or
- (e) are objects in natural history collections or for the promotion of science and they have been:
 - preserved in media, such as alcohol or formaldehyde, which allow display of the items; or
 - (ii) embedded completely on micro-slides;
- (f) are processed DNA samples intended for repositories for the promotion of biodiversity research, ecology, medical and veterinary science or biology.

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- 2. Game trophies or other preparations, other than those referred to under points B and C.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, may be placed on the market, provided that:
 - (a) in the case of game trophies or other preparations solely of bone, horns, hooves, claws, antlers or teeth,
 - they 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) they have been disinfected with a product authorised by the competent authority, in particular with hydrogen peroxide where parts consisting of bone are concerned;
 - (iii) they have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
 - (iv) they are accompanied by a health certificate certifying that the conditions set out in (i), (ii) and (iii) have been met;
 - (b) in case of game trophies or other preparations consisting solely of hides or skin,
 - (i) they have been:
 - dried.
 - dry- or wet-salted for a period of at least 14 days before the date of dispatch, or
 - subject to a preservation process other than tanning;

- (ii) they have been packaged, immediately after treatment, without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination; and
- (iii) they are accompanied by a commercial document or a health certificate certifying that the conditions set out in (i) and (ii) have been met.

CHAPTER VII

Specific requirements for wool, hair, pig bristles, feathers, parts of feathers and down

A. Raw material

 Untreated wool, untreated hair, untreated pig bristles and untreated feathers, parts of feathers and down must be Category 3 materials referred to in Article 10(b) (iii), (iv) and (v) and Article 10(h) and (n) of Regulation (EC) No 1069/2009.

They must be securely enclosed in packaging and dry.

However, in the case of untreated feathers, parts of feathers and down sent directly from the slaughterhouse to the processing plant, the competent authority may allow a derogation from the requirement to dry materials transported on its territory, provided that:

- (a) all necessary measures are taken to avoid any possible spread of disease;
- (b) the transport takes place in waterproof containers and/or vehicles which must be cleaned and disinfected immediately after each use.

▼ M2

2. Movements of pig bristles and wool and hair of animals of the porcine species from regions in which African swine fever is endemic shall be prohibited except for pig bristles and wool and hair of animals of the porcine species that have:

▼B

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

B. End point for wool and hair

Factory-washed wool and hair, and wool and hair which has been treated by another method which ensures that no unacceptable risks remain, may be placed on the market without restrictions in accordance with this Regulation.

Member States may authorise the placing on the market of untreated wool and hair from farms or from establishments or plants which have been registered in accordance with Article 23 of Regulation (EC) No 1069/2009 or approved in accordance with Article 24(1)(i) of the same Regulation on their territory without restrictions in accordance with this Regulation, if they are satisfied that no unacceptable risks to public and animal health arise from the wool and from the hair.

▼ M2

Wool and hair produced from animals other than those of the porcine species may be placed on the market without restrictions in accordance with this Regulation, provided:

- (a) it has undergone factory-washing which consists of the immersion of the wool and hair in series of baths of water, soap and sodium hydroxide or potassium hydroxide; or
- (b) it is dispatched directly to a plant producing derived products from wool or hair for the textile industry and such wool or hair has undergone at least one of the following treatments:
 - (i) chemical depilation by means of slaked lime or sodium sulphide;
 - (ii) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours;
 - (iii) industrial scouring which consists of the immersion of wool and hair in a water-soluble detergent held at 60-70 °C;
 - (iv) storage, which may include the journey time, at 37 °C for eight days, 18 °C for 28 days or 4 °C for 120 days.

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C. End point for feathers and down

Feathers, parts of feathers and down which have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes may be placed on the market without restrictions in accordance with this Regulation.

CHAPTER VIII

Specific requirements for 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

Specific requirements for apiculture by-products

Apiculture by-products intended exclusively for use in apiculture must:

- 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 mite (Tropilaelaps spp.); and
- 2. meet the requirements provided for in Article 8(a) of Directive 92/65/EEC.

CHAPTER X

Specific requirements for 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 which are destined for oleochemical purposes must be produced using any of the processing methods 1 to 5 as set out in Chapter III of Annex IV.
- 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

Specific requirements for fat derivatives

- 1. The following processes may be used to produce fat derivatives from rendered fats derived from Category 1 and Category 2 material:
 - (a) transesterification or hydrolysis at least 200 °C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters);
 - (b) saponification with NaOH 12M (glycerol and soap):
 - (i) in a batch process at 95 °C for three hours; or
 - (ii) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or
 - (c) hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes.
- Fat derivatives produced in accordance with this Chapter may only be placed on the market:
 - (a) for uses other than in feed, cosmetics and medicinal products;
 - (b) in addition, in the case of fat derivatives from Category 1 material, for uses other than in organic fertilisers and soil improvers.

▼ M4

3. End point for products derived from rendered fats:

Fat derivatives which have been processed as referred to in point 1 may be placed on the market for uses indicated in point 2 without restrictions in accordance with this Regulation.

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CHAPTER XII

Specific requirements for 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 fertilisers or soil improvers shall be subject to the following conditions:

(a) they must originate from animals that:

- (i) 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
- (ii) did not show clinical signs of any disease communicable through that product to humans or animals;
- (b) they must have undergone a heat treatment for one hour at a core temperature of at least 80 °C;
- (c) the horns must be removed without opening the cranial cavity;
- (d) at any stage of processing, storage or transport, every precaution shall be taken to avoid cross-contamination;
- (e) 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;
- (f) the packaging or containers must:
 - indicate the type of product (such as horns, horn products, hooves or hoof products);
 - (ii) be marked with the name and address of the approved or registered establishment or plant of destination.

▼ M1

CHAPTER XIII

Specific requirements for fish oil for the production of medicinal products

End point for fish oil for the production of medicinal products

Fish oil derived from the materials referred to in point A.2 of Section 3 of Chapter II of Annex X, which has been de-acidified with a NaOH solution at a temperature of 80 °C or more and which has subsequently been purified by distillation at a temperature of 200 °C or more, may be placed on the market for the production of medicinal products without restrictions in accordance with this Regulation.

ANNEX XIV

IMPORTATION, EXPORT AND TRANSIT

CHAPTER I

SPECIFIC REQUIREMENTS FOR THE IMPORTATION INTO AND TRANSIT THROUGH THE UNION OF CATEGORY 3 MATERIAL AND DERIVED PRODUCTS FOR USES IN THE FEED CHAIN OTHER THAN FOR PETFOOD OR FOR FEED TO FUR ANIMALS

Section 1

As referred to in Article 41(1)(a) and Article 41(3) of Regulation (EC) No 1069/2009, the following requirements shall apply to imported consignments of Category 3 material and derived products therefrom for uses in the feed chain other than for petfood or for feed to fur animals and consignments of such materials and products in transit:

- (a) they must consist of or have been produced from, as applicable, Category 3 material referred to in the column 'raw materials' of Table 1;
- (b) they must comply with the import and transit conditions set out in the column 'import and transit conditions' of Table 1;

▼ M4

- (c) they must come from a third country or part of a third country listed in the column 'third countries' list' of Table 1;
- (d) they must come from an establishment or plant which is registered or approved by the competent authority of the third country, as applicable, and which is on the list of such establishments and plants referred to in Article 30; and
- (e) they must be:
 - (i) 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 column 'certificates/model documents' of Table 1; or
 - (ii) 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 column 'certificates/model documents' of Table 1.

•	No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
▼ <u>M12</u>	1	Processed animal protein, including mixtures and products other than petfood containing such protein, and compound feeds containing such proteins as defined in Article 3(2)(h) of Regulation (EC) No 767/2009	Category 3 materials referred to in Article 10(a), (b), (d), (e), (f), (h), (i), (j), (k), (l) and (m).	 (a) The processed animal protein must have been produced in accordance with Section 1 of Chapter II of Annex X; and (b) the processed animal protein shall comply with the additional requirements set out in Section 2 of this Chapter. 	 (a) In the case of processed animal proteins excluding fishmeal: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010. (b) In the case of fishmeal: Third countries listed in Annex II to Decision 2006/766/EC. 	 (a) In the case of processed animal protein other than those derived from farmed insects: Annex XV, Chapter 1. (b) In the case of processed animal protein derived from farmed insects: Annex XV, Chapter 1a.
<u>▼B</u>	2	Blood products for feed material	Category 3 materials referred to in Article 10 (a) and (b)(i).	► M9 The blood products must have been produced in accordance with Section 2 of Chapter II of Annex X and Section 5 of Chapter I of Annex XIV. ◀	 (a) In the case of blood products from ungulates: Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which imports of all categories of fresh meat of the respective species are authorised. (b) In the case of blood products from other species: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010. 	Annex XV, Chapter 4(B).

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
3	Rendered fats and fish oil	 (a) In the case of rendered fats excluding fish oil: Category 3 materials referred to in Article 10(a), (b), (d), (e), (f), (g), (h), (i), (j) and (k). (b) In the case of fish oil: Category 3 materials referred to in Article 10(e), (f), (i) and (j). 	 (a) The rendered fat and the fish oil must have been produced in accordance with Section 3 of Chapter II of Annex X; and (b) The rendered fat shall comply with the additional requirements set out in Section 3 of this Chapter. 	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.	(a) In the case of rendered fats excluding fish oil: Annex XV, Chapter 10 (A).(b) In the case of fish oil: Annex XV, Chapter 9.
4	Milk, milk-based products and milk-derived products, colostrum, products	 (a) Milk, milk-based products: Category 3 materials referred to in Article 10(e), (f) and (h). (b) Colostrum, colostrum products Category 3 materials from live animals that did not show any signs of disease transmissible through the colostrums to humans or animals. 	The milk, milk-based products, colostrum and colostrum products shall comply with the requirements set out in Section 4 of this Chapter.	 (a) In the case of milk and milk-based products: Authorised third countries listed in Annex I to Regulation (EU) No 605/2010. (b) In the case of colostrum and colostrum products: Third countries listed as authorised in column 'A' of Annex I to Regulation (EU) No 605/2010. 	 (a) In the case of milk, milk-based products and milk-derived products: Annex XV, Chapter 2(A). (b) In the case of colostrum and colostrums products: Annex XV, Chapter 2(B).

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
5	Gelatine and hydrolysed protein	Category 3 materials referred to in Article 10(a), (b), (e), (f), (g), (i) and (j), and, in the case of hydrolysed protein: Category 3 materials referred to in Article 10(d), (h) and (k).	The gelatine and the hydrolysed protein must have been produced in accordance with Section 5 of Chapter II of Annex X.	 (a) Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries: (KR) South Korea (MY) Malaysia (PK) Pakistan (TW) Taiwan. (b) In the case of gelatine and hydrolysed proteins from fish: Third countries listed in Annex II to Decision 2006/766/EC. 	(a) In the case of gelatine: Annex XV, Chapter 11.(b) In the case of hydrolysed protein: Annex XV, Chapter 12.
6	Dicalcium phosphate	Category 3 materials referred to in Article 10(a), (b), (d),(e), (f), (g), (h), (i), (j) and (k).	The dicalcium phosphate must have been produced in accordance with Section 6 of Chapter II of Annex X.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries: (KR) South Korea (MY) Malaysia (PK) Pakistan (TW) Taiwan.	Annex XV, Chapter 12.

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
7	Tricalcium phosphate	Category 3 materials referred to in Article 10(a), (b), (d),(e), (f), (g), (h), (i) and (k).	The tricalcium phosphate must have been produced in accordance with Section 7 of Chapter II of Annex X.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries:	Annex XV, Chapter 12.
				(KR) South Korea	
				(MY) Malaysia	
				(PK) Pakistan	
				(TW) Taiwan.	
8	Collagen	Category 3 materials referred to in Article 10(a), (b), (e), (f), (g), (i) and (j).	The collagen must have been produced in accordance with Section 8 of Chapter II of Annex X.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries:	Annex XV, Chapter 11.
				(KR) South Korea	
				(MY) Malaysia	
				(PK) Pakistan	
				(TW) Taiwan.	
9	Egg products	Category 3 materials referred to in Article 10(e), (f) and (k)(ii).	The egg products must have been produced in accordance with Section 9 of Chapter II of Annex X.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and third countries or parts of third countries from which Member States authorise imports of fresh poultrymeat, eggs and egg products, which are listed in Part 1 of Annex I to Regulation (EC) No 798/2008.	Annex XV, Chapter 15.

Section 2

▼ M1

Imports of processed animal protein, including mixtures and products other than petfood containing such protein, and compound feeds containing such protein as defined in Article 3(2)(h) of Regulation (EC) No 767/2009

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The following requirements shall apply to the importation of processed animal protein:

 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 general requirements of Chapter I of Annex X.

The competent authority must:

- (a) sample each consignment of products carried in bulk;
- (b) carry out random sampling of consignments of products packaged in the manufacturing plant of origin.
- 2. By way of derogation from point 1, when six consecutive tests on bulk consignments originating in a given third country prove negative, the competent authority of the border inspection post may carry out random sampling of subsequent bulk consignments from that third country.

If one of those random samples proves positive, the competent authority carrying out the sampling must inform the competent authority of the third country of origin so that it can take appropriate measures to remedy the situation.

The competent authority of the third 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 of the border inspection post 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 imported into the Union proves to be positive for salmonella or where it does not meet the microbiological standards for enterobacteriaceae set out in Chapter I of Annex X, 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 or enterobacteriaceae, as necessary, by the competent authority in accordance with Chapter I of Annex X, and a negative result obtained.

▼ M<u>12</u>

- 5. Processed animal protein obtained from farmed insects may be imported into the Union provided that it has been produced in compliance with the following conditions:
 - (a) the insects belong to one of the following species:
 - Black Soldier Fly (Hermetia illucens) and Common Housefly (Musca domestica),

▼M12

- Yellow Mealworm (Tenebrio molitor) and Lesser Mealworm (Alphitobius diaperinus),
- House cricket (Acheta domesticus), Banded cricket (Gryllodes sigillatus) and Field Cricket (Gryllus assimilis);
- (b) the substrate for the feeding of insects may only contain products of non-animal origin or the following products of animal origin of Category 3 material:
 - fishmeal,
 - blood products from non-ruminants,
 - di and tricalcium phosphate of animal origin,
 - hydrolysed proteins from non-ruminants,
 - hydrolysed proteins from hides and skins of ruminants,
 - gelatine and collagen from non-ruminants,
 - eggs and egg products,
 - milk, milk based-products, milk-derived products and colostrum,
 - honey,
 - rendered fats;
- (c) the substrate for the feeding of insects and the insects or their larvae have not been in contact with any other materials of animal origin than those mentioned in point (b) and the substrate did not contain manure, catering waste or other waste.

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Section 3

Imports of rendered fats

The following 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 third country or a part of the territory of a third 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 third country or a part of the territory of a third 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 third country or a part of the territory of a third country free from foot-andmouth 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 diseases referred to in points (a), (b) and (c) during the relevant period referred to in those points, have been subjected to one of the following heat treatments:
 - (i) at least 70 °C for at least 30 minutes; or
 - (ii) at least 90 °C for at least 15 minutes.

Details of the critical control points shall be recorded by operators and maintained so that the owner, operator or their representative and, as necessary, the competent authority can monitor the operation of the plant; and the recorded information shall include the particle size, critical temperature and, as appropriate, the absolute time, pressure profile, raw material feed rate and fat recycling rate.

Section 4

Imports of milk, milk-based products, milk-derived products, colostrum and colostrum products

- A. The following requirements shall apply to the importation of milk, milk-based products, milk-derived products, colostrum and colostrum products:
 - 1. Milk, milk-based products and milk-derived products shall:
 - (a) have undergone at least one of the treatments provided for in points 1.1, 1.2, 1.3 and point (a) of point B.1.4 of Part I of Section 4 of Chapter II of Annex X;
 - (b) comply with points B.2 and B.4, and, in the case of whey, point B.3 of Part I of Section 4 of Chapter II of Annex X.
 - 2. By way of derogation from point B.1.4 of Part I of Section 4 of Chapter II of Annex X, milk, milk-based products and milk-derived products may be imported from third countries so authorised in column 'A' of Annex I to Regulation (EU) No 605/2010, provided that the milk, milk-based products or milk-derived products have undergone a single HTST treatment and:
 - (a) have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country; or
 - (b) have been presented at a border inspection post of entry into the Union at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country.
- B. The following requirements shall apply to the importation of colostrum and colostrum products:
 - 1. The materials shall have undergone a single HTST treatment and:
 - (a) have not been shipped before a period of at least 21 days has elapsed after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country; or
 - (b) have been presented at a border inspection post of entry into the Union at least 21 days after production and during that period no case of foot-and-mouth disease has been detected in the exporting third country.
 - The materials shall have been obtained from bovine animals subject to regular veterinary inspections to ensure that they come from holdings on which all bovine herds are:
 - (a) either recognised as officially tuberculosis-free and officially brucellosis-free as defined in Article 2(2)(d) and (f) of Directive 64/432/EEC or not restricted under the national legislation of the third country of origin of the colostrum regarding eradication of tuberculosis and brucellosis; and
 - (b) either recognised as official enzootic-bovine-leukosis-free as defined in Article 2(2)(j) of Directive 64/432/EEC or included in an official system for the control of enzootic bovine leukosis and there has been no evidence as a result of clinical and laboratory testing of this disease in the herd during the past two years.
 - 3. After completion of the processing, every precaution shall have been taken to prevent contamination of the colostrum or colostrum products.

- 4. The final product must bear a label so as to indicate that it contains Category 3 material and is not intended for human consumption, and it must have been:
 - (a) packed in new containers; or
 - (b) transported in bulk in containers or other means of transport that before use were thoroughly cleaned and disinfected.

▼ M9

Section 5

Imports of blood products for the feeding of farmed animals

The following requirements shall apply to the importation of blood products, including spray dried blood and blood plasma which have been derived from porcine animals intended for the feeding of porcine animals:

These derived products must be:

- (a) subjected to a heat treatment at a temperature of at least 80 °C throughout the substance and the dry blood and blood plasma is of not more than 8 % moisture with a water activity (Aw) of less than 0,60;
- (b) stored in dry warehouse conditions under room temperature for at least 6 weeks.

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CHAPTER II

SPECIFIC REQUIREMENTS FOR THE IMPORTATION INTO AND TRANSIT THROUGH THE UNION OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS FOR USES OUTSIDE THE FEED CHAIN FOR FARMED ANIMALS OTHER THAN FUR ANIMALS

Section 1

Specific requirements

As referred to in Article 41(1)(a) and (2)(c) and Article 41(3) of Regulation (EC) No 1069/2009, the following specific requirements shall apply to imported consignments of animal by-products and derived products for uses outside the feed chain for farmed animals and consignments of such products in transit:

- (a) they must consist of or have been produced from animal by-products referred to in the column 'raw materials' of Table 2;
- (b) they must comply with the import and transit conditions set out in the column 'import and transit conditions' of Table 2;

▼ M4

- (c) they must come from a third country or part of a third country listed in the column 'third countries' list' of Table 2;
- (d) they must come from an establishment or plant which is registered or approved by the competent authority of the third country, as applicable, and which is on the list of such establishments and plants referred to in Article 30; and
- (e) they must be:
 - (i) 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 column 'certificates/model documents' of Table 2; or
 - (ii) 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 column 'certificates/model documents' of Table 2.

Table 2

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
1	Processed manure, derived products from processed manure and guano from bats	Category 2 material referred to in Article 9(a).	The processed manure, the derived products from processed manure and the guano from bats must have been produced in accordance with Section 2 of Chapter I of Annex XI.	Third countries listed in: (a) Part 1 of Annex II to Regulation (EU) No 206/2010; (b) Annex I to Decision 2004/211/EC; or (c) Part 1 of Annex I to Regulation (EC) No 798/2008.	Annex XV, Chapter 17.
2	Blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals	Category 1 material referred to in Article 8(c) and (d) and Category 3 material referred to in Article 10(a), (b), (d) and (h).	The blood products must have been produced in accordance with Section 2.	The following third countries: (a) in the case of untreated blood products of ungulates: Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 from which imports of fresh meat of any domestic ungulate species is authorised and only for the period indicated in 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 I to Regulation (EC) No 798/2008. Japan. (c) in the case of untreated blood products of other animals:	 (a) In the case of untreated blood products: Annex XV, Chapter 4 (C). (b) In the case of treated blood products: Annex XV, Chapter 4 (D).

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
				Third countries listed either in Part 1 of Annex II to Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008, or in Part 1 of Annex I to 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 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.	
3	Blood and blood products from equidae	Category 3 materials referred to in Article 10(a), (b), (d) and (h).	The blood and the blood products shall comply with the requirements set out in Section 3.	The following third countries: (a) in the case of blood that has been collected in accordance with point 1 of Chapter IV of Annex XIII 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 XIII:	Annex XV, Chapter 4(A).

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
				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.	
4	Fresh or chilled hides and skins of ungulates	Category 3 materials referred to in Article 10 (a) and (b)(iii).	The hides and skins shall comply with the requirements set out in Section 4, points 1 and 4.	The hides and skins come from a third country, or, in the case of regionalisation in accordance with Union legislation, a part of a third country listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat from the same species.	Annex XV, Chapter 5(A).
5	Treated hides and skins of ungulates	Category 3 materials referred to in Article 10 (a), (b)(i) and (iii) and (n).	The hides and skins shall comply with the requirements set out in Section 4, points 2, 3 and 4.	 (a) In the case of treated hides and skins of ungulates: Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010. (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, other than those which comply with the requirements set out in Section 4, point 2: Annex XV, 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 XV, Chapter 5(C).

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
					(c) In the case of treated hides and skins of ungulates which comply with the requirements set out in Section 4, point 2: No certificate is required.
6	Game trophies and other preparations from animals	Category 2 materials referred to in Article 9, point (f) derived from wild animals not suspected of being infected with a disease communicable to humans or animals and Category 3 material referred to in Article 10(a), (b)(i), (iii) and (v) and (n).	shall comply with the requirements set out	 (a) In the case of game trophies and other preparations referred to in Section 5, point 2: Any third country. (b) In the case of game trophies and other preparations referred to in Section 5, point 3: (i) Game trophies from birds: Third countries listed in Part 1 of Annex I to 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 Regulation (EU) No 206/2010, including any restrictions laid down in the column for special remarks for fresh meat. 	trophies referred to in Section 5, point 3: Annex XV, Chapter 6(B).

	No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
	7	Pig bristles	Category 3 materials referred to in Article 10 (b)(iv).	The pig bristles must have been obtained from animals originating, and slaughtered in a slaughterhouse, in the third country of origin.	 (a) In the case of untreated pig bristles: Third countries, or, in the case of regionalisation, regions thereof, listed in part 1 of Annex II to Regulation (EU) No 206/2010, which are free of African swine fever for the 12 months prior to the date of importation. (b) In the case of treated pig bristles: Third countries listed in part 1 of Annex II to Regulation (EU) No 206/2010, which may not be free of African swine fever for the last 12 months prior to the date of importation. 	 (a) If no case of African swine fever has occurred during the 12 previous months: Annex XV, Chapter 7(A). (b) In case one or more cases of African swine fever have occurred during the previous 12 months: Annex XV, Chapter 7(B).
▼ <u>M2</u>	8	Untreated wool and hair produced from animals other than those of the porcine species	Category 3 materials referred to in Article 10(h) and (n).	 (1) The dry untreated wool and hair must be (a) securely enclosed in packaging; and (b) sent directly to a plant producing derived products for uses outside the feed chain or a plant carrying out intermediate operations, under conditions which prevent the spreading of pathogenic agents. 	(1) Any third country.	(1) For imports of untreated wool and hair, no health certificate is required.

▼<u>M2</u>

	No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
				(2) The wool and hair are wool and hair as referred to in Article 25(2)(e).	(2) Third country or region thereof (a) listed in Part 1 of Annex II to Regulation (EU) No 206/2010 and authorised for imports into the Union of fresh meat of ruminants not subject to supplementary guarantees A and F mentioned therein; and (b) free of foot-and-mouth disease and, in case of wool and hair of sheep and goats, of sheep pox and goat pox in accordance with Annex II to Council Directive 2004/68/EC.	(2) A declaration of the importer in accordance with Chapter 21 of Annex XV is required.
▼ <u>B</u>	9	Treated feathers, parts of feathers and down	Category 3 materials referred to in Article 10 (b)(v) and (h) and (n).	The treated feathers or parts of feathers shall comply with the requirements set out in Section 6.	Any third country.	For imports of treated feathers, parts of feathers and down, no health certificate is required.

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
10	Apiculture by-products	Category 3 materials referred to in Article 10 (e).	 (a) In the case of apiculture by-products intended for use in apiculture, other than beeswax in the form of honeycomb: (i) The apiculture by-products have been subjected to a temperature of - 12°C or lower temperature for at least 24 hours; or (ii) In the case of beeswax, the material has been processed in accordance with any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV, and refined before importation. (b) In the case of beeswax, other than beeswax in the form of honeycomb, for purposes other than feeding to farmed animals, the beeswax has been refined or processed in accordance with any of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV 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 Regulation (EU) No 206/2010, and the following country: (CM) Cameroon. (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 XV, Chapter 13. (b) In the case of beeswax for purposes other than feeding to farmed animals: A commercial document attesting the refinement or processing.

V <u>Б</u>						
	No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
	11	Bones and bone products (excluding 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	Category 3 materials referred to in Article 10(a) (b)(i) and (iii), (e) and (h).	The products shall comply with the requirements set out in Section 7.	Any third country.	The products shall be accompanied by: (a) a commercial document as et out in Section 7, point 2; and (b) a declaration of the importer in accordance with Annex XV, 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.
▼ <u>M10</u>	12	Petfood, including dogchews	 (a) In the case of processed petfood and of dogchews: materials referred to in Article 35(a)(i) and (ii). (b) In the case of raw petfood: materials referred to in Article 35(a)(iii). 	The petfood and the dogchews must have been produced in accordance with Chapter II of Annex XIII.	(a) In the case of raw petfood: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species and where only bone-in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC. (b) In the case of dogchews and petfood other than raw petfood:	 (a) In the case of canned petfood: Annex XV, Chapter 3(A). (b) In the case of processed petfood other than canned petfood: Annex XV, Chapter 3(B). (c) In the case of dogchews: Annex XV, Chapter 3(C). (d) In the case of raw petfood: Annex XV, Chapter 3(D).

▼<u>M10</u>

	No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
					Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries:	
					(JP) Japan	
					(EC) Ecuador	
					(LK) Sri Lanka	
					(TW) Taiwan.	
					In the case of processed petfood derived from fish materials, third countries listed in Annex II to Decision 2006/766/EC.	
▼ <u>M4</u>						
	13	Flavouring innards for the manufacture of petfood		The flavouring innards must have been produced in accordance with Chapter III of Annex XIII.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is authorised.	Annex XV, Chapter 3(E).
					In the case of flavouring innards from fish materials, third countries listed in Annex II to Decision 2006/766/EC.	
					In the case of flavouring innards from poultry meat third countries listed in Part 1 of Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh poultry meat.	

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
14	Animal by-products for the manufacture of petfood other than raw petfood and of derived products for uses outside the feed chain	 M4 (a) Category 3 materials referred to in Article 10(a) to (m). ◀ (b) In the case of materials for the manufacture of petfood, Category 1 materials referred to in Article 8(c). (c) In the case of fur for the manufacture of derived products, Category 3 materials referred to in Article 10(n). 	The products shall comply with the requirements set out in Section 8.	(a) In the case of animal by-products for the 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 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 Regulation (EC) No 798/2008. (iii) Raw material from fish: Third countries listed in Annex II to Decision 2006/766/EC. (iv) Raw material from other wild land mammals and leporidae: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EC) No 798/2008.	(a) In the case of animal by-products for the manufacture of processed petfood: Annex XV, Chapter 3(F). (b) In the case of animal by-products for the manufacture of products for uses outside the feed chain for farmed animals: Annex XV, Chapter 8.

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
				(b) In the case of animal by-products for the manufacture of pharmaceuticals: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008 or in Part 1 of Annex I to Regulation (EC) No 119/2009, and the following third countries: (JP) Japan (PH) Philippines	
				(TW) Taiwan. (c) In the case of animal by-products for	
				the manufacture of products for uses outside the feed chain for farmed animals, other than pharmaceuticals:	
				Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 from which imports of fresh meat of the respective species is authorised, in Part 1 of Annex I to Regulation (EC) No 798/2008, in Part 1 of Annex I to Regulation (EC) No 119/2009, or, in the case of material from fish, third countries listed in Annex II to Decision 2006/766/EC.	

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	No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
▼ <u>M4</u>						
	15	Animal by-products for use as raw petfood	Category 3 materials referred to in Article 10(a) and Article 10(b)(i) and (ii).	The products shall comply with the requirements set out in Section 8.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.	Annex XV, Chapter 3(D).
	16	Animal by-products for use in feed for fur animals	Category 3 materials referred to in Article 10(a) to (m)	The products shall comply with the requirements set out in Section 8.	Third countries listed in part 1 of Annex II to Commission Regulation (EU) No 206/2010, or in Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species and where only bone in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.	Annex XV, Chapter 3(D).

_	No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
▼ <u>M1</u>						
	17	Rendered fats for certain purposes outside the feed chain for farmed animals	► M4 (a) In the case of materials destined for the production of biodiesel or oleochemical products: Categories 1, 2 and 3 materials referred to in Articles 8, 9 and 10. ◀	The rendered fats shall comply with the requirements set out in Section 9.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 and, in the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.	Chapter 10(B) of Annex XV.
			(b) In the case of materials destined to the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV:			
			Category 2 and 3 materials referred to in Articles 9 and 10.			
			(c) In the case of materials destined to organic fertilisers and soil improvers:			
			Category 2 materials referred to in Article 9, points (c) and (d) and Article 9, point (f)(i) and Category 3 materials referred to in Article 10, other than in points (c) and (p).			

▼<u>M1</u>

	No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
			(d) In the case of materials destined to other purposes:			
			Category 1 materials referred to in Article 8, points (b), (c) and (d), Category 2 materials referred to in Article 9, points (c), (d) and Article 9, point (f)(i) and Category 3 materials referred to in Article 10, other than in points (c) and (p).			
▼ <u>M4</u>						
	18	Fat derivatives	for uses outside the feed chain for farmed animals: Category 1 materials referred to in Article 8(b), (c) and (d), Category 2 materials referred to in Article 9(c) and (d) and Article 9(f)(i) and Category 3 materials referred to in Article 10. (b) In the case of fat derivatives for use as feed: Category 3 materials other than materials referred to in	The fat derivatives shall comply with the requirements set out in Section 10.	Any third country.	 (a) In the case of fat derivatives for uses outside the feed chain for farmed animals: Annex XV, Chapter 14(A). (b) In the case of fat derivatives for use as feed: Annex XV, Chapter 14(B).
-			Article 10(n), (o) and (p);			

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
19	Photogelatine	Category 1 materials referred to in Article 8(b) and Category 3 materials referred to in Article 10.	The imported photogelatine shall comply with the requirements set out in Section 11.	Photogelatine may only be imported from establishments of origin in the United States and in Japan that are authorised in accordance with Section 11.	Annex XV, Chapter 19.
20	Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, for the production of organic fertilisers or soil improvers	Category 3 materials referred to in Article 10(a), (b), (h) and (n).	The products shall comply with the requirements set out in Section 12.	Any third country.	Annex XV, Chapter 18.

Section 2

Imports of blood and blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals

The following requirements shall apply to the import of blood and blood products, excluding those from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals:

 The blood products must originate from a plant for the production of derived products for uses outside the feed chain for farmed animals which meets the specific conditions laid down in this Regulation or from the establishment of collection.

▼ M4

- 2. The blood from which blood products for the manufacture of derived products for uses outside the feed chain for farmed animals are produced must have been collected under veterinary supervision:
 - (a) in slaughterhouses:
 - (i) approved in accordance with Regulation (EC) No 853/2004; or
 - (ii) approved and supervised by the competent authority of the country of collection; or
 - (b) from live animals in facilities approved and supervised by the competent authority of the country of collection.

▼<u>B</u>

- 3.1. In the case of blood products for the manufacture of derived products for uses outside the feed chain for farmed animals 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 must 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 the case of blood products not treated in accordance with point (a) the products must originate from a third country or region:
 - (i) where no case of rinderpest, peste des petits ruminants and Rift Valley fever has been recorded for a period of at least 12 months and in which vaccination has not been carried out against those diseases for a period of at least 12 months;
 - (ii) where no case of foot-and-mouth disease has been recorded for a period of at least 12 months, and,
 - in which vaccination has not been carried out against this disease for a period of at least 12 months, or

- in which vaccination programmes against foot-and-mouth disease are being officially carried out and controlled in domestic ruminant animals for a period of at least 12 months; in this case, following the veterinary checks 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.
- 3.2. In addition to point (b)(i) and (ii) of point 3.1, in the case of animals other than Suidae and Tayassuidae, one of the following conditions must be complied with:
 - (a) in the third country or region of origin no case of vesicular stomatitis and bluetongue (including the presence of seropositive animals) has been recorded for a period of at least 12 months and vaccination has not been carried out against those diseases for a period of at least 12 months in the susceptible species;
 - (b) following the veterinary checks 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.
- 3.3. In addition to point (b)(i) and (ii) of point 3.1, in the case of Suidae and Tayassuidae, in the third country or region of origin no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for a period of at least 12 months, vaccination has not been carried out against those diseases for a period of at least 12 months and one of the following conditions are complied with:
 - (a) in the country or region of origin no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for a period of 12 months and vaccination has not been carried out against this disease for a period of at least 12 months in the susceptible species;
 - (b) following the veterinary checks 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 for farmed animals which have been derived from poultry and other avian species, they must comply with the following conditions of either point (a) or (b):
 - (a) the products must 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 must originate from a third country or region:
 - which has been free from Newcastle disease and highly pathogenic avian influenza as listed in the Terrestrial Animal Health Code of the OIE, 2010 edition;
 - (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.

Section 3

Imports of blood and blood products from equidae

The following requirements shall apply to the import of blood and blood products from equidae:

▼ M4

- 1. The blood must comply with the conditions set out in point 1(a) of Chapter IV of Annex XIII and must be collected under veterinary supervision:
 - (a) in slaughterhouses:
 - (i) approved in accordance with Regulation (EC) No 853/2004; or
 - (ii) approved and supervised by the competent authority of the country of collection; or
 - (b) from live equidae in facilities approved and furnished with a veterinary approval number and supervised by the competent authority of the country of collection for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding.

▼B

The blood products must comply with the conditions set out in point 2 of Chapter IV of Annex XIII.

In addition, the blood products referred to in point 2(b)(i) of Chapter IV of Annex XIII 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 points (a) and (b) of the first subparagraph of Article 5(2) of Directive 2009/156/EC;
- (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 point 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;

▼ M4

(d) in the case of blood products other than serum and plasma, vesicular stomatitis for a period of at least six months.

▼<u>B</u>

- Blood products must come from an establishment or plant which has been approved or registered by the competent authority of the third country.
- 4. Blood and blood products shall be packed and labelled in accordance with point 3 of Chapter IV of Annex XIII.

Section 4

Imports of hides and skins of ungulates

The following requirements shall apply to the 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 Table 2 set out in Section 1 which, as appropriate to the species concerned:
 - for a period of at least 12 months before dispatch, has been free from all of the following diseases:
 - classical swine fever,
 - African swine fever, and
 - Rinderpest; and
 - (ii) has been free from foot-and-mouth disease for a period of at least 12 months before the date of dispatch and where, for a period of at least 12 months before the date of dispatch, no vaccination has been carried out against that disease;
 - (b) they have been obtained from:
 - (i) animals that have remained in the territory of the third country of origin for a period of 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.
- Treated hides and skins referred to in point C.2 of Chapter V of Annex XIII may be imported without any restrictions.
- 3. Other 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 column 'third countries' list' of row 5 of Table 2 set out in Section 1 from which imports of fresh meat of the corresponding species are authorised and they have been treated as referred to in point 28(a), (b) and (c) of Annex I;
 - (ii) a third country appearing on the list set out in point (a) of the applicable column of row 5 of Table 2 set out in Section 1 and they have been treated as referred to in point 28(c) or (d) of Annex I; or
 - (iii) equidae or ruminant animals from a third country appearing on the list set out in point (b) of the column 'third countries' list' of row 5 of Table 2 of Section 1, and have been treated as referred to in point 28(a), (b) and (c) of Annex I and after treatment have been kept separate for a period of 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 point 28(b) or (c) of Annex I and have been kept separated after treatment during transportation for a period of at least 14 days in the case of the treatment referred to in point 28(b) or seven days in the case of the treatment referred to in point 28(c) before importation and the health certificate accompanying the consignment attests such treatment and the duration of the transportation.
- 4. Fresh, chilled or treated hides and skins of ungulates must be imported in containers, road vehicles, railway wagons or bales sealed under the responsibility of the competent authority of the third country of dispatch.

Section 5

Imports of game trophies and other preparations from animals

The following requirements shall apply to the import of game trophies and other preparations from animals:

- Game trophies or other preparations from animals which fulfil the conditions referred to in points B and C.1 of Chapter VI of Annex XIII may be imported without restrictions.
- 2. Treated game trophies or other preparations from birds and ungulates, being solely comprised of bones, horns, hooves, claws, antlers, teeth, hides or skins, from third countries may be imported if they comply with the requirements of point C.1(a) and point C.2(a), (i) to (iii) and (b)(i) and (ii) of Chapter VI of Annex XIII.

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.

- 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.

Section 6

Imports of treated feathers, parts of feathers and down

Treated feathers and parts of feathers and down may be imported:

- (a) if they are treated decorative feathers, treated feathers carried by travellers for their private use or consignments of treated feathers or down sent to private individuals for non-industrial purposes; or
- (b) if they are accompanied by a commercial document stating that the feathers and parts of feathers or down have been treated with a steam current or by another method that ensures that no unacceptable risks remain and are securely enclosed in packaging and dry; and
- (c) unless the commercial document states that they have been factory-washed and treated with hot steam at 100 °C for at least 30 minutes, they are sent to a registered establishment or plant for such treatment.

Section 7

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

- 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 feed chain if:
 - (a) the products are dried before export to the Union and not chilled or frozen:

▼ M9

(b) the products are conveyed from the third country of origin directly to a border inspection post of entry into the Union and are not transhipped at any port or place outside the Union;

▼ <u>B</u>

(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 third 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) confirmation of the fact that the product was:
 - (i) derived from healthy animals slaughtered in a slaughterhouse;
 - (ii) dried for a period of 42 days at an average temperature of at least 20 °C;
 - (iii) heated for one hour to at least 80 °C to the core before drying;
 - (iv) ashed for one hour to at least 800 °C to the core before drying;
 - (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 fertilisers or soil improvers.

3. On dispatch to the Union, 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 veterinary checks 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 directly to the registered establishment or plant of destination.

Section 8

Imports of animal by-products for the manufacture of feed for fur animals, petfood, other than raw petfood, and derived products for uses outside the feed chain for farmed animals

Animal by-products intended for the manufacture of feed for fur animals, petfood, other than raw petfood, and for derived products for uses outside the feed chain for farmed animals may be imported provided that:

- 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;
- the animal by-products have undergone all precautions to avoid contamination with pathogenic agents;
- the animal by-products were packed in new packaging preventing any leakage or in packaging which has been cleaned and disinfected before use;

- 4. following the veterinary 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 to:
 - (a) a petfood plant or to a registered establishment or plant of destination, which has provided a 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 establishment or plant untreated other than for direct disposal;
 - (b) an establishment or plant which has been approved in accordance with Article 24(1)(h) of Regulation (EC) No 1069/2009;
 - (c) a registered user or collection centre, which has provided a guarantee that the animal by-products shall be used only for permitted purposes, as specified by the competent authority if necessary; or
 - (d) an establishment or plant which has been approved in accordance with Article 24(1)(a) of Regulation (EC) No 1069/2009; and
- 5.1. in the case of raw material for petfood production referred to in Article 35(a)(ii) of Regulation (EC) No 1069/2009, the raw material shall:
 - (a) be marked in the third country before entry into 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 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); or
 - (ii) an establishment or plant of destination which has been approved in accordance with Article 24(1)(h) of Regulation (EC) No 1069/2009, in accordance with point 4(b) of this Section 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 5.1, 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 points (a) and (b) only in the petfood plant of destination and only immediately prior to use of the material for the manufacture of petfood, in accordance with the conditions applicable to petfood produced from Category 3 material set out in Chapter II of Annex XIII;

- 5.2. in the case of consignments made up of raw material, which has been treated as referred to in point 5.1 above and other non-treated raw material, all the raw materials in the consignment have been marked as laid down in point 5.1(a) and (b) above;
- 5.3. the marking referred to in point 5.1(a) and (b) and point 5.2 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 Regulation (EC) No 1069/2009 shall be stored before production, used and disposed of 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.

Section 9

Imports of rendered fats for certain purposes outside the feed chain for farmed animals

Rendered fats which are not destined to the production of feed for farmed animals, the manufacture of cosmetics, medicinal products or medical devices, may be imported, provided:

(a) they are derived from:

▼ M4

 (i) in the case of materials destined for the production of biodiesel or oleochemical products, animal by-products referred to in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009;

▼B

(ii) in the case of materials destined to the production of organic fertilisers and soil improvers, Category 2 materials referred to in points (c), (d) and (f)(i) of Article 9 of Regulation (EC) No 1069/2009, or Category 3 materials, other than materials referred to in points (c) and (p) of Article 10 of Regulation (EC) No 1069/2009;

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- (iii) in the case of materials destined to the production of renewable fuels referred to in point J of Section 2 of Chapter IV of Annex IV of this Regulation, Category 2 materials referred to in Article 9 of Regulation (EC) No 1069/2009 and Category 3 materials referred to in Article 10 of that Regulation;
- (iv) in the case of other materials Category 1 materials referred to in points (b), (c) and (d) of Article 8 of Regulation (EC) No 1069/2009, Category 2 materials referred to in points (c) and (d) and point (f)(i) of Article 9 of Regulation (EC) No 1069/2009 or Category 3 materials, other than the materials referred to in points (c) and (p) of Article 10 of that Regulation;

▼<u>B</u>

- (b) they have been processed by processing method 1 (pressure sterilisation) or in accordance with one of the other processing methods referred to in Chapter III of Annex IV;
- (c) in the case of fat from ruminant origin, insoluble impurities in excess of 0,15 % by weight have been removed;

- (d) they have been marked before shipment to the Union so that the minimum concentration of GTH referred to in point 1(b) of Chapter V of Annex VIII is achieved;
- (e) following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, the rendered fats are transported directly to the registered establishment or plant of destination, under conditions which prevent contamination; and
- (f) they bear labels, on the packaging or container indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION'.

Section 10

Imports of fat derivatives

- Fat derivatives may be imported if the health certificate accompanying the consignment certifies:
 - (a) whether the fat derivatives derive from Category 1, 2 or 3 materials;
 - (b) in the case of fat derivatives produced from Category 2 material, that the products:
 - have been produced using a method that at least meets the standards of one of the processes referred to in point 1 of Chapter XI of Annex XIII; and
 - (ii) shall only be used in organic fertiliser or soil improvers or other uses outside the feed chain for farmed animals, other than in cosmetics, pharmaceuticals and medical devices;
 - (c) in the case of fat derivatives produced from Category 1 material, that the products must not be used in organic fertilisers and soil improvers, cosmetics, pharmaceuticals and medical devices; however, they may be used for other purposes outside the feed chain for farmed animals.
- 2. The health certificate referred to in point 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.
- Following the veterinary 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.

Section 11

Imports of photogelatine

- Gelatine which has been produced from material containing bovine vertebral column comprising of Category 1 material in accordance with Article 8(b) of Regulation (EC) No 1069/2009 and which is intended for the photographic industry (photogelatine) may be imported, provided the photogelatine:
 - (a) originates from one of the plants of origin indicated in Table 3;
 - (b) has been produced in accordance with point 6;
 - (c) is imported through one of the border inspection posts of first entry into the Union indicated in Table 3; and
 - (d) is destined for production in an approved photographic factory indicated in Table 3.

Table 3

Imports of photogelatine

Third country of origin	Plants of origin	Member State of destination	Border inspection post of first entry into the Union	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	The Netherlands	Rotterdam	FujifilmEurope, Oudenstaart 1, 5047 TK Tilburg, The Netherlands
	Shizuoka 418-0073 Japan			
	Nitta Gelatin Inc., 2-22 Futamata Yao-City, Osaka 581-0024 Japan	United Kingdom	Liverpool Felixstowe Heathrow	Kodak Ltd. Headstone Drive, Harrow, Middlesex, HA4 4TY, United Kingdom
		Czech Republic	Hamburg	FOMA Bohemia, spol. SRO Jana Krušinky 1604 501 04 Hradec Králove, Czech Republic
United States	Eastman Gelatine Corporation, 227 Washington Street, Peabody,	United Kingdom	Liverpool Felixstowe Heathrow	Kodak Ltd. Headstone Drive, Harrow, Middlesex, HA4 4TY, United Kingdom
	MA, 01960 USA Gelita North America, 2445 Port Neal Industrial Road Sergeant Bluff, Iowa, 51054 USA	Czech Republic	Hamburg	FOMA Bohemia spol. SRO Jana Krušinky 1604 501 04 Hradec Králove, Czech Republic

- 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.
- Following the veterinary 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 Regulation (EC) No 1069/2009 or exported to the third country of origin in accordance with Regulation (EC) No 1013/2006.
- 6. Photogelatine shall be produced according to the following requirements:
 - (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 (pressure sterilisation) as referred to in Chapter III of Annex IV or subjected to a treatment with acid or alkali for a period of at least two days, washing with water, and:
 - (i) following an acid treatment, treating with alkaline solution for a period of at least 20 days; or
 - (ii) following an acid treatment, treating with an acid solution for a period of 10 to 12 hours.

The pH must then be adjusted and the material purified by means of filtration and sterilisation at 138°C to 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 reuse.
- (e) Wrapping and packages containing the photogelatine must carry the words 'photogelatine for the photographic industry only'.

Section 12

Imports of 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

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 that:

- 1. they have been produced in accordance with Chapter XII of Annex XIII; and
- they are conveyed following the veterinary checks 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.

CHAPTER III

SPECIAL RULES FOR CERTAIN SAMPLES

Section 1

Research and diagnostic samples

Unless they are kept for reference purposes or redispatched to the third country of origin, research and diagnostic samples and any products derived from the use of those samples shall be disposed of:

- (a) as waste by incineration;
- (b) by pressure sterilisation and subsequent disposal or use in accordance with Articles 12 to 14 of Regulation (EC) No 1069/2009; or
- (c) in accordance with point 4(b) of Section 1 of Chapter I of Annex VI in case:
 - (i) of quantities not exceeding 2 000 ml; and
 - (ii) provided the samples or derived products have been produced in and dispatched from third countries or parts of third countries, from which Member States authorise imports of fresh meat of domestic bovine animals, which are listed in Part I of Annex II to Regulation (EU) No 206/2010.

Section 2

Trade samples

- The competent authority may authorise the import and transit of trade samples, provided that:
 - (a) they originate from:
 - (i) third countries referred to in the column 'third countries' list' of row 14 of Table 2 of Section 1 of Chapter II of this Annex;
 - (ii) in the case of trade samples which consist of milk, milk-based products or milk-derived products, authorised third countries listed in Annex I to Regulation (EU) No 605/2010;
 - (b) they are accompanied by a health certificate as referred to in Chapter 8 of Annex XV; and

- (c) following the veterinary checks provided for in Directive 97/78/EC, and in accordance with the conditions laid down in Article 8(4) of that Directive, they are transported directly to the approved or registered establishment or plant indicated in the authorisation of competent authority.
- 2. Unless the trade samples are kept for reference purposes, they shall be:
 - (a) disposed of or used in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009; or
 - (b) redispatched to the third country of origin.
- If trade samples are used for testing of machinery, the testing shall be carried out:
 - (a) with dedicated equipment; or
 - (b) with equipment which is cleaned and disinfected before it is used for purposes other than the testing.

During transport to the approved or registered establishment or plant, the trade samples must be packaged in leak-proof containers.

Section 3

Display items

- Import and transit of display items shall take place in accordance with the following conditions:
 - (a) they originate from third countries referred to in the column 'third countries' list' of row 14 of Table 2 of Section 1 of Chapter II;
 - (b) their introduction has been authorised in advance by the competent authority of the Member State where the display item is intended to be used;
 - (c) following the veterinary checks provided for in Directive 97/78/EC, display items must be sent directly to the authorised user.
- 2. Each consignment must be packed in packaging preventing any leakage and must be accompanied by a commercial document which specifies:
 - (a) the description of the material and the animal species of origin;
 - (b) the category of the material;
 - (c) the quantity of the material;
 - (d) the place of dispatch of the material;
 - (e) the name and the address of the consignor;
 - (f) the name and the address of the consignee; and
 - (g) details allowing the identification of the authorisation of the competent authority of destination.

- After the exhibition or after the artistic activity has been concluded, display items shall be:
 - (a) redispatched to the third country of origin;
 - (b) dispatched to another Member State or third country, if such dispatch has been authorised by the competent authority of the Member State or third country of destination in advance; or
 - (c) disposed of in accordance with Articles 12, 13 and 14 of Regulation (EC) No 1069/2009.

CHAPTER IV

SPECIFIC REQUIREMENTS FOR CERTAIN MOVEMENTS OF ANIMAL BY-PRODUCTS

Section 1

Imports of certain Category 1 materials

Materials referred to in Article 26 shall be imported under the following conditions:

- The materials shall be imported with a label attached to the packaging, container or vehicle which indicates 'Prohibited in food, feed, fertilisers, cosmetics, medicinal products and medical devices'.
- 2. The materials shall be directly delivered to an approved or registered establishment or plant for the manufacture of derived products, other than the products referred to in point 1.
- Unused or surplus materials shall be used or disposed of in accordance with Article 12 of Regulation (EC) No 1069/2009.

Section 2

Imports of certain materials for purposes other than feeding to farmed land animals

- 1. The competent authority may authorise the import of the following materials for purposes other than feeding to farmed land animals, except for feeding to fur animals, provided there is no unacceptable risk for the transmission of diseases communicable to humans or animals:
 - (a) animal by-products from aquatic animals and derived products from aquatic animals;
 - (b) aquatic invertebrates and derived products from aquatic invertebrates;
 - (c) terrestrial invertebrates, including any of their transformation forms, such as larvae, and derived products therefrom;
 - (d) products generated by the animals referred to in points (a), (b) and (c), such as fish eggs;
 - (e) Category 3 material comprising of animals and parts thereof of the zoological orders of Rodentia and Lagomorpha.
- Imports of consignments of the materials referred to in point 1 shall take place in accordance with sanitary certification requirements in accordance with national rules.

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CHAPTER V

RULES FOR THE EXPORT OF CERTAIN DERIVED PRODUCTS

Rules applicable to the export of the derived products listed below as referred to in Article 25(4):

	Derived products	Rules for export
1	fertilizers, compost or digestion residues from biogas trans- formation containing no other animal by-products or derived	Processed manure and organic fertilizers, compost or digestion residues from biogas transformation containing no other animal by-products or derived products than processed manure must comply at least with the conditions set out in points (a), (b), (d) and (e) of Section 2 of Chapter I of Annex XI.

ANNEX XV

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 third country, based on the models set out in this Annex, according to the layout of the model that corresponds to the animal by-products or derived products concerned. Thev 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 e), comprises more than one page, each page shall be numbered (page number) of (total number of pages) at the bottom of the page and shall bear the code number of the certificate that has been designated by the competent authority at the top of the page.
- (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 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.

Veterinary certificate to EU

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COUNTRY:

CHAPTER 1

Health certificate

For processed animal protein, other than those derived from farmed insects, not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through (2) the European Union

	l.1.	Consignor						Certificate refere	nce No	1.2.a.		
		Name Address					I.3. Central competent authority I.4. Local competent authority					
		Tel.										
nment	1.5.	Consignee Name Address					I.6. Person responsible for the load in EU Name Address					
ned consign		Postcode Tel.						Postcode Tel.				
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code		Region of origin	Code	1.9.	Country of destination	ISO code	I.10. Region of destination	Code	
l : Detai	l.11.	.11. Place of origin					I.12.	Place of destinat	ion	I		
Part		Name Approval number Address Name Approval number						Name Address	-	om warehouse oval number		
		Address Name Approval number Address						Postcode				
	I.13. Place of loading				1.14.	Date of departure	e					
	l.15.	i. Means of transport Aeroplane □ Ship □ Railway wagon □ Road vehicle □ Other □					I.16.	Entry BIP in EU				
		Identification					1.17.					
		Documentation references										

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I.18.	Description of commodit	ty			I.19. Commo	odity c	ode (HS code)
						1.20.	Quantity
l.21.	Temperature of product Ambient □	Chilled		Frozen 🖸]	1.22.	Number of packages
1.23.	Seal/Container No					1.24.	Type of packaging
1.25.	Commodities certified for	or:					
	Animal feedingstuff □	Technic	cal use 🗖	Manufacture of	petfood \square		
1.26.	For transit through EU to	o third country		I.27. For import	or admission in	ito EU	
	Third country	ISO code					
1.28.	Identification of the com			-6 - 4-b-12-b4-			
		Appr	ovai number	of establishments			
Sp	pecies (Scientific Na name)	ature of commodity	Manufacti	uring plant	Net weight		Batch number

▼<u>M15</u>

COUNTRY

II.

Health information

Processed animal protein, other than those derived from farmed insects, not intended for human consumption including mixtures and products other than petfood containing such protein

II.b.

		the E	uropean Parli	amen	I veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of and of the Council (1a) and in particular Article 10 thereof, and Commission Regulation and in particular Section 1 of Chapter II of Annex X, and Chapter I of Annex XIV thereto and						
1110111	II.1.		the processed animal protein or product described above contains exclusively processed animal protein not intended for human consumption that:								
art III. Certiiicatioii		(a)			d and stored in an establishment or plant approved and supervised by the competent ance with Article 24 of Regulation (EC) No 1069/2009, and						
מון ווי		(b)	has been pre	epared	exclusively with the following animal by-products:						
_			(²) either	[-	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;]						
			(²) and/or	[-	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) carcases 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;						
					(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 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 intended 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	[-	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 establishments or plants manufacturing products for human consumption;]						

II.a. Certificate reference No

Part II: Certification

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COUNTRY

Processed animal protein, other than those derived from farmed insects, not intended for human consumption including mixtures and products other than petfood containing such protein

						containing such protein
II.	Health informatio	n		II.a.	Certificate reference No	II.b.
	(²) and/or	[-			erial originating from animals which did ough that material to humans or animal	
			(i) shells	from s	shellfish with soft tissue or flesh;	
			(ii) the fo	llowing	g originating from terrestrial animals:	
			— I	natcher	ry by-products,	
			_ 6	eggs,		
			_ 6	∍gg by-	-products, including egg shells;	
			(iii) day-o	ld chicl	ks killed for commercial reasons;]	
	(²) and/or	[-	aquatic and and other th		strial invertebrates other than species pects;]	athogenic to humans or animals
	(²) and/or	[-	Category 1	materia	thereof of the zoological orders of Ro ial as referred to in Article 8(a)(iii), (iv) rticle 9(a) to (g) of Regulation (EC) No	and (v) and Category 2 material
	and					
	(c) has been so	ubjecte	d to the follov	ving pr	rocessing standard:	
	(²) either	at a	pressure (al	osolute	perature of more than 133°C for at least e) of at least 3 bars produced by satur ot more than 50 millimetres;]	
	(²) or			(indica	nmalian protein other than fishmeal, the ate the processing method) as set ou 2/2011;]	
	(²) or	(ind			the processing method 1-2-3-4-5-6-7 g method) as set out in Chapter III c	
	(²) or	(ind No	icate the pro	cessing ere in	plood, the processing method 1-2-3-4-5- g method) as set out in Chapter III c case of method 7 a heat treatment of e;]	f Annex IV to Regulation (EU)
II.2.	the competent aut following standard		examined a r	andom	n sample immediately prior to dispatch	and found it to comply with the
	Salmonella:		Abser	nce in 2	25 g: n = 5, c = 0, m = 0, M = 0	
	Enterobacteriacea	ıe:	n = 5,	c = 2,	m = 10, M = 300 in 1g;	
II.3.	the product has ur	ndergoi	ne all precaut	ions to	avoid recontamination with pathogenic	agents after treatment;
II.4.	the end product:					
	(²) either [was p	acked	in new or ste	rilised I	bags,]	

COUNTRY

Processed animal protein, other than those derived from farmed insects, not intended for human consumption including mixtures and products other than petfood containing such protein

II.	Health information			II.a.	Certificate reference No	II.b.	
	(²) or		ansported in ted before u		in cont	ainers or other means of transport tha	t were thoroughly cleaned and
	which bear	r labels in	ndicating 'NC	T FOR	R HUM	AN CONSUMPTION';	
II.5.	the end pro	oduct wa	s stored in e	nclosed	d stora	ge;	
(²) [II.6.	the proces			or pro	oduct o	described above contains or is derive	d from animal-by products of
	(²) (either		e with		atry or region, which is classified as p ion 2007/453/EC, and in which there	0 00
	(2) (or	with Decis by-product ban on th	ion 200 t or der ne feed as def	07/453, rived p ding of fined in	try or region classified as posing a neg /EC in which there has been an indiger roduct were derived from animals borr if ruminants with meat-and-bone me the OIE Terrestrial Animal Health Code , and]	nous BSE case, and the animal nafter the date from which the al and greaves derived from
	(²) 6	either	[is derived	from o	ther ru	minants than bovine, ovine or caprine a	nimals.]
	(²) (or	[is derived	from b	ovine,	ovine or caprine animals and does not o	contain and is not derived from:
			(²) either	contin	nuously	ne and caprine materials other than the reared and slaughtered in a country of EF risk in accordance with Decision 200	or region classified as posing a
			(²) or	[(a)		ified risk material as defined in point 1 99/2001 of the European Parliament an	
				(b)	capri reare negli	nanically separated meat obtained from animals, except from those animals and and slaughtered in a country or gible BSE risk in accordance /453/EC (⁵), in which there has been no	s that were born, continuously region classified as posing a with Commission Decision
				(c)	capri centr introd crani and s	al by-product or derived product ob ne animals which have been killed, after al nervous tissue by means of an elco duced into the cranial cavity, or by m al cavity, except for those animals that slaughtered in a country or region classion an accordance with Decision 2007/453/E	er stunning, by laceration of the ongated rod-shaped instrument neans of gas injected into the were born, continuously reared fied as posing a negligible BSE
II.7.	the proces	sed anim	nal protein or	produc	ct desc	ribed above:	
	(²) either		ot contain m animals, oth			oducts of ovine or caprine animal origir imals.]	n or is not intended for feed for
	(²) or			ilk or milk products of ovine or caprine animal origin and is intended for feed for farmed er than fur animals, and the milk or milk products:			
						I caprine animals which have been ke conditions are fulfilled:	pt continuously since birth in a
		(i)	C	lassical	ıl scrap	ie is compulsorily notifiable;	

COUNTRY

Processed animal protein, other than those derived from farmed insects, not intended for human consumption including mixtures and products other than petfood containing such protein

					containing such protein		
II.	Health information		II.a.	Certificate reference No	II.b.		
	(ii)	an awar	eness	s, surveillance and monitoring system is	in place for classical scrapie;		
	(iii)			tions apply to holdings of ovine or ca SE or the confirmation of classical scrap			
	(iv)	ovine ar	ovine and caprine animals affected with classical scrapie are killed and destroyed;				
	(v)	defined Health	the feeding to ovine and caprine animals of meat-and-bone meal or greaves, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), of ruminant origin has been banned and effectively enforced in the whole country for a period of at least the preceding seven years;				
	(b) originate from			ere no official restrictions are imposed d	lue to a suspicion of TSE;		
				ere no case of classical scrapie has be en years or, following the confirmation of			
	(²) e	slaughte carrying	ered, e at lea	d caprine animals on the holding have except for breeding rams of the ARR/ ast one ARR allele and no VRQ allele a RR allele;]	ARR genotype, breeding ewes		
	(2) (and the of confi including laborate No 999,	holdir rmatio g testii ory me /2001,	which classical scrapie was confirmed ng has been subjected for a period of a on of the last classical scrapie case ng with negative results for the presence thods set out in point 3.2 of Chapter C of all of the following animals which a animals of the ARR/ARR genotype:	at least two years since the date to intensified TSE monitoring, se of TSE in accordance with the of Annex X to Regulation (EC)		
		— anir	nals w	hich have been slaughtered for human	consumption; and		
				hich have died or been killed on the hol work of a disease eradication campaign			
II.8.				escribed above contains or is derived fement of the Consignor referred to in Bo			
	(²) either [not inten	ded for the produ	ction o	of feed for farmed animals, other than fu	ır animals.]		
	Consigno results of	r has undertaker	n to er rried o	feed for non-ruminant farmed animals, nsure that the Border Inspection Post obut in accordance with the methods set [.]	of entry will be provided with the		

Notes

Part I:

- Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if
 it is a certificate for a commodity to be transited through the European Union; it may be filled in if the certificate is for a
 commodity that is to be imported into the European Union.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. Products in transit may 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 animal protein, other than those derived from farmed insects, not intended for human consumption including mixtures and products other than petfood containing such protein

					<u> </u>	
II.	Health information	II.a.	Certificate reference No		II.b.	
_	Box reference I.19: use the appropriate HS of	ode: (05.05; 05.06; 05.07; 05.11	; 23.01 or 23.09).	
-	Box reference I.25: technical use: any us production or manufacturing of pet food.	e othe	er than feeding of farme	d animals, oth	er than fur animals, and the	
_	Box reference I.26 and I.27: fill in according	to whe	ether it is a transit or an im	port certificate.		
_	Box reference I.28: Species: select from th Suidae, Pesca, Mollusca, Crustacea, inverte the scientific name of the fish.					
Par	t II:					
(^{1a})	OJ L 300, 14.11.2009, p. 1.					
(1b)	OJ L 54, 26.2.2011, p. 1.					
(2)	Delete as appropriate.					
(3)	Where:					
	n = number of samples to be tested;					
	m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;					
	M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and					
	c = number of samples the bacterial cou acceptable if the bacterial count of the			m and M, the	sample still being considered	
(4)	OJ L 147, 31.5.2001, p. 1.					
(⁵)	OJ L 172, 30.6.2007, p. 84.					
(6)	The Person responsible for the load referred to in Box I.6 must ensure that, if the processed animal protein or product described in this health certificate is intended to be used for the production of feed for non-ruminant farmed animals, other than fur animals, the consignment must be analysed, in accordance with the methods set out in Annex VI to Regulation (EC) No 152/2009, in order to verify the absence of unauthorised constituents of animal origin. The information on the result of such analysis must be attached to this health certificate when presenting the consignment at an EU border inspection post.					
(7)	OJ L 54, 26.2.2009, p. 1.					
_	The signature and the stamp must be in a di	fferent	t colour to that of the printi	ng.		
_	Note for the person responsible for the consi and must accompany the consignment until				is only for veterinary purposes	
Offic	cial veterinarian/Official inspector					
	Name (in capital letters):			Qualification a	and title:	
	Date:			Signature:		
	Stamp:					

CHAPTER 1a

Health certificate

For processed animal protein derived from farmed insects not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through $\binom{2}{}$ the European Union

cou	OUNTRY:									Veter	inary certifica	te to EU
	l.1.	Consignor					1.2.	Certificate referen	nce No	1.2.	a	
		Name					Central competent authority Local competent authority					
		Address										
		T-1										
	1.5.	Tel. Consignee					1.6.	Dorson rosponsil	olo for the le	od in EU		
Ŧ	1.5.	Name	•				I.6. Person responsible for the load in EU Name					
men		Address					Address					
sign		Address						Address				
Con		Postcode						Postcode				
ched		Tel.						Tel.				
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code	1.8.	Region of origin	Code	1.9.	Country of destination	ISO code	I.10.	Region of destination	Code
ils of												
Deta	1.11.	Place of origin Name Approval number			l.12.	Place of destinati	on					
= =							Cust	om ware	house			
Par		Address				Name		oval num		_		
		Name		Appro	val number			Address				
		Address										
		Name		Appro	val number			Postcode				
		Address										
	I.13.	Place of lo	ading				I.14. Date of departure					
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU				
		Aeroplane	☐ Ship	П	Railway wa	agon 🗖						
		Road vehic			ranway w	agon —	1.17.					
		Identification	-									
		Document	ation referen	ces								
	I.18.	I.18. Description of commodity					I.19. Comr	modity co	de (HS code)			
										1.00	Overstitus	
	101	T									Quantity	-1
	1.21.		re of produc	t	Obille d F	,			ı	1.22.	Number of pa	ickages
	1.00	Ambient C			Chilled C			Frozen	1	104	Tong of acid	
	1.23.	Seal/Conta	amer No							1.24.	Type of packa	aging

1.25.	Commodities certified for:						
	Animal feedingstuff □		Technical use □		Manufacture of petfood \square		
1.26.	For transit through EU to third country			I.27. For import or admission into EU			
	Third country	ISO cod	е				
I.28.	28. Identification of the commodities Approval number of establishments						
Sp	ecies (Scientific name)	Nature of commo	dity Manufactu	iring plant	Net weight	Batch number	

COUNTRY

Processed animal protein derived from farmed insects not intended for human consumption including mixtures and products other than petfood containing such protein

	II. Health information		th information	II.a. Certificate reference No	II.b.					
		the E	, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Section 1 of Chapter II of Annex X, and Chapter I of Annex XIV thereto and certify that:							
ation	II.1.		processed animal protein derived fro essed animal protein not intended for hi	m farmed insects or product described abuman consumption that:	pove contains exclusively					
Part II: Certification		(a)		n establishment or plant approved and sup 4 of Regulation (EC) No 1069/2009, and	ervised by the competent					
art II:		(b)	has been prepared exclusively from fa	armed insects of the following species:						
			(²) either [- Black Soldier Fly	(Hermetia illucens);]						
			(²) and/or [- Common Housefl	ly (Musca domestica);]						
			(²) and/or [- Yellow Mealworm	(Tenebrio molitor);]						
			(²) and/or [- Lesser Mealworm	(Alphitobius diaperinus);]						
			(²) and/or [- House cricket (Ac	cheta domesticus);]						
			(²) and/or [- Banded cricket (6	Gryllodes sigillatus);]						
			(²) and/or [- Field Cricket (Gry	llus assimilis).]						
		and								
		(c)	has been processed by method [1]-(EU) No 142/2011;	2]-[3]-[4]-[5]-[7] (²) as set out in Chapter III (of Annex IV to Regulation					
		and								
		(d)	the substrate for the feeding of far following products of animal origin of	med insects may only contain products of Category 3 material:	non-animal origin or the					
			fishmeal;							
			 blood products from non-rumina 	nts;						
			 di and tricalcium phosphate of a 	nimal origin;						
			 hydrolysed proteins from non-ru 	minants;						
			 hydrolysed proteins from hides a 	and skins of ruminants;						
			gelatine and collagen from non-	ruminants;						
			eggs and egg products;							
			 milk, milk based-products, milk-o 	derived products, and colostrum;						
			— honey;							

rendered fats;

COUNTRY

Processed animal protein derived from farmed insects not intended for human consumption including mixtures and products other than petfood containing such protein

II.	Health information		II.a. Certificate reference No	II.b.			
	and						
	materials o		sects and the insects or their larvae have not be hose referred to in point (d) and the substrat				
II.2.	the competent authority examined a random sample immediately prior to dispatch and found it to co following standards $(^3)$:						
	Salmonella:	Absenc	ce in 25 g: n = 5, c = 0, m = 0, M = 0				
	Enterobacteriacea	e: n = 5, c	= 2, m = 10, M = 300 in 1g;				
II.3.	the product has ur	ndergone all precaution	ns to avoid recontamination with pathogenic age	nts after treatment;			
II.4.	the end product:						
	(²) either [was p	acked in new or sterili	sed bags,]				
		ransported in bulk in cted before use,]	containers or other means of transport that we	re thoroughly cleaned and			
	which bear labels indicating 'NOT FOR HUMAN CONSUMPTION/ PROCESSED INSECT PROTEIN – SHALL NOT BE USED IN FEED FOR FARMED ANIMALS EXCEPT AQUACULTURE AND FUR ANIMALS';						
II.5.	the end product wa	as stored in enclosed	storage;				
(²) [II.6.	the processed an ruminant origin and		uct described above contains or is derived fr	om animal-by products of			
	(²) either		country or region, which is classified as posing a negligible BSE risk in ecision 2007/453/EC, and in which there has been no indigenous BSE				
	(²) or	with Decision 2007 by-product or deriv ban on the feedi	country or region classified as posing a negligit (453/EC in which there has been an indigenous ed product were derived from animals born aft ng of ruminants with meat-and-bone meal a ed in the OIE Terrestrial Animal Health Code, ha gion, and]	BSE case, and the animal er the date from which the nd greaves derived from			
	(²) either	[is derived from oth	er ruminants than bovine, ovine or caprine anima	als.]]			
	(²) or	[is derived from boy	rine, ovine or caprine animals and does not conta	ain and is not derived from:			
		continuo	ovine and caprine materials other than those obusty reared and slaughtered in a country or release to BSE risk in accordance with Decision 2007/45	gion classified as posing a			
			specified risk material as defined in point 1 of A No 999/2001 of the European Parliament and of				
			mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except from those animals that were born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Commission Decision 2007/453/EC (5), in which there has been no indigenous BSE case,				

COUNTRY

Processed animal protein derived from farmed insects not intended for human consumption including mixtures and products other than petfood containing such protein

		-	and produc	cis other than petioou	containing such protein
II. Health in	formation		II.a. Certificate refe	erence No	II.b.
		caprii centra introd crania and s	ne animals which haval nervous tissue by luced into the cranical cavity, except for the laughtered in a coun	ve been killed, after stu means of an elongate al cavity, or by means hose animals that were	d from bovine, ovine or nning, by laceration of the ed rod-shaped instrument of gas injected into the born, continuously reared as posing a negligible BSE
II.7. the proce	ssed animal protein or	product desc	ribed above:		
(²) either	[does not contain m farmed animals, othe			prine animal origin or is	s not intended for feed for
(²) or			of ovine or caprine a nd the milk or milk pr		ended for feed for farmed
			caprine animals wh conditions are fulfille		ntinuously since birth in a
	(i) cl	ssical scrapi	e is compulsorily noti	fiable;	
	(ii) aı	awareness,	surveillance and mor	nitoring system is in plac	ce for classical scrapie;
				s of ovine or caprine of classical scrapie;	animals in the case of a
	(iv) o	ne and capri	ne animals affected v	with classical scrapie ar	e killed and destroyed;
	de H	fined in the alth (OIE), o	Terrestrial Animal Ho of ruminant origin ha	ealth Code of the Worl	one meal or greaves, as d Organisation for Animal effectively enforced in the ears;
	(b) originate from	oldings whe	re no official restrictio	ons are imposed due to	a suspicion of TSE;
				al scrapie has been dia ne confirmation of a cas	ignosed during a period of se of classical scrapie:
	SI Ca	ughtered, ex	ccept for breeding rate one ARR allele and	ams of the ARR/ARR	n killed and destroyed or genotype, breeding ewes ner ovine animals carrying
	ar of in la N	d the holding confirmation luding testine oratory meth 999/2001, (g has been subjected of the last classic g with negative resul- nods set out in point	If for a period of at leass all scrapie case to infits ts for the presence of T 3.2 of Chapter C of Ar g animals which are ov	been killed and destroyed, t two years since the date tensified TSE monitoring, SE in accordance with the nnex X to Regulation (EC) yer the age of 18 months,
	-	animals wh	iich have been slaugl	ntered for human consu	mption; and
	_		nich have died or bee ork of a disease erac		out which were not killed in
				ns or is derived from a r referred to in Box I.1,	nimal-by products of non-

COUNTRY

(4) OJ L 147, 31.5.2001, p. 1. (5) OJ L 172 30.6.2007, p. 84. Processed animal protein derived from farmed insects not intended for human consumption including mixtures and products other than petfood containing such protein

			not intended for human consu and products other than petfo			
II.	Health inf	formation	II.a. Certificate reference No	II.b.		
	(²) either	[not intended for the production	of feed for farmed animals, other than fur an	imals.]		
	(²) (°) or [intended for the production of feed for non-ruminant farmed animals, other than fur animals, and the Consignor has undertaken to ensure that the border inspection post of entry into the European Unior will be provided with the results of the analyses carried out in accordance with the methods set out in Annex VI to Commission Regulation (EC) No 152/2009 (⁷).]					
Not	es					
Par	: I:					
-	it is a certificate		signment in the European Union: this box is nrough the European Union; it may be filled i n.			
-			is to be filled in only if it is a certificate for a arehouses and custom warehouses.	transit commodity. Products		
-	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, 23.01 or 23.09.			
_		I.25: technical use: any use oth anufacturing of pet food	ner than feeding of farmed animals, other	than fur animals, and the		
_	Box reference I	26 and I.27: fill in according to wh	ether it is a transit or an import certificate.			
_	Box reference I.	28: Species: insects, specify its so	cientific name.			
Par	: II:					
(^{1a})	OJ L 300, 14.11	.2009, p. 1.				
(1b)	OJ L 54, 26.2.20	011, p. 1.				
(²)	Delete as appro	priate.				
(3)	Where:					
	n = number of	samples to be tested;				
		value for the number of bacterial loes not exceed m;	a; the result is considered satisfactory if the	e number of bacteria in all		
		value for the number of bacteria; amples is M or more; and	the result is considered unsatisfactory if th	e number of bacteria in one		

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.

COUNTRY

Processed animal protein derived from farmed insects not intended for human consumption including mixtures and products other than petfood containing such protein

l	II.	Health information	II.a. Certificate reference	e No	II.b.		
	(⁶)	The Person responsible for the load referred to in described in this health certificate is intended to be than fur animals, the consignment must be analys (EC) No 152/2009, in order to verify the absence result of such analysis must be attached to this Inspection Post.	e used for the production of sed, in accordance with the e of unauthorised constitue	feed for non-ruming methods set out i ents of animal origin	ant farmed animals, other in Annex VI to Regulation n. The information on the		
	(⁷)	OJ L 54, 26.2.2009, p. 1.					
	_	The signature and the stamp must be in a different colour to that of the printing.					
	_	Note for the person responsible for the consignment and must accompany the consignment until it reactions.			nly for veterinary purposes		
	Offic	ial veterinarian/Official inspector					
		Name (in capital letters):		Qualification and t	itle:		
		Date:		Signature:			
		Stamp:					
L							

CHAPTER 2(A)

Health certificate

For milk, milk-based products and milk-derived products not intended for human consumption for dispatch to or transit through $(^2)$ the European Union

COL	JNTR	/ :				Veterinary certifica	te to EU
	l.1.	Consignor	1.2.	Certificate referen	nce No	I.2.a.	
		Name	1.3.	I.3. Central competent authority			
		Address	1.4.	I.4. Local competent authority			
		Tel.					
	1.5.	Consignee	1.6.	I.6. Person responsible for the load in EU			
nen		Name		Name			
ign		Address		Address			
cons		Postcode		Postcode			
ped		Tel.		Tel.			
Part I : Details of dispatched consignment	1.7.	Country ISO code I.8. Region of Code	1.9.	Country of	ISO	I.10. Region of	Code
fdis		of origin origin		destination	code	destination	ı
ils			1				
Deta	l.11.	Place of origin	I.12.	Place of destinati	on		
= =		Name Approval number				Custom warehouse	
Pa		Address		Name		Approval number	
		Name Approval number		Address		Approvarriamber	
		Address		Address			
		Name Approval number		Postcode			
		Address					
	I.13.	Place of loading	1.14.	Date of departure	<u> </u>		
	I.15.	Means of transport	I.16.	Entry BIP in EU			
		Aeroplane ☐ Ship ☐ Railway wagon ☐					
		Road vehicle Other O	117	Number(s) of CIT	FS		
		Identification	1	rvambor(o) or orr			
		Documentation references					
	I.18.	Description of commodity			I.19. Comn	nodity code (HS code)	
						I.20. Quantity	
	I.21.	Temperature of product				I.22. Number of page	ckages
		Ambient ☐ Chilled ☐		Frozen \Box	<u> </u>		
	123	Seal/Container No				124 Type of packa	aina

1.25.	Commodities certified for:			
	Animal feedingstuff ☐ Technical use ☐	Further process C	Production of pet	food 🗆
1.26.	For transit through EU to third	d country	I.27. For import or admission into EU	
	Third country	ISO code		
1.28.	Identification of the commodit	ties		
		Approval number	of establishments	
	Species (Scientific name)	Manufacturing plant	Net weight	Batch number

COUNTRY

Milk, milk-based products and milk-derived products not for human consumption

	II.	Health infor	mation		II.a.		Certificate ref	ference No		11.1).		
		the Europear (EU) No 142/	igned official vet n Parliament and /2011 (^{1b}), and in the milk (²), the mil conditions:	of the operations	Cound or Sec	icil ctic	(^{1a}), and in pon 4 of Chapt	oarticular A er II of Ann	rticle 10 th	ereof, Chapt	and Cor er I of An	mmission Reinex XIV the	egulation reto, and
e o	II.1.		oduced and deriv										
Part II: Certification		listed in Part mouth diseas	I of Annex II to (se (FMD) and rir against rinderpest	Commiss nderpest	ion R for a	Reg a pe	gulation (EU) eriod of 12 m	No 605/20	10 (4), and	which	has bee	n free from t	oot-and-
Part	II.2.	any disease	oduced from raw transmissible thi to production or	rough m	lk to	hι	umans or ani	imals, and	which had	been	kept for	a period of	at least
	II.3.	they are milk	or milk products	that:									
		(²) either	[have undergo	ne one c	f the	tre	eatments or c	ombination	s thereof de	escrib	ed in poir	nt II.4;]	
		(²) or	[comprise whe										and that
			(²) either	[the whe	y wa	is c	collected at le	ast 16 hou	rs after clot	tting a	nd has a	pH below 6;]
			(²) (⁵) or				been produc s of FMD hav						ring that
			(²) (⁵) or	voyage	durat	tio	been produce in, being at le on post of the	east 21 da	ys before t				
	II.4.	they have be	en subject to one	of the f	ollowi	ing	g treatments:						
		(²) either	[high tempera pasteurisation with:										
			(²) either	15 seco	nds c	or a	second high t an equivalent se test in bov	t pasteuris					
			(²) or				drying proc additional hea				milk inte	nded for fe	eding is
			(²) or	[a subsellevel be			process by wl	hich the ph	l is reduced	d and	kept for a	at least one l	nour at a
			(²) (⁵) or		of s	ship	hat the milk/r pping and dui ountry;]						
			(²) (⁵) or	conside	ration	1 o	roduct has be of the foreseer gnment is pr	n voyage d	uration, bei	ng at	east 21 d	days prior to	the date
			(²) or	[sterilisa	tion a	at a	a level of at le	east F ₀ 3;]]					

COUNTRY

Milk, milk-based products and milk-derived products not for human consumption

						for human consumption
II.	Health info	rmation	П	.a.	Certificate reference No	II.b.
	(²) or	[ultra high tem	perature tre	atr	nent at 132°C for at least one second	in combination with:
		(²) either			nt drying process that in the case n additional heating to 72°C or higher;]	
		(²) or	[a subseque level below		t process by which the pH is reduced]	and kept for at least one hour at a
		(²) (⁵) or		sh	that the milk/milk product has been pipping and during that period no cases ntry;]	
		(²) (⁵) or	considerat	ion	product has been produced on// of the foreseen voyage duration, bein signment is presented to a border i	g at least 21 days prior to the date
.5.	every preca processing;	aution was taker	n to avoid	cor	ntamination of the milk/milk-based p	product/milk-derived product after
.6.	the milk/milk	k-based product/n	nilk-derived	pro	oduct was packed:	
	(²) either	[in new contain	ners;]			
	(²) or	[in vehicles of competent aut		ıtaiı	ners disinfected prior to loading us	sing a product approved by the
	and		bear labels		so as to indicate the nature of the mil dicating that the product is Category	•
1.7.	the milk, mil	k-based products	and milk-d	eriv	red products described above:	
	(²) either	[does not cont farmed animal			c products of ovine or caprine animal o ur animals.]	origin or is not intended for feed for
	(²) or				cts of ovine or caprine animal origin a als, and the milk or milk products:	nd is intended for feed for farmed
		(a)			om ovine and caprine animals which hatry where the following conditions are	
			(i)		classical scrapie is compulsorily notifia	able;
			(ii)		an awareness, surveillance and mo classical scrapie;	onitoring system is in place for
			(iii)		official restrictions apply to holdings c case of a suspicion of TSE or the conf	
			(iv)		ovine and caprine animals affected widestroyed;	rith classical scrapie are killed and
			(v)		the feeding to ovine and caprine an greaves, as defined in the Terrestrial Organisation for Animal Health (Olf banned and effectively enforced in the least the preceding seven years;	Animal Health Code of the World E), of ruminant origin has been
		(b)	originate fi of TSE;	om	holdings where no official restriction	s are imposed due to a suspicion

COUNTRY

Milk, milk-based products and milk-derived products not

000111				mink, mink-based producte	for human consumption
II.	Health information	1	l.a. Ce	ertificate reference No	II.b.
	(c)		eriod of	oldings where no case of classic f at least the preceding seven year al scrapie:	
		(²) either	des gen	ovine and caprine animals on th troyed or slaughtered, except for otype, breeding ewes carrying at le le and other ovine animals carrying	breeding rams of the ARR/ARF east one ARR allele and no VRC
		(²) or	and leas scra neg labo Reg are	animals in which classical scrapie destroyed, and the holding has but two years since the date of capie case to intensified TSE mative results for the presence coratory methods set out in point 3 over the age of 18 months, exceptotype:	peen subjected for a period of a confirmation of the last classica onitoring, including testing with of TSE in accordance with the 3.2 of Chapter C of Annex X tall of the following animals which
			_	animals which have been slaug and	ghtered for human consumption
			-	animals which have died or bee were not killed in the frame campaign.]]	
Notes					
Part I:					
				the European Union: this box is re the European union; it may be t	

- commodity to be imported into the European Union.
- 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 the 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: 04.01; 04.02; 04.03; 04.04; 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.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the production or manufacturing of pet food.
- 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:

- (1a) OJ L 300, 14.11.2009, p. 1.
- (1b) OJ L 54, 26.2.2011, p. 1.

COUNTRY

Milk, milk-based products and milk-derived products not for human consumption

II.	Health information	II.a.	Certificate reference No		II.b.
(2)	Delete as appropriate.				
(3)	For completion if the authorisation to import the third country concerned.	t into d	or transit through the Euro	pean Union	is restricted to certain regions of
(4)	OJ L 175, 10.7.2010, p. 1.				
(⁵)	this condition applies only to third countries	isted i	n column 'A' of Annex I to	Regulation (EU) No 605/2010.
(⁶)	OJ L 147, 31.5.2001, p. 1.				
_	The signature and the stamp must be in a di	fferen	t colour to that of the printir	ng.	
_	Note for the person responsible for the cons and must accompany the consignment until				ate is only for veterinary purposes
Offic	cial veterinarian/Official inspector				
	Name (in capital letters):			Qualification	n and title:
	Date:			Signature:	
	Stamp:				

CHAPTER 2(B)

Health certificate

For colostrum and colostrum products from bovine animals not intended for human consumption for dispatch to or transit through $(^2)$ the European Union

COL	JNTR	/ :				Veterinary certifica	te to EU
	l.1.	Consignor	1.2.	Certificate referen	nce No	I.2.a.	
		Name	1.3.	Central competer	nt authority		
		Address	1.4.	Local competent	authority		
		Tel.					
	1.5.	Consignee	1.6.	Person responsib	le for the loa	ad in EU	
nen		Name		Name			
ign		Address		Address			
cons		Postcode		Postcode			
ped		Tel.		Tel.			
Part I : Details of dispatched consignment	1.7.	Country ISO code I.8. Region of Code	1.9.	Country of	ISO	I.10. Region of	Code
fdis		of origin origin		destination	code	destination	ı
ils			1				
Deta	l.11.	Place of origin	I.12.	Place of destinati	on		
= =		Name Approval number				Custom warehouse	
Pa		Address		Name		Approval number	
		Name Approval number		Address		Approvarriamber	
		Address		Addiess			
		Name Approval number		Postcode			
		Address					
	I.13.	Place of loading	1.14.	Date of departure	<u> </u>		
	I.15.	Means of transport	I.16.	Entry BIP in EU			
		Aeroplane ☐ Ship ☐ Railway wagon ☐					
		Road vehicle Other O	117	Number(s) of CIT	FS		
		Identification	1	rvambor(o) or orr			
		Documentation references					
	I.18.	Description of commodity			I.19. Comn	nodity code (HS code)	
						I.20. Quantity	
	I.21.	Temperature of product				I.22. Number of page	ckages
		Ambient ☐ Chilled ☐		Frozen \Box	<u> </u>		
	123	Seal/Container No				124 Type of packa	aina

1.25.	Commodities certified for:			
	Animal feedingstuff ☐ Technical use ☐	Further process C	Production of pet	food 🗆
1.26.	For transit through EU to third	d country	I.27. For import or admission into EU	
	Third country	ISO code		
1.28.	Identification of the commodit	ies		
		Approval number	of establishments	
	Species (Scientific name)	Manufacturing plant	Net weight	Batch number

COUNTRY

Colostrum and colostrum products from bovine animals not for human consumption

II.	Health informa	ation	II.a. Certificate reference No	II.b.					
	the European (EU) No 142/20	Parliament and of the 011 (^{1b}), and in particu	an, declare that I have read and understood e Council (¹a), and in particular Article 10 the ular Section 4 of Chapter II of Annex X and C olostrum products (²) referred to in box I.28 co	ereof, and Commission Regulation Chapter I of Annex XIV thereto, and					
II.1.			(in						
	listed in Annex disease (FMD)	I to Commission Re	(in gulation (EU) No 605/2010 (⁴), and which h a period of 12 months immediately prior that period;	as been free from foot-and-mouth					
II.2.	any disease tra	insmissible through co the date of production	derived from animals which at the time of m olostrum to humans or animals, and which ha on on holdings that were not subject to officia	ad been kept for a period of at leas					
II.3.	pasteurisation	at 72°C for at least 1	ducts of bovine animals that have been subj 5 seconds, or an equivalent pasteurisation n, in combination with:						
	(²) (⁵) either	(5) either [the condition that the colostrum or colostrum products have been produced during a period a least 21 days before the date of shipping and during this period no cases of FMD have been detected in the exporting country,]							
	(²) (⁵) or	(²) (⁵) or [the condition that the colostrum or colostrum products have been produced on// (inset the date), this date, in consideration of the foreseen voyage duration, being at least 21 day before the consignment is presented to a border inspection post of the European Union,]							
	and		led from animals subject to regular veterina gs on which all bovine herds are:	ry inspections to ensure that they					
		(²) (⁵) either	[recognised as officially tuberculosis and br	ucellosis free (6),]					
		(²) (⁵) or	[not restricted under the national legislation eradication of tuberculosis and brucellosis,]						
	and	(²) (⁵) either	[recognised as official enzootic-bovine-leukosis-free $(^6)$,]						
		(²) (⁵) or	[included in an official system for the contr there has been no evidence as result of cl disease in the herd during the period of the	inical and laboratory testing of this					
II.4.	every precaution	on has been taken to a	avoid contamination of the colostrum/colostru	ım product after processing;					
II.5.	the colostrum o	or colostrum product v	vas packed:						
	(²) either	[in new containers	3,]						
	(²) or	[in vehicles or be competent author	ulk containers disinfected prior to loading ity,]	using a product approved by the					
	and		e marked so as to indicate the nature of the ating that the product is Category 3 mate						
II.6.	the colostrum o	or colostrum product d	loes not contain milk or milk products of ovine	e or caprine animal origin.					
Notes									
Part I:									
cer	tificate for a com		the load in the European Union: this box is and through the European Union; it may be						

COUNTRY

Colostrum and colostrum products from bovine animals not for human consumption

II.	Health information	II.a.	Certificate reference No		II.b.			
_	Box reference I.12: Place of destination: thi	s box	is to be filled in only if it is a	certificate f	or transit commodity.			
_	Box reference I.15: Registration number (ris to be provided. In the case of unloading inspection post of the European Union.							
_	Box reference I.19: use the appropriate H 23.09.10, 23.09.90, 35.01, 35.02 or 35.04.	armor	nised System (HS) code of	the World	Customs Organisation: 04.04.90;			
_	Box reference I.23: for bulk containers, the	conta	ner number and the seal nu	ımber (if apı	olicable) must be included.			
_	Box reference I.25: technical use: any u production or manufacturing of pet food	se ot	ner than feeding of farme	d animals,	other than fur animals, and the			
_	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': p	rovide	the registration number of	the treatme	nt or processing establishment.			
Par	t II:							
(^{1a})	OJ L 300, 14.11.2009, p. 1.							
(1b)	OJ L 54, 26.2.2011, p. 1.							
(2)	Delete as appropriate.							
(3)	For completion if the authorisation for introcountry concerned.	oducti	on into the European Unio	n is restrict	ed to certain regions of the third			
(4)	OJ L 175, 10.7.2010, p. 1.							
(5)	This condition applies only to third coun No 605/2010 (OJ L 175, 10.7.2010, p. 1).	tries	authorised in column 'A' o	of Annex I	to Commission Regulation (EU)			
(⁶)	Officially tuberculosis-free and brucellosis-29.7.1964, p. 1977/64) and officially enzo Directive.							
_	The signature and the seal must be in a diff	ferent	colour from that of the print	ng.				
_	Note for the importer: this certificate is only the border inspection post of the European			t accompan	y the consignment until it reaches			
Offi	cial veterinarian/Official inspector							
	Name (in capital letters):			Qualification	on and title:			
	Date:			Signature:				
	Stamp:							

CHAPTER 3(A)

Health certificate

For canned petfood intended for dispatch to or for transit through $(^2)$ the European Union

COUNTRY:										Vete	erinary certifica	te to EU
	l.1.	Consignor					1.2.	Certificate refere	nce No	1.2	2.a.	
		Name					1.3.	Central compete	nt authority			
		Address					1.4.	Local competent	authority			
		Tel.										
	1.5.	Consignee)				1.6.	Person responsil	ole for the loa	ad in E	U	
ent		Name						Name				
gnm		Address						Address				
onsi												
ğ		Postcode						Postcode				
tche		Tel.						Tel.				
lispa	1.7.	Country of origin	ISO code	1.8.	Region of origin	Code	1.9.	Country of destination	ISO code	I.10.	Region of destination	Code
of d												
Part I : Details of dispatched consignment	l.11.	Place of or	rigin	1			1.12.	Place of destinat	ion			
 De												
ar -		Name		Appro	val number					Cus	tom warehouse	
۵		Address						Name		Арр	roval number	
		Name		Appro	val number			Address				
		Address										
		Name		Appro	val number			Postcode				
		Address										
	I.13.	Place of lo	ading				1.14.	Date of departure	Э			
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU				
		Aeroplane	☐ Ship		Railway wa	agon 🗖						
		Road vehi	cle 🔲 Othe	er 🗆			1.17.					
		Identificati	on									
		Document	ation referen	ces								
	I.18.	Description	n of commod	ity					I.19. Comr	nodity	code (HS code)	
											23.09	
										1.20	. Quantity	
	I.21.	Temperatu	ire of produc	t						1.22	. Number of pa	ckages
		Ambient 🗖]		Chilled C]		Frozen 🗖]	\perp		
	123	Seal/Conta	ainer No							124	Type of nacka	aina

1.25.	Commodities certified for:			
	Petfood \square		Technical use \square	
I.26.	For transit through EU to third	d country	I.27. For import or admission into EU	
	Third country	ISO code		
l.28.	Identification of the commodit	ties Approval number	of establishments	
	Species (Scientific name)	Manufacturing plant	Net weight	Batch number

n.	Health info	mati	on	II.a. Certificate reference No	II.b.
	the Europea Regulation (an Pa EU) I	irliament and of th	an, declare that I have read and understood Reg ne Council (^{1a}), and in particular Articles 8 and and in particular Chapter II of Annex XIII and Ch d above:	ulation (EC) No 1069/2009 o 10 thereof, and Commission
II.1.				establishment or plant approved and supervised ation (EC) No 1069/2009;	by the competent authority in
II.2.	has been pro	epare	d exclusively with t	the following animal by-products:	
	(²) either	[-	killed, and which	rts of animals slaughtered or, in the case of gam are fit for human consumption in accordance with an consumption for commercial reasons;]	
	(²) and/or	[-	slaughterhouse a mortem inspection	following parts originating either from animals that nd were considered fit for slaughter for human control or bodies and the following parts of animals accordance with Union legislation:	onsumption following an ante-
			C	arcases or bodies and parts of animals which ar onsumption in accordance with Union legislation igns of disease communicable to humans or anim	, but which did not show any
			(ii) h	eads of poultry;	
			ir	ides and skins, including trimmings and splitt ncluding the phalanges and the carpus and me netatarsus bones;	
			(iv) p	ig bristles;	
			(v) fe	eathers;]	
	(²) and/or	[-	Article 1(3)(d) of	cts from poultry and lagomorphs slaughtered o Regulation (EC) No 853/2004 of the Europ h did not show any signs of disease communicable	ean Parliament and of the
	(²) and/or	[-	humans or anima having been cor	which did not show any signs of disease cor ils, obtained from animals that have been slaught nsidered fit for slaughter for human consumption ordance with Union legislation;]	ered in a slaughterhouse after
	(²) and/or	[-		cts arising from the production of products inten- sed bone, greaves and centrifuge or separator sluce	
	(²) and/or	[-	intended for huma	al origin, or foodstuffs containing products of anim an consumption for commercial reasons or due to s or other defects from which no risk to public or a	problems of manufacturing or
	(²) and/or	[-	derived products	dingstuffs of animal origin, or feedingstuffs cont which are no longer intended for feeding for c ufacturing or packaging defects or other defects f ie;]	commercial reasons or due to
	(²) and/or	[-		wool, feathers, hair, horns, hoof cuts and raw mill w signs of any disease communicable through	
	(²) and/or	[-		and parts of such animals, except sea mammals, nunicable to humans or animals;]	which did not show any signs
	(²) and/or	[-	animal by-produc	ts from aquatic animals originating from plants or an consumption:	establishments manufacturing

II. Health information			II.a.	Certificate reference No	II.b.
	(²) and/or	[- the following	g material orig	ginating from animals which did not	
		communica	ole through that	material to humans or animals:	
		(i)	shells from	shellfish with soft tissue or flesh;	
		(ii)	the following	ng originating from terrestrial animals:	
			— hatche	ery by-products,	
			— eggs,		
			— egg by	y-products, including egg shells;	
		(iii)	day-old chi	cks killed for commercial reasons;]	
	(²) and/or	[- animal by- humans or		iquatic or terrestrial invertebrates othe	r than species pathogenic to
	(²) and/or	Category 1	material as refe	f of the zoological orders of Roden rred to in Article 8(a)(iii), (iv) and (v) of F referred to in Article 9(a) to (g) of that R	Regulation (EC) No 1069/2009
	(²) and/or	Council Dir	ective 96/22/EC	h have been treated with certain substact (2b), the import of the material being n (EC) No 1069/2009;]	
1.3.	has been su	bjected to heat tre	atment to a min	imum Fc value of 3 in hermetically seale	ed containers;
II. 4 .				ast five samples from each processed l the whole consignment as foreseen und	
II.5.	has undergo	one all precautions	to avoid contan	nination with pathogenic agents after tre	atment.
(²) [II.6.	the petfood	described above			
	(²) either	[is derived fron	other ruminant	s than bovine, ovine or caprine animals.	.]
	(²) or	[is derived fron	bovine, ovine	or caprine animals and does not contain	and is not derived from:
		(²) either	continuous	ine and caprine materials other than tho ly reared and slaughtered in a country o 3SE risk in accordance with Decision 20	or region classified as posing a
		(²) or		offied risk material as defined in point 1 999/2001 of the European Parliament ar	
		(²) or	(b) mec capi rear negl		and of the Council (3); m bones of bovine, ovine of stat were born, continuously region classified as posing a with Commission Decision

COL	UNTRY	_	Canned Petfood
II.	Health information	II.a. Certificate reference No	II.b.
Not	es		
Part	t I :		
_	Box reference I.6: Person responsible for the it is a certificate for a commodity to be tran commodity to be imported into the European	sited through the European Union; it may	
_	Box reference I.12: Place of destination: this transit may only be stored in free zones, free		te for transit commodity. Products in
_	Box reference I.15: Registration number (ra information is to be provided in the event of		
_	Box reference I.23: for bulk containers, the c	container number and the seal number (if	applicable) must be given.
_	Box reference I.25: technical use: any us production or manufacturing of pet food	se other than feeding of farmed animal	s, other than fur animals, and the
-	Box reference I.26 and I.27: fill in according	to whether it is a transit or an import certif	icate.
_	Box reference I.28: Species: select from th Suidae, Pesca, Mollusca, Crustacea, inverte		
Part	t II:		
(^{1a})	OJ L 300, 14.11.2009, p. 1.		
(1b)	OJ L 54, 26.2.2011, p. 1.		
(2)	Delete as appropriate.		
(^{2a})	OJ L 139, 30.4.2004, p. 55.		
(^{2b})	OJ L 125, 23.5.1996, p. 3.		
(3)	OJ L 147, 31.5.2001, p. 1.		
(4)	OJ L 172, 30.6.2007, p. 84.		
_	The signature and the stamp must be in a di	ifferent colour to that of the printing.	
_	Note for the person responsible for the cons and must accompany the consignment until		ificate is only for veterinary purposes
Offic	cial veterinarian/Official inspector		
	Name (in capital letters):	Qualific	ation and title:
	Date:	Signatu	re:
	Stamp:		

(CHAPTER 3(B)

Health certificate

For processed petfood other than canned petfood, intended for dispatch to or for transit through $\binom{2}{2}$ the European Union

COL	JNTRY	Y :								Vete	erinary certifica	te to EU	
	l.1.	Consignor					1.2.	Certificate refere	nce No	1.2	2.a.		
		Name					1.3.	Central compete	nt authority				
		Address					I.4. Local competent authority						
		Tel.											
	1.5.	Consignee)				1.6.	Person responsil	ole for the lo	ad in E	U		
Jent		Name						Name					
Is of disp		Address					Address						
suo		Dantanda						Destanda					
ed c		Postcode						Postcode					
atch		Tel.	100		Danier of	0-4-	1.0	Tel.	100	140	Danies of	0-4-	
dsip	1.7.	Country of origin	ISO code	1.8.	Region of origin	Code	1.9.	Country of destination	ISO code	1.10.	Region of destination	Code	
of													
tails	l.11.	Place of or	rigin				I.12.	Place of destinat	ion				
ä													
art		Name		Appro	val number					Cus	tom warehouse		
-		Address						Name		Арр	roval number		
		Name		Appro	val number			Address					
		Address											
		Name		Appro	val number			Postcode					
		Address											
	I.13.	Place of lo	ading				1.14.	Date of departure	Э				
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU					
		Aeroplane	☐ Ship		Railway wa	agon 🗖							
		Road vehi	cle 🔲 Othe	er 🔲			1.17.						
		Identificati	on										
		Document	ation referen	ces									
	I.18.	Description	n of commod	ity					I.19. Comr	nodity (code (HS code)		
1										1.20	. Quantity		
	1.21.	Temperatu	re of product	i						1.22	. Number of pa	ckages	
		Ambient C]		Chilled C]		Frozen]				
	123	Seal/Conta	ainer No							124	Type of packs	aina	

1.25.	Commodities certified for:			
	Petfood 🗆		Technical use ☐	
1.26.	For transit through EU to th	nird country	I.27. For import or admission into EU	
	Third country	ISO code		
1.28.	Identification of the commo		of establishments	
	Species (Scientific name)	Manufacturing plant	Net weight	Batch number

▼M15

COUNTRY

Processed petfood other than canned petfood II. Health information Certificate reference No I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (1a), and in particular Articles 8 and 10 thereof, and Commission Regulation (EU) No 142/2011 (1b), and in particular Chapter II of Annex XIII and Chapter II of Annex XIV thereto, 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; Part II: Certification 11.2. has been prepared exclusively with the following animal by-products: (2) either 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;] 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-(2) and/or [mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation: carcases or bodies and parts of animals which are rejected as unfit for human (i) 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; (iv) pig bristles; feathers:1 (v) animal by-products from poultry and lagomorphs slaughtered on the farm as referred to in Article 1(3)(d) of Regulation (EC) No 853/2004 of the European Parliament and of the (2) and/or [-Council (2a), which did not show any signs of disease communicable to humans or animals] (2) and/or blood of animals which did not show any signs of disease communicable through blood to ſhumans or animals, obtained from 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;] animal by-products arising from the production of products intended for human consumption, (2) and/or [including degreased bone, greaves and centrifuge or separator sludge from milk processing;] products of animal origin, or foodstuffs containing products of animal origin, which are no longer (2) and/or [intended 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 feedingstuffs of animal origin, or feedingstuffs 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 arise:1 (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;]

	Health info	rmati	on		II.a.	Certificate reference No	II.b.					
	(²) and/or	[-		by-products f ts for human		aquatic animals originating from planting fr	ants or establishments	manufacturing				
	(²) and/or	[-				riginating from animals which d at material to humans or animals:	id not show any sig	ns of disease				
			(i)	shells from s	hellfi	sh with soft tissue or flesh;						
			(ii)	the following	origi	nating from terrestrial animals:						
				hatche	ry by	-products,						
				— eggs,								
				— egg by	-prod	lucts, including egg shells,						
			(iii)	day-old chicl	ks kill	ed for commercial reasons;]						
	(²) and/or	[-		by-products s or animals;]		aquatic or terrestrial invertebrate	es other than species	pathogenic t				
	(²) and/or	[-	Catego	ry 1 material	as re	eof of the zoological orders of ferred to in Article 8(a)(iii), (iv) and as referred to in Article 9(a) to (g) o	(v) of Regulation (EC)					
	(²) and/or	[-	Counci	Directive 96	3/22/E	ich have been treated with certain EC (2b), the import of the material ion (EC) No 1069/2009;]						
3.												
	(²) either	[wa	[was subjected to a heat treatment of at least 90 °C throughout its substance;]									
	(²) or	[wa	s produc	ed as regards	s ingre	edients of animal origin using exclu	usively products which	had been:				
		(a)			mal by-products or derived products from meat or meat products subjected to a at least 90 °C throughout its substance;							
		(b)	in the c	ase of milk ar	and milk based products,							
			(i)	Commission	Reg	nird countries or parts of third cour ulation (EU) No 605/2010 (³) sub uce a negative phosphatase test;						
			(ii)	column C of	Anne	d to less than 6 from third countri ex I to Regulation (EU) No 605/20 nt to produce a negative phosphat	10, first submitted to a					
			(iii)	Regulation ((EU)	nird countries or parts of third cour No 605/2010, submitted to a st each treatment was sufficient to p	erilisation process or	a double hea				
			(iv)	Regulation (disease in	(EU) the p	nird countries or parts of third cour No 605/2010, where there has be preceding 12 months or where a carried out in the preceding12 mo	been an outbreak of to vaccination against to	oot-and-mout				
				either								
				— a steril	isatio	n process whereby an Fc value ec	ual or greater than 3 is	achieved				
				or								
						at treatment with a heating effect						

▼M15

COUNTRY Processed petfood other than canned petfood II. Health information Certificate reference No 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 (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, 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 only material with a molecular weight below 10000 Dalton and a process involving the preparation of raw Category 3 material by brining, liming and intensive washing followed by: exposure of the material to a pH of more than 11 for more than three hours at a temperature of more than 80 $^{\circ}\text{C}$ and subsequently by heat treatment at more than 140 °C for 30 minutes at more than 3,6 bar; or exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed by (ii) 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 Chapter III of Annex IV to Regulation (EU) No 142/2011; or treated in accordance with Chapter II of Section X of Annex III to Regulation (EC) No 853/2004; 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 Chapter III of Annex IV to Regulation (EU) No 142/2011; (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; 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 Chapter III of Annex IV to Regulation (EU) No 142/2011: in the case of fishmeal submitted to any of the processing methods 1 to 7 as referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011 or to a method and parameters which ensure that the product complies with the microbiological standards for derived products set out in Chapter I of Annex X to Regulation (EU) No 142/2011; in the case of rendered fat, including fish oils, submitted to any of the processing methods 1 to

5 or 7 (and method 6 in the case of fish oil) as referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011 or produced in accordance with Chapter II of Section XII of Annex III to Regulation (EC) No 853/2004; rendered fats from ruminant animals must be purified in such a way that the maximum level of the remaining total insoluble impurities does not excess 0,15% in

II.	Health inf	ormati	on		II.a	. Certifi	cate ref	erence N	0	П	.b.
		(I)	in the	case of di	calcium	phospha	te produ	iced by a	process that		
			(i)	and trea	ited with	dilute hy	drochlo		at a minimum		nd degreased with hot wate entration of 4 % and a pH o
			(ii)								of the obtained phosphori ate at pH 4 to 7; and
			(iii)						m phosphate °C and 65 °C		nlet temperature of 65 °C
		(m)	in the	case of tri	calcium	phospha	ite produ	iced by a	process that	ensur	es
			(i)			y 3 bone chips les			y crushed an	nd deg	reased in counter-flow wit
			(ii)	continuo	ous cook	ing with	steam a	t 145 °C	during 30 min	utes a	it 4 bar;
			(iii)	separati centrifuç			ein brot	h from t	he hydroxya	patite	(tricalcium phosphate) b
			(iv)	granulat	ion of th	e tricalci	um phos	sphate af	er drying in a	fluid k	oed with air at 200 °C ;
		(n)		ensure t							nt method and parameters I standards referred to i
	(²) or			ct to a tr authority;]		such a	s drying	g or ferm	nentation, wh	ich ha	as been authorised by th
	(²) or	anir	nals, ha	as been su	ubject to	a treatm	nent whi	ch has b	een authorise	d by t	pathogenic to humans on the competent authority an animal health;]
II.4.	was analy storage at									essed	batch taken during or afte
	Salmonella	a:		absence	e in 25g:	n = 5, c	= 0, m =	0, M = 0	,		
	Enterobac	teriacea	ae:	n = 5, c	= 2, m =	10, M =	300 in 1	I gramme	; ;		
II.5.	has under	gone al	l precau	utions to a	void con	taminatio	on with p	athogeni	c agents after	r treat	ment;
II.6.		that th	e cont								ckages on which it is clearl ating "NOT FOR HUMAI
(²) [II.7.	the petfood	d descr	ibed ab	ove							
	(²) either	[is d	lerived [.]	from other	ruminar	nts than t	oovine, o	ovine or c	aprine anima	ls.]	
	(²) or	[is d	lerived [.]	from bovin	ie, ovine	or caprii	ne anim	als and d	oes not conta	iin and	is not derived from:
		(²) e	either	continuo	ously rea	ared and	d slaugl	ntered in		or reg	erived from animals born ion classified as posing .]]

(2b) OJ L 125, 23.5.1996, p. 3. (3) OJ L 175, 10.7.2010, p. 1.

	UNTRY	·	od other than canned petfood
II.	Health information	II.a. Certificate reference No	II.b.
	ani sla acc	chanically separated meat obtained from bon mals, except from those animals that were ughtered in a country or region classified as produce with Commission Decision 2007/453/lindigenous BSE case,	born, continuously reared and posing a negligible BSE risk in
	ani nei the thc or	mal by-product or derived product obtained mals which have been killed, after stunning rous tissue by means of an elongated rod-sha cranial cavity, or by means of gas injected in se animals that were born, continuously reare region classified as posing a negligible BSE ris 17/453/EC.]]]	, by laceration of the centra aped instrument introduced into to the cranial cavity, except for d and slaughtered in a country
Not	es		
Par	t I:		
-		ne consignment in the European Union: this box nsited through the European Union; it may be t n Union.	
-	Box reference I.12: Place of destination: thi intransit may only be stored in free zones, f	s box is to be filled in only if it is a certificate fo ree warehouses and custom warehouses.	r a transit commodity. Products
_		ailway wagons or container and lorries), flight no I reloading, the consignor must inform the bord	
-		monized System (HS) code under the following 15.01, 15.02, 15.03, 15.04, 23.01, 23.09; 28.	
_	Box reference I.23: for bulk containers, the	container number and the seal number (if applic	cable) must be given.
-	Box reference I.25: technical use: any u production or manufacturing of pet food.	se other than feeding of farmed animals, oth	ner than fur animals, and the
_	Box reference I.26 and I.27: fill in according	to whether it is a transit or an import certificate.	
_	Box reference I.28: Species: select from t Suidae, Pesca, Mollusca, Crustacea, Invert	ne following: Aves, Ruminantia, Suidae, Mamr ebrates other than Mollusca and crustacea.	nalia other than Ruminantia o
Par	t II:		
(^{1a})	OJ L 300, 14.11.2009, p. 1.		
(^{1b})	OJ L 54, 26.2.2011, p. 1.		
(²)	Delete as appropriate.		
(^{2a})	OJ L 139, 30.4.2004, p. 55.		

COL	JNTR	Υ		Pro	cessed petfoo	d other than canned petfood
II.		Health information	II.a.	Certificate reference No		II.b.
(4)	Whe	re:				
	n =	number of samples to be tested;				
	m =	threshold value for the number of basamples does not exceed m;	cteria;	the result is considered	satisfactory if	the number of bacteria in all
	M =	maximum value for the number of bac more samples is M or more; and	teria; tł	he result is considered uns	satisfactory if th	e number of bacteria in one or
	c =	number of samples the bacterial cou acceptable if the bacterial count of the			m and M, the	sample still being considered
(5)	OJ L	147, 31.5.2001, p. 1.				
(⁶)	OJ L	172, 30.6.2007, p. 84.				
-	The	signature and the stamp must be in a di	fferent	colour to that of the printing	ng.	
_		for the person responsible for the cons must accompany the consignment until				
Offic	cial ve	terinarian/Official inspector				
	Nam	e (in capital letters):			Qualification a	and title:
	Date	:			Signature:	
	Stam	np:				

CHAPTER 3(C)

Health certificate

For dogchews intended for dispatch to or for transit through $(^2)$ the European Union

COL	JNTRY	/ :				Veterinary certificate to EU			
	l.1.	Consignor	1.2.	Certificate refere	nce No	I.2.a.			
		Name	1.3.	Central compete	nt authority				
		Address	1.4.	I.4. Local competent authority					
		Tel.	10	D	h l - C - 10 - 1-	ara en			
	1.5.	Consignee Name	1.6.	Person responsi	pie for the loa	ad in EU			
men		Address		Address					
sign		Address		Address					
Cons		Postcode		Postcode					
ped		Tel.		Tel.					
Part I : Details of dispatched consignment	1.7.	Country ISO code I.8. Region of Code origin	1.9.	Country of destination	ISO code	I.10. Region of Code destination			
tails	1.11.	Place of origin	1.12.	Place of destinat	ion				
e									
ar -		Name Approval number				Custom warehouse			
		Address		Name		Approval number			
		Name Approval number		Address					
		Address							
		Name Approval number		Postcode					
		Address							
	I.13.	Place of loading	I.14.	Date of departure	е				
	I.15.	Means of transport	I.16.	Entry BIP in EU					
		Aeroplane ☐ Ship ☐ Railway wagon ☐							
		Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐	1.17.						
		Identification	1.17.						
		Documentation references							
	I.18.	Description of commodity			I.19. Comr	modity code (HS code)			
				L		I.20. Quantity			
	1.21.	Temperature of product				I.22. Number of packages			
		Ambient ☐ Chilled ☐		Frozen C]				
	1.23.	Seal/Container No				I.24. Type of packaging			

1.25.	Commodities certified for:			
	Petfood 🗆		Technical use ☐	
1.26.	For transit through EU to th	nird country	I.27. For import or admission into EU	
	Third country	ISO code		
1.28.	Identification of the commo		of establishments	
	Species (Scientific name)	Manufacturing plant	Net weight	Batch number

II.	Health info	rmati	on		II.a.	Certificat	e referer	nce No		II.b.			
	I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (¹a), and in particular Article 10 of that Regulation, and Commission Regulation (EU) No 142/2011 (¹b), and in particular Chapter II of Annex XIII and Chapter II of Annex XIV thereto, and certify that the dogchews described above:												
II.1.	have been prepared exclusively with the following animal by-products:												
	(²) either [- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of killed, and which are fit for human consumption in accordance with Union legislation, but intended for human consumption for commercial reasons;]												
	(²) and/or	[-	slaugh morter	ses and the faterhouse and inspection mption in ac	nd were	consider dies and	ed fit for the follo	slaughter wing par	r for huma	an consun	ption fol	lowing a	n ante
_			(i)	carcases consumpti disease co	on in ac	ccordanc	e with Ur	nion legis	lation, but				
			(ii)	heads of p	oultry;								
			(iii)	hides and phalanges									ing th
			(iv)	pig bristles	s;								
			(v)	feathers;]									
	(²) and/or	[-	humar having	of animals ns or animals g been cons ction in accor	s, obtair sidered	ned from fit for s	animals laughter	that have for huma	been slau	ughtered i	n a slaug	hterhous	se afte
	(²) and/or	[-		l by-product ing degrease									
	(²) and/or	[-		c animals, a ease commu					ea mamm	als, which	did not	show an	y sign
	(²) and/or	[-		l by-products cts for huma			nimals ori	iginating f	rom plant	s or estab	ishments	s manufa	cturin
	(²) and/or	nd/or [- material from animals which have been treated with certain substances which are pro Council Directive 96/22/EC (^{2a}), the import of the material being permitted in accord Article 35(a)(ii) of Regulation (EC) No 1069/2009;]											
II.2.	have been	subje	cted										
	(²) either			of dogchew athogenic o								atment su	ıfficier
	(²) and/or			e of dogchev a heat treat							nd skins	of ungul	ates c
II.3.				om sampling plant and c						ssed bate	taken	during o	or afte
	Salmonella	:		absence	in 25g:	n = 5, c	= 0, m = 0	0, M = 0,					
	Enterobacte	eriace	ae:	n = 5 c :	= 2. m =	10. M =	300 in 1	gramme;					

▼M15

COUNTR	TRY Dogchews											
II.	Health info	mation		II.a.	Certificate reference No	II.b.						
11.4.	have underg	one all preca	utions to a	avoid cor	ntamination with pathogenic agents after	treatment;						
II.5.	were packed	d in new pack	aging;									
(²) [II.6.	the dogchews described above											
	(²) either	(²) either [is derived from other ruminants than bovine, ovine or caprine animals.]]										
	(²) or	[is derived from bovine, ovine or caprine animals and does not contain and is not derived from:										
		(²) either [bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC.]]										
		(²) or		specified risk material as defined in point 1 of Annex V to Regulation No 999/2001 of the European Parliament and of the Council (4);								
			° a s	nimals, laughter ccordan	ally separated meat obtained from bot except from those animals that were ed in a country or region classified as ce with Commission Decision 2007/453 nous BSE case,	born, continuously reared and posing a negligible BSE risk in						
			r tl tl	nimals vinimals vinimals to the crania	y-product or derived product obtained which have been killed, after stunnin issue by means of an elongated rod-shal cavity, or by means of gas injected in mals that were born, continuously rear classified as posing a negligible BSE r (EC.]]]	g, by laceration of the central aped instrument introduced into nto the cranial cavity, except for ed and slaughtered in a country						

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 a commodity to be imported into the European
 Union
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. Products
 in transit may 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);
 the information is to be provided in the event of unloading and reloading in the European Union.
- Box reference I.19: 05.11, 23.09, 41.01 or 42.05.
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be given.
- Box reference I.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the
 production or manufacturing of pet food.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
- Box reference I.28: Species: select from the following: Aves, Ruminantia, Suidae, Mammalia Other Than Ruminantia or Suidae, Pesca, Mollusca, Crustacea, Invertebrates Other Than Mollusca And Crustacea.

Part II:

- (^{1a}) OJ L 300, 14.11.2009, p. 1.
- (1b) OJ L 54, 26.2.2011, p. 1.

COL	JNTRY					Dogchews				
II.	Health infor	mation	II.a.	Certificate reference No		II.b.				
(2)	Delete as appropri	ate.								
(^{2a})	OJ L 125, 23.5.199	96, p. 3.								
(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.									
(4)	OJ L 147, 31.5.200	01, p. 1.								
(5)	OJ L 172, 30.6.200	07, p. 84.								
_	The signature and	the stamp must be in a di	fferer	nt colour to that of the printir	ng.					
_				ent in the European Union: ches the border inspection p		te is only for veterinary purposes into the European Union.				
Offic	cial veterinarian/Offi	cial inspector								
		•								
	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 fur animals, intended for dispatch to or for transit through $(^2)$ the European Union

COL	JNTR	Y :								Veterinary certific	ate to EU
	l.1.	Consignor					1.2.	Certificate refere	nce No	I.2.a.	
		Name					1.3.	Central compete	nt authority	Lance Control of the	
		Address					1.4.	Local competent	authority		
		Tel.									
	1.5.	Consignee Name					1.6.	Person responsil	ole for the loa	ad in EU	
men		Address						Name Address			
sign		Address						Address			
CO		Postcode						Postcode			
hed		Tel.						Tel.			
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code	1.8.	Region of origin	Code	1.9.	Country of destination	ISO code	I.10. Region of destination	Code
s of											
etail	l.11.	Place of orig	gin				I.12.	Place of destinat	ion		
□ ::											
Part	Name Approval number									Custom warehouse	
		Address						Name		Approval number	
		Name		Appro	val number			Address			
		Address									
		Name		Appro	val number			Postcode			
		Address						5			
	1.13.	Place of loa	ding				I.14. 	Date of departure	9		
	I.15.	Means of tra	ansport				I.16.	Entry BIP in EU			
		_	_	_							
		Aeroplane D			Railway wa	agon 🛘					
		Road vehicl		rШ			l.17.				
	Identification Documentation references										
	140								140 0		
	1.18.	Description	or commodi	ty					1.19. Comr	modity code (HS code)	
								L		I.20. Quantity	
	1.21.	Temperatur	e of product							I.22. Number of pa	ackages
		Ambient \square			Chilled C]		Frozen C]		
	123	Seal/Contain	ner No							124 Type of nack	aning

1.25.	Commodities certific	ed for:									
	Petfood			Technical use □							
1.26.	For transit through I	EU to third country		I.27. For import of	or admission into EU						
	Third country	ISO code									
1.28.	I.28. Identification of the commodities Approval number of establishments										
(8	Species Scientific name)	Nature of commodity	Manufactu	uring plant	Net weight	Batch number					

COUNTRY

Raw petfood for direct sale or animal by- products to be fed to fur animals

	II.	Health informati	on	II.a. Certificate reference No	II.b.							
		the European Pa (EU) No 142/201	rliament and of the Council	re that I have read and understood Regula (1a) and in particular Article 10 thereof, ar pter II of Annex XIII and Chapter II of Ann scribed above:	nd Commission Regulation							
_	II.1.	consist of animal	by-products that satisfy the	health requirements below;								
icatio	II.2.	consist of animal	by-products:									
Certif		(a) derived from	m meat which satisfies the re	elevant animal and public health requiremen	its laid down in:							
Part II: Certification		derive	ed come from the third count	206/2010 (³) and provided that the animatives, territories or parts thereof								
		meat case	is derived come from the thi of a country, or codes in the	EC) No 798/2008 (4), and provided that the countries, territories or parts thereof e case of territories or parts thereof) as liste ease and avian influenza for the last 12 more	(ISO code in the ed in that Regulation which							
		meat case has b vesici	— and/or Commission Regulation (EC) No 119/2009 (⁵), and provided that the animals from which the meat is derived come from the third countries, territories or parts thereof									
		period of 2	4 hours before the time of s	hterhouse, have passed the ante-mortem halaughter and have shown no evidence of the halaman are susceptible; and								
		killing in ac	ccordance with the relevant	nandled in the slaughterhouse before and provisions of Union legislation and have rs II and III of Council Regulation (EC) No 1	met requirements at least							
		public heal	th requirements laid down in	e derived from aquatic animals which satis n Commission Decision 2006/766/EC $(^7)$, a O code of the country) as listed in Annex II	and come from countries or							
	II.3.1.	consist only of the	e following animal by-produc	ts:								
		were deem		ntered or, in the case of game, bodies or parts of animals killed which oftion in accordance with Union legislation until irreversibly declared as asons;								
		signs of di		e rejected as unfit for human consumption lumans or animals and derived from carca legislation;								
	II.3.2.	in the case of fee	d for fur animals in addition t	to II.3.1. consist also of the following animal	by-products:							
		(²) either [-	Article 1(3)(d) of Regulat	poultry and lagomorphs slaughtered on t ion (EC) No 853/2004 of the Europea show any signs of disease communicable to	n Parliament and of the							
		(²) and/or [-	humans or animals, obtain	lid not show any signs of disease comm led from animals that have been slaughtere fit for slaughter for human consumption vith Union legislation;]	d in a slaughterhouse after							
		(²) and/or [-		g from the production of products intende greaves and centrifuge or separator sludge								

COUNTRY

Raw petfood for direct sale or animal by- products to be fed to fur animals

				<u> </u>	red to fur animais
II.	Health info	rmat	ion	II.a. Certificate reference No	II.b.
	(²) and/or	[-	intended for human consu	or foodstuffs containing products of anin imption for commercial reasons or due to r defects from which no risk to public or a	problems of manufacturing or
	(²) and/or	[-	derived products, which a	s of animal origin, or feedingstuffs contained no longer intended for feeding for cg or packaging defects or other defects to	commercial reasons or due to
	(²) and/or	[-		thers, hair, horns, hoof cuts and raw mil of any disease communicable through	
	(²) and/or	[-	aquatic animals, and parts of diseases communicable	s of such animals, except sea mammals, e to humans or animals;]	which did not show any signs
	(²) and/or	[-	animal by-products from a products for human consu	equatic animals originating from plants or imption;]	establishments manufacturing
	(²) and/or	[-		riginating from animals which did not at material to humans or animals:	show any signs of disease
			(i) shells from shellfis	sh with soft tissue or flesh;	
			(ii) the following origin	nating from terrestrial animals:	
			hatchery b	y-products,	
			— eggs,		
			— egg by-pro	oducts, including egg shells,	
			(iii) day-old chicks kille	ed for commercial reasons;]	
	(²) and/or	[-	animal by-products from humans or animals;]	aquatic or terrestrial invertebrates othe	r than species pathogenic to
	(²) and/or	[-	Category 1 material as ref	of of the zoological orders of Roden ferred to in Article 8(a)(iii), (iv) and (v) of F is referred to in Article 9(a) to (g) of that F	Regulation (EC) No 1069/2009
II.4.				ntact with other material which does not a and it has been handled so as to avoid a	
II.5.	CONSUMP CONSUMP preventing NOT FOR I	TION TION any I HUM	' or 'ANIMAL BY-PRODL ' and then placed in leak eakage and officially sealed AN CONSUMPTION' or 'AN	ch bear labels indicating 'RAW PET F JCTS FOR FEED FOR FUR ANIMA c-proof and officially sealed boxes/cont d boxes/containers which bear labels in IIMAL BY-PRODUCTS FOR FEED FOR d the address of the establishment of des	LS — NOT FOR HUMAN tainers or in new packaging dicating 'RAW PET FOOD — FUR ANIMALS — NOT FOR
II.6.	in the case	of rav	v petfood:		
	` '		orepared and stored in a pla 24 of Regulation (EC) No 1	ant approved and supervised by the com 069/2009 and	petent authority in accordance
			ined by random sampling o and complies with the following	of at least five samples from each batch ng standards (8):	taken during storage (before

▼M15

COUNTRY

Raw petfood for direct sale or animal by- products to be fed to fur animals

II.	Health informati	on		II.a. Certificate reference No	II.b.					
	Salmonella:	abs	sence in 25 g	: n=5, c=0, m=0, M=0						
	Enterobacteriace	ae: n=5	5, c=2, m=10	0, M=5000 in 1 gram;						
(²) [II.7.	[the petfood or a products of rumin			ed to fur animals described above contains or is derived from animal-by						
	(²) either			ry or region, which is classified as posing a negligible BSE risk in 2007/453/EC, and in which there has been no indigenous BSE case,						
	(²) or	Decision 200 product or de the feeding defined in the	originates from a country or region classified as posing a negligible BSE risk in accordance with recision 2007/453/EC in which there has been an indigenous BSE case, and the animal byroduct or derived product were derived from animals born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as efined in the OIE Terrestrial Animal Health Code, has been effectively enforced in that country region, and]]							
	(²) either	[is derived fro	om other rum	inants than bovine, ovine or caprine animals	.]]					
	(²) or	[is derived fro	om bovine, ov	vine or caprine animals and does not contain	and is not derived from:					
		(²) either	continuous	ovine and caprine materials other than those derived from animals born, usly reared and slaughtered in a country or region classified as posing a BSE risk in accordance with Decision 2007/453/EC.]]						
		(²) or		ecified risk material as defined in point 1 of A 9999/2001 of the European Parliament and o						
			ca _l an BS	echanically separated meat obtained from prine animals, except from animals that were d slaughtered in a country or region classi E risk in accordance with Commission De- iich there has been no indigenous BSE case	e born, continuously reared fied as posing a negligible cision 2007/453/EC (10), in					
			ca the ins inte	imal by-product or derived product obtain prine animals which have been killed, after a central nervous tissue by means of strument introduced into the cranial cavity, or the cranial cavity, except for those nitinuously reared and slaughtered in a cousing a negligible BSE risk in accordance with	stunning, by laceration of an elongated rod-shaped r by means of gas injected animals that were born, ntry or region classified as					

Notes

Part I:

- Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if
 it is a certificate for a commodity to be transited through the European Union; it may be filled in if the certificate is for a
 commodity to be imported into the European Union.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. Products in transit may 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) is to be provided. In case of unloading and reloading, the consignor must inform the border inspection post of entry into the European Union.
- Box I.19: use the appropriate Harmonized System (HS) code under the following heading: 04.08; 05.06; 05.08; 05.11, 23.01 or 23.09.
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be given.
- Box reference I.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the
 production or manufacturing of pet food.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

COUNTRY

Raw petfood for direct sale or animal by- products to be fed to fur animals

II.	Health information	II.a. Certificate reference No II.b.									
_	Box reference I.28:										
	Nature of commodity: select raw petfood or animal I	py-product.									
	In the case of raw material for the manufacture of ra	w pet food indicate the scientific	c name of the species.								
	In case of raw material for manufacture of feed Mammalia other than Ruminantia or Suidae, Pe Crustacea.										
Part	t II:										
(^{1a})	OJ L 300, 14.11.2009, p. 1.										
(1b)	OJ L 54, 26.2.2011, p. 1.										
(2)	Delete as appropriate.										
(^{2a})	OJ L 139, 30.4.2004, p. 55.										
(3)	OJ L 73, 20.3.2010, p. 1.										
(4)	OJ L 226, 23.8.2008, p. 1.										
(⁵)	OJ L 39, 10.2.2009, p. 12.										
(⁶)	OJ L 303, 18.11.2009, p. 1.										
(7)	OJ L 320, 18.11.2006, p. 53.										
(8)	Where:										
	n = number of samples to be tested;										
	m = threshold value for the number of bacteria; samples does not exceed m;	the result is considered satisfa	actory if the number of bacteria in all								
	M = maximum value for the number of bacteria; t or more samples is M or more; and	ne result is considered unsatisf	actory if the number of bacteria in one								
	c = number of samples the bacterial count of v acceptable if the bacterial count of the other s		M, the sample still being considered								
(⁹)	OJ L 147, 31.5.2001, p. 1.										
(10)	OJ L 172, 30.6.2007, p. 84.										
_	The signature and the stamp must be in a different	colour to that of the printing.									
_	Note for the person responsible for the consignmen and must accompany the consignment until it reach										
Offic	cial veterinarian/Official inspector										
	Name (in capital letters):	Quali	fication and title:								
	Date:	Signa	ature:								
	Stamp:										

CHAPTER 3(E)

Health certificate

For flavouring innards for use in the manufacture of petfood, intended for dispatch to or for transit through $(^2)$ the European Union

COL	JNTR	Y :								Veterinary certific	ate to EU
	l.1.	Consignor					1.2.	Certificate refere	nce No	I.2.a.	
		Name					1.3.	Central compete	nt authority	Lance Control of the	
		Address					1.4.	Local competent	authority		
		Tel.									
	1.5.	Consignee Name					1.6.	Person responsil	ole for the loa	ad in EU	
men		Address						Name Address			
sign		Address						Address			
CO		Postcode						Postcode			
hed		Tel.						Tel.			
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code	1.8.	Region of origin	Code	1.9.	Country of destination	ISO code	I.10. Region of destination	Code
s of											
etail	l.11.	Place of orig	gin				I.12.	Place of destinat	ion		
□ ::											
Part	Name Approval number									Custom warehouse	
		Address						Name		Approval number	
		Name		Appro	val number			Address			
		Address									
		Name		Appro	val number			Postcode			
		Address						5			
	1.13.	Place of loa	ding				I.14. 	Date of departure	9		
	I.15.	Means of tra	ansport				I.16.	Entry BIP in EU			
		_	_	_							
		Aeroplane D			Railway wa	agon 🛘					
		Road vehicl		rШ			l.17.				
	Identification Documentation references										
	140								140 0		
	1.18.	Description	or commodi	ty					1.19. Comr	modity code (HS code)	
								L		I.20. Quantity	
	1.21.	Temperatur	e of product							I.22. Number of pa	ackages
		Ambient \square			Chilled C]		Frozen C]		
	123	Seal/Contain	ner No							124 Type of nack	aning

1.25.	Commodities certific	ed for:				
	Petfood \square			Technical use □		
1.26.	For transit through I	EU to third country		I.27. For import	or admission into EU	
	Third country	ISO code				
1.28.	Identification of the					
		Appro	oval number	of establishments		
(8	Species Scientific name)	Nature of commodity	Manufactu	uring plant	Net weight	Batch number

COUNTRY

Flavouring innards for use in the manufacture of petfood

							of petfood			
	II.	Health info	rmati	on	II.a.	Certificate reference No	II.b.			
		the Europe Regulation	an Pa (EU) I	arliament and of the	Counci in part	that I have read and understood Reg (^{1a}), and in particular Article 8 and icular Chapter III of Annex XIII and Ch described above:	10 thereof, and Commission			
	II.1.	consist of a	nimal	by-products that satisf	y the a	nimal health requirements below;				
cation	II.2.	have been	prepar	ed and include the foll	owing a	animal by-products which are exclusive	ely:			
Part II: Certification		(²) either	[-	killed, and which are	fit for h	als slaughtered or, in the case of gan numan consumption in accordance with ption for commercial reasons;]				
Parl		(²) and/or	[-	slaughterhouse and mortem inspection of	ollowing parts originating either from animals that have been slaughtered in a d were considered fit for slaughter for human consumption following an anteor bodies and the following parts of animals from game killed for human cordance with Union legislation:					
				consumption	in acc	s and parts of animals which are ordance with Union legislation, but whole to humans or animals;				
				(ii) heads of pou	ltry;					
						cluding trimmings and splitting thereof, carpus and metacarpus bones, tarsus a				
				(iv) pig bristles;						
				(v) feathers;]						
		(²) and/or	[-	humans or animals,	obtaine ered fi	d not show any signs of disease cold from animals that have been slaught t for slaughter for human consumpti th Union legislation;]	ered in a slaughterhouse after			
		(²) and/or	[-		arising from the production of products intended for human consumption, bone, greaves and centrifuge or separator sludge from milk processing;]					
		(²) and/or	[-	intended for human of	onsum	r foodstuffs containing products of anin ption for commercial reasons or due to defects from which no risk to public or a	problems of manufacturing or			
		(²) and/or	[-	derived products, wh	nich are	of animal origin, or feedingstuffs con e no longer intended for feeding for c or packaging defects or other defects t	commercial reasons or due to			
		(²) and/or	[-			ers, hair, horns, hoof cuts and raw mil f any disease communicable through				
		(²) and/or	[-			of such animals, except sea mammals, o humans or animals;]	which did not show any signs			
		(²) and/or	[-	animal by-products fr products for human o		uatic animals originating from plants or ption;]	establishments manufacturing			
		(²) and/or	[-			I originating from animals which did not show any signs of disease n that material to humans or animals:				
				(i) shells from sl	nellfish	with soft tissue or flesh;				

COUNTRY

Flavouring innards for use in the manufacture of petfood

					_		of petfood
II.	Health info	rmation			II.a.	Certificate reference No	II.b.
		(i	ii) the	following	origina	iting from terrestrial animals:	
			_	hatche	ery by-	products,	
			_	eggs,			
			-	egg b	y-prod	ucts, including egg shells;	
		(i	iii) day	old chick	s killed	for commercial reasons;]	
	(²) and/or		animal by-p numans or a		rom a	quatic or terrestrial invertebrates other	er than species pathogenic to
	(²) and/or	· C	Category 1	material a	as refer	f of the zoological orders of Roder rred to in Article 8(a)(iii), (iv) and (v) of referred to in Article 9(a) to (g) of that I	Regulation (EC) No 1069/2009
	(²) and/or	· c	Council Dire	ective 96/	/22/EC	n have been treated with certain subsite (^{2a}), the import of the material being n (EC) No 1069/2009;]	
II.3.	have been order to kill				ccorda	nce with Chapter III of Annex XIII to Re	egulation (EU) No 142/2011, in
II.4.						east five samples from each processe with the following standards (3):	ed batch taken during or after
	Salmonella	:	al	sence in	25g: n	= 5, c = 0, m = 0, M = 0,	
	Enterobacte	eriaceae	: n	= 5, c = 2	, m = 1	10, M = 300 in 1 gramme;	
II.5.	the end pro	duct was	s:				
	(²) either	[packe	ed in new o	r sterilised	d bags	.]	
	(²) or					ers or other means of transport that proved by the competent authority before	
	and which b	oear labe	els indicatin	g 'NOT F	OR HL	JMAN CONSUMPTION';	
II.6.	the end pro	duct was	s stored in	enclosed :	storage	e;	
II.7.	the product	has und	lergone all	precaution	ns to a	void contamination with pathogenic ag	ents after treatment;
(²) [II.8.	the flavouri	ng innard	ds products	describe	d abov	ve	
	(²) either	[is der	ived from c	ther rumii	nants t	than bovine, ovine or caprine animals.]]
	(²) or	[is der	ived from b	ovine, ov	ine or o	caprine animals and does not contain a	and is not derived from:
		(²) eith	con	inuously	reared	caprine materials other than those d and slaughtered in a country or in in accordance with Decision 2007/453/	region classified as posing a
		(²) or	[(a)			sk material as defined in point 1 of 1 of the European Parliament and of th	
			(b)	anima slaugh accore	als, exi htered dance	y separated meat obtained from bone cept from those animals that were to in a country or region classified as p with Commission Decision 2007/453/Eus BSE case,	oorn, continuously reared and oosing a negligible BSE risk in
			(c)	anima nervo the cr those or reg	als whi us tiss anial c anima	product or derived product obtained find have been killed, after stunning, the by means of an elongated rod-shabeavity, or by means of gas injected intelled that were born, continuously reared assified as posing a negligible BSE risc.]]]	, by laceration of the central ped instrument introduced into to the cranial cavity, except for and slaughtered in a country

COUNTRY

Flavouring innards for use in the manufacture of petfood

COL	UNIKI		of petfood						
II.	Health information	II.a. Cer	tificate reference No	II.b.					
Note	es								
Part	tl:								
_		odity to be transited through	nt in the European Union: this box n the European Union; it may be fi						
_	Box reference I.12: Place of transit may only be stored in		filled in only if it is a certificate for s and custom warehouses.	transit commodity. Products in					
-	 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 in the European Union. 								
_	Box reference I.19: use the	appropriate HS code: 05.04;	05.06, 05.11 or 23.09 .						
_	Box reference I.23: for bulk	containers, the container nur	nber and the seal number (if applic	able) should be given.					
_	Box reference I.25: technic production or manufacturing		n feeding of farmed animals, oth	er than fur animals, and the					
_	Box reference I.26 and I.27:	fill in according to whether it	is a transit or an import certificate.						
_	Box reference I.28:								
		ne following: Aves, Ruminar Invertebrates other than Moll	itia, Suidae, Mammalia other than usca and crustacea	Ruminantia or Suidae, Pesca,					
	 define the innard prod 	uct.							
Part	t II:								
(^{1a})	OJ L 300, 14.11.2009, p. 1.								
(1b)	OJ L 54, 26.2.2011, p. 1.								
(²)	Delete as appropriate.								
(^{2a})	OJ L 125, 23.5.1996, p. 3.								
(3)	Where:								
	n = number of samples to	be tested;							
	m = threshold value for the samples does not exce		result is considered satisfactory if	the number of bacteria in all					
	M = maximum value for th or more samples is M		sult is considered unsatisfactory if	the number of bacteria in one					
		ne bacterial count of which erial count of the other sampl	may be between m and M, the es is m or less.	sample still being considered					
(4)	OJ L 147, 31.5.2001, p. 1.								
(⁵)	OJ L 172, 30.6.2007, p. 84.								
_	The signature and the stamp	must be in a different colou	r to that of the printing.						
_		ible for the consignment in th nsignment until it reaches th	ne European Union: This certificate e border inspection post.	is only for veterinary purposes					
Offic	cial veterinarian/Official inspec	otor							
	Name (in capital letters):		Qualification a	and title:					
	Date:		Signature:						
	Stamp:								

CHAPTER 3(F)

Health certificate

For animal by-products $(^3)$ for the manufacture of petfood, intended for dispatch to or for transit through $(^2)$ the European Union

COL	JNTRY	Y :								Vete	erinary certifica	te to EU	
	l.1.	Consignor					1.2.	Certificate refere	nce No	1.2	2.a.		
		Name					1.3.	Central compete	nt authority				
Part I: Details of dispatched consignment		Address					1.4.	Local competent	authority				
		- .											
		Tel.					I.6. Person responsible for the load in EU						
	1.5.	Consignee Name	;				I.6. Person responsible for the load in EU Name						
men		Address					Address						
sign		Address						Address					
Con		Postcode						Postcode					
hed		Tel.						Tel.					
of dispato	1.7.	Country of origin	ISO code	I.8.	Region of origin	Code	1.9.	Country of destination	ISO code	I.10.	Region of destination	Code	
tails	1.11.	Place of origin					1.12.	Place of destinat	ion				
ě													
art		Name Approval number								Cus	tom warehouse		
		Address						Name		Арр	roval number		
		Name Approval number					Address						
		Address											
		Name		Appro	val number		Postcode						
		Address											
	I.13.	Place of lo	ading				1.14.	Date of departure	e				
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU					
		Aeroplane	•		Railway wa	agon 🗖							
		Road vehi	cle 🔲 Othe	er 🔲			l.17.			_			
		Identificati											
			ation referen										
	I.18.	Description	n of commodi	ity					I.19. Comr	nodity	code (HS code)		
							I.20. Quantity						
	1.21.	I.21. Temperature of product								1.22	. Number of pa	ckages	
		Ambient C]		Chilled C]		Frozen 🗖	1				
	123	Seal/Cont:	ainer No							124	Type of packa	naina	

1.25.	Commodities certified for:										
	Manufacture of pe	tfood 🗖	Further pro	ocess 🗆	Technical use \Box						
1.26.	For transit through	EU to third country	, 🗆	I.27. For import or							
	Third country	ISO co	de								
1.28.	8. Identification of the commodities Approval number of establishments										
(Sci	Species entific name)	Nature of commodity	Manufacturing plant	Number of packages	Net weight	Batch number					

COUNTRY

	II. Health information		tion	II.a. Certificate reference No	II.b.					
		the Europ	ean I	Parliament and of the	an, declare that I have read and underst he Council (^{1a}) and Commission Regu nereto, and certify that the animal by-pro	lation (EU) No 142/2011 (1b), and in				
	II.1.1.	consist of	anima	al by-products that s	atisfy the animal health requirements be	low;				
<u>loi</u>	II.1.2.	have beer	n obta	ined in the territory of	of: (¹º) fror	m animals:				
Part II: Certification		(²) either	[(a)	that have remained the date of slaughte	I in this territory since birth or for a perier or production;]	od of at least three months preceding				
5 ∺		(²) or	[(b)	killed in the wild in	this territory (^{1d});]					
Paı		(²) or	[(c)	derived from roden	ts, lagomorphs, aquatic animals or terres	strial or aquatic invertebrates;]				
	II.1.3.	have beer	n obta	ined from or produce	ed by animals:					
		(²) either	[(a)	coming from holdin	gs:					
				no case/ou pathogenic African swi	the following diseases for which the ani tbreak of rinderpest, swine vesicular of avian influenza during the period of the ine fever during the period of the pre their vicinity within a 10 km radius, durin	disease, Newcastle disease or highly preceding 30 days, nor of classical or ceding 40 days; nor in the holdings				
				the precedi	e has been no case/outbreak of foot-an ng 60 days, nor in the holdings situated period of the preceding 30 days; and					
			(b)	which:						
				(i) were not kil	lled to eradicate any epizootic disease;					
				of departure	ned in their holdings of origin for a perion e and which have been transported dire n other animals which did not comply wit	ctly to the slaughterhouse without any				
				of 24 hours	phterhouse, have passed the ante-morte preceding the time of slaughter and have above for which the animals are suscept	ve shown no evidence of the diseases				
				accordance	handled in the slaughterhouse before as with the relevant provisions of Union luivalent to those laid down in Chapters (4)]	egislation and have met requirements				
		(²) or	[(a)	captured and killed	in the wild in an area:					
		(i) in which within a 25 km radius there has been no case/outbreak of any of the diseases for which the animals are susceptible: foot-and-mouth disease, in Newcastle disease or highly pathogenic avian influenza during the periodic preceding 30 days, nor of classical or African swine fever during the periodic preceding 40 days; and								
				country not	a distance of at least 20 km from an a authorised for export to the European 30 days or of porcine material during the	Union of poultry material during the				
			(b)	either to a collection	were transported within a period of 12 on centre and immediately afterwards the landling establishment;]					

COUNTRY

II.	Health inf	orma	ation	II.a.	Certificat	te reference No		II.b.			
II.1.4.	of the dise 30 days o Union has	eases or, in s bee	nined in an establish referred to in point the event of a case an authorised only a under the control of	II.1.3 f of dis after th	or which the ease, the e remova	ne animals are so preparation of ra I of all meat, an	usceptik aw mat	ole during erial for	g the per exportati	iod of the pont on to the f	oreceding European
II.1.5.			tained and prepare ired above, and it h								
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 PET FOOD' and the name and address of the establishment of destination in the European Union;										
II.1.7.	consist on	ly of	the following animal	by-pro	ducts:						
	(²) either [- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed which were deemed fit for human consumption in accordance with Union legislation until irreversibly declared as animal by-products for commercial reasons;]										
	(²) and/or	[-	carcases and the slaughterhouse ar mortem inspection consumption in ac	d were	considered	ed fit for slaughte the following pa	er for hu	ıman cor	nsumptio	n following	an ante-
			consumpti	on in a	ccordance	parts of animals with Union legis umans or animals	slation,				
			(ii) heads of p	oultry;							
						trimmings and sp and metacarpus b					
			(iv) pig bristles	;							
			(v) feathers;]								
	(²) and/or	[-	animal by-product including degrease								
	(²) and/or	[-	products of animal intended for huma packaging defects	n cons	umption fo	r commercial rea	sons or	due to p	roblems	of manufa	
	(²) and/or	[-	aquatic animals, a of diseases comm				sea ma	mmals, v	hich did	not show a	any signs
	(²) and/or	[-	animal by-products			imals originating	from pla	ants or e	stablishn	nents manı	ufacturing
	(²) and/or	[-	the following mat					id not s	how an	y signs of	disease
			(i) shells from	shellfi	sh with so	ft tissue or flesh;					
			(ii) the following	ng origi	nating fror	n terrestrial anim	als:				
			— hat	chery I	oy-product	s,					
			— egg	js,							
			— eg	g by-pr	oducts, inc	cluding egg shells	3;				

COUNTRY

			_		of petfood
II.	Health inf	formation	II.a.	Certificate reference No	II.b.
		(iii) day-old chi	cks kil	led for commercial reasons;]	
	(²) and/or	[- animal by-products humans or animals		aquatic or terrestrial invertel	orates, other than species pathogenic to
	(²) and/or	Category 1 materia	l as re		of Rodentia and Lagomorpha, except and (v) of Regulation (EC) No 1069/2009 (g) of that Regulation;]
	(²) and/or	Council Directive 9	96/22/E		ertain substances which are prohibited by terial being permitted in accordance with
II.1.8.	legislation		will no	ot spoil between dispatch and	red in accordance with European Union delivery to the plant of destination in the
II.1.9.	Directive 9				ted with certain substances prohibited by rmitted in accordance with Article 35(a)(ii)
	lique trans of de of ea	efied charcoal or activated sported in pallets which a estination in the Europeal	carbo e not unio	on on each outer side of each divided into separate consignr in or during the transit through	tory of the European Union by a cross of frozen block, or, when the raw material is nents during transport to the petfood plant the European Union, on each outer side the diagonal length of the frozen block and
	entry	y into the territory of the I	Europe		been marked in the third country before iquefied charcoal or by applying charcoal terial; and
		er non-treated raw materia			nas been treated as referred to above and marked as referred to in point (a) and (b)
(²) (⁵) [II.2.	Specific re	equirements			
(²) (⁶) [II.2.1.	(II.1.2), w		nmes	against foot-and-mouth disea	en kept in the territory referred to in point ase are being regularly carried out and
(²) (⁷) [II.2.2.	ruminants hours, or i	s, which have maturated a	at an a	ambient temperature of more	is derived from trimmed offal of domestic than + 2 °C for a period of at least three ed meat of domestic animals, for a period
(²) [II.3.	the anima origin and		ufactui	re of petfood contains or is de	rived from animal-by products of ruminant
	(²) either			egion, which is classified as pond in which there has been no	osing a negligible BSE risk in accordance indigenous BSE case, and]]
	(²) or	Decision 2007/453/EC i or derived product were ruminants with meat-ar	n which derivend- nd-bon	ch there has been an indigence ed from animals born after the e meal and greaves derived	negligible BSE risk in accordance with bus BSE case, and the animal by-product date from which the ban on the feeding of from ruminants, as defined in the OIE d in that country or region, and]]
	(²) either	[is derived from other ru	minant	ts than bovine, ovine or caprin	e animals.]

▼M15

COUNTRY

Animal by-products for the manufacture of petfood

II.	Health i	information		II.a. Certificate reference No II.b.
	(²) or	[is derived	from bo	ovine, ovine or caprine animals and does not contain and is not derived from:
		(²) either	contir	ne, ovine and caprine materials other than those derived from animals born, nuously reared and slaughtered in a country or region classified as posing a gible BSE risk in accordance with Decision 2007/453/EC.]]]
		(²) or	[(a)	specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council (8);
			(b)	mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except from those animals that were born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Commission Decision 2007/453/EC(⁹), in which there has been no indigenous BSE case,
			(c)	animal by-product or derived product obtained from bovine, ovine or caprine animals which have been killed, after stunning, by laceration of the centra nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity, or by means of gas injected into the cranial cavity, except for those animals that were born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC.]]]]

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 a commodity to be imported into the European
 Union.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. Products
 in transit may 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 case of unloading and reloading in the European Union.
- Box reference I.19: use the appropriate HS code: 05.04; 05.06; 05.07; 05.11.91 or 05.11.99; 23.01; 41.01.
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.
- Box reference I.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the
 production or manufacturing of pet food.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
- Box reference I.28:
 - species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or Suidae, Pesca, Mollusca, Crustacea, invertebrates other than Mollusca and Crustacea;
 - Manufacturing plant: provide the veterinary control number of the approved establishment.

Part II:

- (^{1a}) OJ L 300, 14.11.2009, p. 1.
- (1b) OJ L 54, 26.2.2011, p. 1.

COUNTRY

II.	Health information	II.a.	Certificate reference No	II.b.							
(^{1c})	The name and ISO code number of the expo	orting c	ountry as laid down in:								
	 Part 1 of Annex II to Regulation (EU) N 	lo 206	/2010;								
	 Part 1 of Annex I to Regulation (EC) N 	o 798/	2008, and								
	 Part 1 of Annex I to Regulation (EC) N 	o 119/	2009.								
	In addition the ISO code of regionalisation in the abovementioned Annexes (where applicable for the susceptible species concerned) must be included.										
(^{1d})	Only for countries from which game meat intended for human consumption of the same animal species is authorised for importation into the European Union.										
(²)	Delete as appropriate.										
(3)	Excluding raw blood, raw milk, hides and skins, hooves and horn, pig bristles and feathers (see relevant specific certificates in that Annex for the import of these products).										
(4)	OJ L 303, 18.11.2009, p. 1.										
(^{4a})	OJ L 125, 23.5.1996, p. 3.										
(5)	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 deboned fresh meat of domestic ruminants for human consumption is permitted for exportation to the European Union. The whole masseter muscles of bovine animals, incised in accordance with Part B.1 of Chapter I of Section IV of Annex I to Regulation (EC) No 854/2004 of the European Parliament and of the Council (OJ L 139, 30.4.2004, p. 206), are also permitted.										
(⁶)	Only for certain South American countries.										
(⁷)	Only for certain South American and South A	∖frican	countries.								
(8)	OJ L 147, 31.5.2001, p. 1.										
(⁹)	OJ L 172, 30.6.2007, p. 84.										
_	The signature and the stamp must be in a dif	fferent	colour to that of the printing.								
_	Note for the person responsible for the cons and must accompany the consignment until i										
Offic	cial veterinarian/Official inspector										
	Name (in capital letters):		Qua	alification and title:							
	Date: Signature:										
	Stamp:										

▼<u>M4</u>

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 through $\binom{2}{2}$ the European Union

COL	INTR	Υ				Veterinary certificate to El
	l.1.	Consignor Name	1.2.	Certifica	te reference No	1.2.a.
		Address	1.3.	Central	competent authority	
		Tel.	1.4.	Local co	empetent authority	
Part I: Details of dispatched consignment	1.5.	Consignee Name Address	I.6.	Name Address		ad in EU
ped c		Postcode Tel.		Postcod Tel.	е	
dispatc	1.7.	Country of origin ISO code I.8. Region of origin Code	1.9.	Country destinati		I.10. Region of Code destination
S			1.40	D. (
etai	1.11.	Place of origin	1.12.		destination	–
<u> </u>		Name Approval number Address		Name Address		ustom warehouse pproval number
Parl		Name Approval number Address		Postcod	e	•
		Name Approval number Address				
	I.13.	Place of loading	l.14.	Date of	departure	
	l.15.	Means of transport	I.16.	Entry BI	P in EU	
		Aeroplane				
		Road vehicle Other O	1.17.			
		Identification Documentation references	"."			
	1.18.	Description of commodity			I.19. Commodity co	de (HS code)
						I.20. Quantity
	1.21.	Temperature of product				I.22. Number of packages
		Ambient Chilled Chilled			Frozen	
	1.23.	Seal/Container No				I.24. Type of packaging
	1.25.	Commodities certified for:				
		Technical use □				
	1.26.	For transit through EU to third country	1.27.	For impo	rt or admission into E	≣U □
		Third country ISO code				
	1.28.	Identification of the commodities				
		Species (Scientific name)				er of establishments sturing plant

Blood and blood products from equidae for purposes outside the

▼ M4

COUNTRY feed chain II. Health information II.a. Certificate reference No II.b. I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and in particular Article 8(c) and (d) and Article 10 thereof, and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Chapter IV of Annex XIII 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: Certification II.2. consist exclusively of blood or blood products of equidae not intended for human or animal consumption; have been obtained from animals that originate from the EU Member States or from a third country, territory or part thereof listed in the column "third countries' lists" of row No 3 of Table 2 in Section 1 of Chapter II of Annex XIV to Regulation (EU) No 142/2011 where the 11.3. Ë Part following diseases are compulsorily notifiable: African horse sickness, dourine, glanders (Burkholderia mailei), equine encephalomyelitis (all types including Venezuelan equine encephalomyelitis), equine infectious anaemia, vesicular stomatitis, rabies, anthrax; have been derived from blood from equidae, which was collected under the supervision of a veterinarian in slaughterhouses approved in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council (3), in slaughterhouses approved and supervised by the competent authority of the country of collection and in facilities approved and supervised by the competent authority of the country of collection for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding for farmed animals; 11.5. 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 I to Council Directive 2009/156/EC (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), 2010 edition; 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 2009/156/EC; 11.5.2. which had no contact with equidae from a holding which was subject to a prohibition order for animal health reasons pursuant to Article II.5.3. 4(5) of Directive 2009/156/EC; II.5.4. for which the period for the prohibition order referred to in points II.5.2, and II.5.3 has been determined as follows: (2) either [not all the animals of species susceptible to the disease located on the holding have been slaughtered , in which case the period of prohibition must be at least: — six months in the case of glanders (Burkholderia mailei), beginning on the date on which the equidae infected with the disease are slaughtered, - six months in the case of equine encephalomyelitis of any type, including Venezuelan equine encephalomyelitis, beginning on the date on which the equidae infected with the disease are slaughtered. - in the case of equine infectious anaemia, until the date on which, the infected animals having been slaughtered, and the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart, - six months from the date of the last recorded case of vesicular stomatitis - one month from the date of the last recorded case of rabies. - 15 days from the date of the last recorded case of anthrax: (2) or [all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises were disinfected, in which case the period of prohibition must 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 be 15 days;] blood products come from an establishment or plant approved or registered by the competent authority of the third country meeting the specific conditions set out in Article 23 or 24 of Regulation (EC) No 1069/2009; II.6. 11.7. blood products have been produced from blood which fulfils the conditions referred in II.4 and II.5 and (2) either [has been 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;

▼<u>M4</u>

COUNTRY

Blood and blood products from equidae for purposes outside the feed chain

COUNT	RY				feed chain					
II.	Health infor	matic	on		II.a. Certificate reference No	II.b.				
		(b)	Venezuelan	equine encephalomyelitis for a pe	eriod of at least two years;					
		(c)	glanders							
			(²) either	[for a period of three years;]						
			(²) or	slaughterhouse referred to in II.4	e the animals have passed the post-me, including a careful examination of muss and their ramifications, after splitting	icous membranes from the trachea,				
		(d) in the case of blood products other than serum and plasma, 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) é	either	[heat treatment at a temperature	of 65°C for at least three hours;]					
		(²) é	and/or	[irradiation at 25 kGy by gamma	ı rays;]					
		(²) é	and/or	[change in pH to pH 5 for two h	nours;]					
		(²) á	and/or	[heat treatment of at least 80°C	throughout their substance;]]					
II.8.	all precaution and packagin		ve been take	n to avoid contamination of the blo	ood and blood products with pathogenic	agents during production, handling				
II.9.	blood and I CONSUMPT				neable containers clearly labelled "N	NOT FOR HUMAN OR ANIMAL				
	(a) in the ca	se of	blood, the a	approval number of the establishm	nent of collection;					
	(b) in the ca	se of	blood produ	ucts, the approval number of the e	establishment of production;					
II.10.	the products	were	stored in e	enclosed storage.						
Notes										
Part I:										
				ible for the consignment in the Eu e certificate is for import commodi	ropean Union: this box is to be filled ity.	n only if it is a certificate for transit				
	reference I.11 nority.	and	I.12: Approv	val number: the registration number	er of the establishment or plant, which	has been issued by the competent				
				ation: this box is to be filled in only houses and custom warehouses.	y if it is a certificate for transit commod	ity. The products in transit can only				
				ımber (railway wagons or containe he consignor must inform the BIP	er and lorries), flight number (aircraft) of of entry into the EU.	or name (ship) is to be provided. In				
— Вох	(I.19: use the	appro	opriate Harm	monized System (HS) code under	the following heading: 30.02.					
— Вох	reference I.23	3: for	bulk contain	ners, the container number and the	e seal number (if applicable) must be	included.				
— Вох	reference I.25	5: tec	hnical use: a	any use other than for animal con	sumption.					
— Вох	reference I.26	3 and	l l.27: fill in a	according to whether it is a transit	t or an import certificate.					
— Вох	reference I.28	3:								
(a)	Manufacturing	plant	t:							
	(i) in the case	e of b	olood, provid	le the approval number of the regi	istered establishment of collection;					

(ii) in the case of blood products, provide the approval number of the establishment of production;

(b) Species: select amongst the following: Equus cabalus, Equus asinus, Equus cabalus*asinus.

▼<u>M4</u>

Blood and blood products from equidae for purposes outside the feed chain COUNTRY II. Health information II.a. Certificate reference No II.b. Part II: (^{1a}) OJ L 300, 14.11.2009, p. 1. (1b) OJ L 54, 26.2.2011, p. 1 (2) Delete as appropriate. (3) OJ L 139, 30.4.2004, p. 55. (4) OJ L 192, 23.7.2010, p. 1. The signature and the stamp must be in a different colour to that of the printing. Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post. Official veterinarian/Official inspector 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

cou	JNTR	/ :							Veterinary certifica	te to EU			
	l.1.	Consignor				1.2.	Certificate refere	nce No	I.2.a.				
		Name				1.3.	Central compete	nt authority					
		Address				1.4.	Local competent	authority		Region of Code lestination			
		Tel.											
	1.5.	Consigned)			I.6. Person responsible for the load in EU							
ţ		Name					Name						
ignme		Address					Address						
cons		Postcode					Postcode						
hed		Tel.					Tel.						
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code	I.8. Region of origin	Code	1.9.	Country of destination	ISO code	I.10. Region of destination	Code			
etails	l.11.	Place of origin					Place of destinat	ion					
art : [Name		Approval number					Custom warehouse				
ď		Address Name Approval number					Name		Approval number				
							Address						
		Address											
		Name		Approval number			Postcode						
		Address											
	I.13.	Place of lo	ading			I.14.	Date of departure	Э					
	l.15.	Means of t	ransport			I.16.	Entry BIP in EU						
		Aeroplane	☐ Ship	☐ Railway w	vagon □								
		Road vehi	cle 🔲 Othe	er 🗆		1.17.							
		Identificati	on										
		Document	ation referen	n references									
	I.18.	Description	n of commod	ity				I.19. Comi	modity code (HS code)				
									I.20. Quantity				
	1.21.	Temperatu	ire of product	<u> </u>					I.22. Number of pa	ckages			
		Ambient C]	Chilled []		Frozen C]					
	123	Seal/Conta	ainer No						124 Type of packs	aging			

1.25.	Commodities certified for:					
	Animal feedingstuff □	Mar	nufactu	re of petfood \square	Technical	use 🗆
1.26.	For transit through EU to third	d country		I.27. For import or admissio	n into EU	
	Third country	ISO code				
1.28.	Identification of the commodit					
		Approval nu	umber	of establishments		
	Species (Scientific name)	Nature of commodity	y	Manufacturing plant		Batch number

COUNTRY

	II.	Health inform	ation	II.a. Certificate reference No	II.b.						
		I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 the European Parliament and of the Council (¹a) and Commission Regulation (EU) No 142/2011 (¹b) and certify the blood products described above:									
	II.1.	consist of blood products that satisfy the health requirements below;									
ation	II.2.	consist exclusively of blood products not intended for human consumption;									
Part II: Certification	II.3.	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;									
art II:	II.4.	have been prepared exclusively with the following animal by-products:									
Δ.		(²) either	er [blood of slaughtered animals, which is fit for human consumption in accordance with Union legislation, but which is not intended for human consumption for commercial reasons;]								
		(²) and/or	(2) and/or [blood of slaughtered animals, which has been rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of diseases communicable to humans or animals, which has been derived from carcases that have been slaughtered in a slaughterhouse and which were considered fit for human consumption following an ante-mortem inspection in accordance with Union legislation;]								
	II.5.	in order to inactivate pathogenic agents, have been submitted									
		(²) either	ither [to processing in accordance with processing method								
		(²) or	[to a method and parameters which ensure that the product complies with the microbic standards set out in Chapter I of Annex X to Regulation (EU) No 142/2011;]								
		(²) or	[in the case of blood products, including spray dried blood and blood plasma, of porcine or intended for the feeding of porcine animals, to a heat treatment at a temperature of at least 8 throughout the substance and the dry blood and blood plasma does not contain more than 8% moisture with a water activity (Aw) of less than 0,60.]								
	II.6.	the end produc	ct was:								
		(²) either	[packed in new or sterilis	ed bags;]							
		(²) or	•	containers or other means of transport that ctant approved by the competent authority be							
		and which bea	r labels indicating 'NOT F	OR HUMAN CONSUMPTION';							
	II.7.	the end produc	ct was stored in enclosed	storage;							
	II.8.	the product ha	s undergone all precaution	ns to avoid contamination with pathogenic ag	ents after treatment;						
		(²) and	and [in the case of blood products, including spray dried blood and blood plasma of porcine origin intended for the feeding of porcine animals, has been stored in dry warehouse conditions under room temperature for a period of at least 6 weeks.]								
	II.9.			under the responsibility of the competent ge which was found to comply with the followi							
		Salmonella:	absence in 25	5g: n = 5, c = 0, m = 0, M = 0,							
		Enterobacteria	n = 5, c = 2, r	m = 10, M = 300 in 1 gram;							

COUNTRY

						C	ould be used as feed material	
II.	Health infor	mation		II.a.	Certificate reference No		II.b.	
(²) [II.10.	the blood products described above							
	(²) either	[is derive	d from other	ruminant	s than bovine, ovine or caprin	ie animals	3.]]	
	(²) or	[is derive	d from bovine	e, ovine c	or caprine animals and does n	not contair	n and is not derived from:	
		(²) either	continuous	sly reared		untry or	e derived from animals born, region classified as posing a [EC.]]	
		(²) or	[(a)		d risk material as defined in 2001 of the European Parliam		of Annex V to Regulation (EC) of the Council (5);	
			(b)	animals, slaughte accorda	except from those animals t red in a country or region clas	that were ssified as	ones of bovine, ovine or caprine born, continuously reared and posing a negligible BSE risk in 453/EC (⁶), in which there has	
			(c)	animals nervous into the except for in a court	which have been killed, after tissue by means of an elong cranial cavity, or by means or those animals that were bo	er stunningated rod of gas i orn, contir	I from bovine, ovine or caprine ig, by laceration of the central -shaped instrument introduced njected into the cranial cavity, huously reared and slaughtered gligible BSE risk in accordance	
II.11.	the blood pro	oducts descr	ibed above:					
	(²) either		ontain milk o nimals, other			imal origir	n or is not intended for feed for	
	(²) or		milk or milk pother than fu			rigin and	is intended for feed for farmed	
		(a)			vine and caprine animals where the following conditions a		been kept continuously since d:	
			(i)	classica	scrapie is compulsorily notific	able;		
			(ii)	an awar scrapie;	reness, surveillance and mor	nitoring s	ystem is in place for classical	
			(iii)		estrictions apply to holdings o ion of TSE or the confirmatior		caprine animals in the case of ical scrapie;	
			(iv)	ovine a		d with cla	assical scrapie are killed and	
			(v)	as define Animal	ed in the Terrestrial Animal Ho Health (OIE), of ruminant o If in the whole country for	ealth Cod rigin has	eat-and-bone meal or greaves, le of the World Organisation for been banned and effectively od of at least the preceding	
		(b)	originate fi TSE;	rom holdi	ings where no official restrict	tions are	imposed due to a suspicion of	
		(c)		of at lea	st the preceding seven years		oie has been diagnosed during ving the confirmation of a case	

COUNTRY

II.	Health inform	nation	II.a.	Certificate reference No		II.b.
		,,	or slaug ewes ca	e and caprine animals on the hatered, except for breeding ranarrying at least one ARR allelicarrying at least one ARR allelica	ns of the e and no	ARR/ARR genotype, breeding
		.,	destroye two yea intensifie presenc point 3.2 the follo	rs since the date of confirmation ed TSE monitoring, including e of TSE in accordance with	n subject on of the testing h the la	cted for a period of at least last classical scrapie case to with negative results for the boratory methods set out in on (EC) No 999/2001, of all of
			— an	imals which have been slaught	ered for	human consumption; and
				imals which have died or beer t killed in the framework of a die		
II.12		ducts described above c ne statement of the Con		r are derived from animal-by pr ferred to in Box I.1,	oducts o	f non-ruminant origin, and are,
	(²) either	[not intended for the pr	oduction	n of feed for farmed animals, ot	her than	fur animals.]
	(²) (⁷) or	Consignor has underta	aken to e es carri	feed for non-ruminant farmed a ensure that the border inspectio ed out in accordance with the No 152/2009 (8).]	n post of	entry will be provided with the
Note Part						
_	it is a certificate for		oe transi	nment in the European Union: ted through the European Unio ean Union.		
_				to be filled in only if it is a certif houses and custom warehouse		a transit commodity. Products
_				agons or container and lorries), g and reloading in the Europear		mber (aircraft) or name (ship);
_	Box reference I.19: u	use the appropriate HS	code: 05	.11.91, 05.11.99, 35.02 or 35.0	14.	
_	Box reference I.23: 1	for bulk containers, the c	container	r number and the seal number ((if applica	able) should be included.
_	Box reference I.25: production or manuf		se other	than feeding of farmed anim	nals, oth	er than fur animals, and the
_	Box reference I.26 a	and I.27: fill in according	to wheth	ner it is a transit or an import ce	rtificate.	
-	Box reference I.28: Suidae , Pesca, Rep		ne follow	ing: Aves, Ruminantia, Suidae	e, Mamm	alia other than Ruminantia or

COUNTRY

II.	Health information	II.a. Certificate reference No	II.b.							
Part	Part II:									
(^{1a})	OJ L 300, 14.11.2009, p. 1.									
(1b)	OJ L 54, 26.2.2011, p. 1.									
(2)	Delete as appropriate.									
(3)	Insert method 1 to 5 or method 7 as applicable	e.								
(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 cour acceptable if the bacterial count of the		nd M, the sample st	ill being considered						
(⁵)	OJ L 147, 31.5.2001, p. 1.									
(⁶)	OJ L 172, 30.6.2007, p. 84.									
(7)	The person responsible for the load referred to in Box I.6 must ensure that, if the blood products described in this health certificate are intended to be used for the production of feed for non-ruminant farmed animals, other than fur animals, the consignment must be analysed, in accordance with the methods set out in Annex VI to Regulation (EC) No 152/2009, in order to verify the absence of unauthorised constituents of animal origin. The information on the result of such analysis must be attached to this health certificate when presenting the consignment at a border inspection post of the European Union.									
(8)	OJ L 54, 26.2.2009, p. 1.									
_	The signature and the stamp must be in a diff	erent 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 point of entry into the European Union.									
Offic	Official veterinarian/Official inspector									
	Name (in capital letters): Qualification and title:									
	Date:	S	gnature:							
	Stamp:									

CHAPTER 4(C)

Health certificate

For untreated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals, intended for dispatch to or for transit through $\binom{2}{2}$ the European Union

COL	JNTR	Y :								Vete	erinary certifica	te to EU
	l.1.	Consignor					1.2.	Certificate refere	nce No	1.2	2.a.	
		Name Address			1.3.	I.3. Central competent authority						
					1.4.	Local competent	authority					
	Tel.											
	1.5.	Consignee				1.6.	Person responsib	le for the lo	ad in E	U		
ar.		Name					Name					
ignme		Address	Address					Address				
cons		Postcode Tel.					Postcode					
hed						Tel.						
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code		Region of origin	Code	1.9.	Country of destination	ISO code	I.10.	Region of destination	Code
etails	l.11.	I.11. Place of origin			I.12.	Place of destinat	on					
- I		Nove de abou								_		
Par	Name		11				Mana			tom warehouse		
		Address Name Approval number				Name		Арр	roval number			
		Name		Approva	ai number			Address				
		Address Name		Approx	al number			Postcode				
		Address		Approve	ai ilullibei			Posicode				
	I 13	Place of loading				114	Date of departure	<u> </u>				
							1.14. Date of departure					
	I.15.	Means of t	ransport				I.16. Entry BIP in EU					
		Aeroplane ☐ Ship ☐ Railway wagon ☐										
		Road vehi				-g <u>-</u>	1.17.					
		Identification										
		Documentation references										
	I.18.	18. Description of commodity						I.19. Comr	modity o	code (HS code)		
								L		1.20	. Quantity	
	1.21.	Temperatu	ure of product	<u> </u>						1.22	. Number of pa	ckages
		Ambient □			Chilled]		Frozen 🗖				-
	122	Sool/Contr	ninor No							124	Type of pecks	aina

1.25.	Commodities certified for:							
	Technical use □							
1.26.	For transit through EU to third country	I.27. For import or admission into EU						
	Third country ISO code							
1.28.	Identification of the commodities							
	Approval number of establishments							
	Species (Scientific name) Manufac	turing plant Batch number						

COUNTRY

Untreated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals

					the feed chain for farmed animals					
	II.	Health inforr	mation	II.a. Certificate reference No	II.b.					
		the European	Parliament and of the Cou	eclare that I have read and understonicil (1ª), and in particular Article 8(c) a 12/2011 (1b), and in particular Chapte	nd Article 8(d) and Article 10 thereof,					
	II.1.	the blood products described above consist of blood products that satisfy the health requirements below;								
ation	II.2.	they consist exclusively of blood products not intended for human or animal consumption;								
Part II: Certification	II.3.	•	en prepared and stored in clusively with the following a	a plant supervised by the competen animal by-products:	t authority or in the establishment of					
Part II		(²) either		animals, which is fit for human contended for human consumption for co						
		(²) and/or	with Union legislation, animals, derived fron	animals, which is rejected as unfit fo but which did not show any signs of on an carcases that have been slaughte nan consumption following an ante-m	diseases communicable to humans or ered in a slaughterhouse and were					
		(²) and/or	humans or animals, of	animals, which did not show any btained from animals that have been a red fit for human consumption follon legislation;]	slaughtered in a slaughterhouse after					
		(²) and/or	[- blood and blood pro consumption;]	products derived from the production of products intended for human						
		(²) and/or		ducts originating from live animals that did not show signs of any disease gh that product to humans or animals;]						
		(²) and/or		erived from animals which have be o(d) of Council Directive 96/22/EC (^{2a}						
		(²) and/or	listed in Group B(3) of	ontaining residues of other substanc f Annex I to Directive 96/23/EC, if sucl islation or, in the absence thereof, in r	n residues exceed the permitted level					
	II.4.	with Union le	gislation, in slaughterhouse	ufactured from, was collected in slauges approved and supervised by the cas approved and supervised by the cas	competent authority of the country of					
	(²) [II.5.	Proboscidea, where no cas least the pre-	including crossbreds between of rinderpest, peste des	d from animals belonging to the ta een species of those taxa, the blood petits ruminants and Rift Valley fever which vaccination has not been carri s, and;	was collected in a country or region has been recorded for a period of at					
		(²) either	country, or codes (3) in to disease has been recorded	es or parts thereof	of) where no case of foot-and-mouth g 12 months and in which vaccination					
		(²) or	country or codes (3) for the been recorded for a per programmes against for	tes or parts thereof	case of foot-and-mouth disease has months and in which vaccination cially carried out and controlled in					

COUNTRY

Untreated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals

II.	Health inform	mation		II.a.	Certificate re	eference No	II.b.		
(²) [II.5.1.	in the case of	f animals othe	er than Suidae	and Ta	ayassuidae, ir	third countries or reg	ions in v	which :	
	(²) either	has been r	ecorded for a p	eriod	of at least the	ue (²) (including the p preceding 12 months period of at least the p	and in v	which vaccinat	tion has not
	(²) or [vesicular stomatitis and bluetongue (²) seropositive animals are present (4);]]								
(²) [II.5.2.	in the case of Suidae and Tayassuidae, in third countries or regions in which no case of swine vesicular disease, classical swine fever and African swine fever has been recorded for a period of at least the preceding 12 months and vaccination has not been carried out against those diseases for a period of at least the preceding 12 months in the susceptible species and:								
	(²) either [no case of vesicular stomatitis (including the presence of seropositive animals) has been recorded for a period of at least the preceding 12 months and in which vaccination has not been carried out against this disease for a period of at least the preceding 12 months;]]								
	(²) or	[vesicular	stomatitis serop	ositive	e animals are	present (4);]]]			
(²) [II.6.			ucts derived fro or region with o			avian species the anin	nals and	the products	come from
	which has be Animal Health			sease	and highly pa	athogenic avian influe	nza as	defined in the	: Terrestrial
	which for a pe	eriod of at lea	ast the precedin	ıg 12 r	months has no	t carried out vaccinati	on agair	nst avian influe	enza,
						e not been vaccinated showing a higher pa			
II.7.	the products	were:							
	(²) either	[packed in	new or sterilise	ed bag	s or bottles,]				
	(²) or					means of transport the competent authority			leaned and
	the outer pac	kaging or cor	ntainers bear la	bels ir	ndicating 'NOT	FOR HUMAN OR AN	IIMAL C	ONSUMPTIO	'N';
II.8.	the products	were stored i	n enclosed stor	age;					
II.9.	all precaution	ns were taken	to avoid conta	minati	on of the prod	ucts with pathogenic a	igents d	luring transpor	t;
(²) [II.10.	the untreated	l blood produ	cts described a	bove					
	(²) either	[is derived	from other rum	inants	than bovine,	ovine or caprine anima	als.]]		
	(²) or	[is derived	from bovine, o	vine or	r caprine anim	als and does not cont	ain and	is not derived	from:
	(²) either [bovine, ovine and caprine materials other than those derived from animals continuously reared and slaughtered in a country or region classified as pos negligible BSE risk in accordance with Decision 2007/453/EC.]]								
	(²) or [(a) specified risk material as defined in point 1 of Annex V to Regulation No 999/2001 of the European Parliament and of the Council (6);							lation (EC)	
			animal slaugh accord	s, exc tered ance v	cept from tho	neat obtained from bo se animals that were or region classified as ion Decision 2007/453	born, posing	continuously i a negligible l	reared and BSE risk in

▼M15

COUNTRY

Untreated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals

II. Health information	II.a. Certificate reference No	II.b.
(c)	animal by-product or derived product obtained animals which have been killed, after stunning nervous tissue by means of an elongated rod-sthe cranial cavity, or by means of gas injected those animals that were born, continuously rea or region classified as posing a negligible BSE 2007/453/EC.]]]	ng, by laceration of the central haped instrument introduced into into the cranial cavity, except for red and slaughtered in a country

Notes

Part I:

- Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if
 it is a certificate for a commodity that is to be transited through the European Union; it may be filled in if the certificate is
 for a commodity that is to be imported into the European Union.
- Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. Products
 in transit may 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) is to be provided. In the case of unloading and reloading in the European Union, the consignor must inform the border inspection post of the point of entry into the European Union.
- Box I.19: use the appropriate Harmonized System (HS) code under the following headings: 05.11; 30.02 or 35.02.
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be included.
- Box reference I.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the
 production or manufacturing of pet food.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
- Box reference I.28 Species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or Suidae, Pesca, Reptilian.

Part II:

- (^{1a}) OJ L 300, 14.11.2009, p. 1.
- (1b) OJ L 54, 26.2.2011, p. 1.
- (2) Delete as appropriate.
- (^{2a}) OJ L 125, 23.5.1996, p. 3.
- (2b) OJ L 125, 23.5.1996, p. 10.
- (3) Code of the territory as it appears in Part 1 of Annex II to Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010, p. 1).
- (4) In this case following the veterinary checks provided for in Directive 97/78/EC (OJ L 24, 30.1.1998, p. 9), and in accordance with the conditions laid down in Article 8(4) of that Directive, the products must be transported directly to the establishment at the place of destination.

COUNTRY

Untreated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals

II.	Health information	II.a. Certificate reference N	No	II.b.				
(5)	Code of the territory as it appears in Part 1 of Annex I to Commission Regulation (EC) No 798/2008 (OJ L 226, 23.8.2008, p. 1).							
(⁶)	OJ L 147, 31.5.2001, p. 1.							
(7)	OJ L 172, 30.6.2007, p. 84.							
_	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 point of entry into the European Union.							
Offi	cial veterinarian/Official inspector							
	Name (in capital letters):		Qualification a	and title:				
	Date: Signature:							
	Stamp:							

CHAPTER 4(D)

Health certificate

For treated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals, intended for dispatch to or for transit through $\binom{2}{2}$ the European Union

COL	JNTRY	Y :								Vete	erinary certifica	te to EU
	l.1.	Consignor					1.2.	Certificate refere	nce No	1.2	2.a.	
		Name					I.3. Central competent authority					
		Address					1.4.	I.4. Local competent authority				
		Tel.										
	1.5.	Consignee)				1.6.	I.6. Person responsible for the load in EU				
ar.		Name						Name				
ignme		Address						Address				
cons		Postcode						Postcode				
hed		Tel.						Tel.				
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code		Region of origin	Code	1.9.	Country of destination	ISO code	I.10.	Region of destination	Code
etails	l.11.	I1. Place of origin				I.12.	Place of destinat	on				
- I		Name Approval number Address										_
Par								Mana			tom warehouse	
								Name		Арр	roval number	
		Name Approval number						Address				
		Address						Postcode				
		Name Approval number Address						Posicode				
	113	Place of lo	ading				114	Date of departure	<u> </u>			
							1.14. Date of departure					
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU				
		Aeroplane	☐ Ship		Railway wa	agon 🗆						
		Road vehi					1.17.					
		Identificati	on									
		Documentation references I.18. Description of commodity										
	I.18.								I.19. Comr	modity o	code (HS code)	
								L		1.20	. Quantity	
	1.21.	Temperatu	ure of product	t						1.22	. Number of pa	ckages
		Ambient 🗆			Chilled]		Frozen 🗆	l			
	122	22 Saal/Container No								124	Type of pecks	aina

1.25.	Commodities certified for:	
	Technical use □	
1.26.	For transit through EU to third country	I.27. For import or admission into EU
	Third country ISO code	
1.28.	Identification of the commodities	
	Approval numbe	r of establishments
	Species (Scientific name) Manufac	turing plant Batch number

COUNTRY

Treated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals

				· · · · · · · · · · · · · · · · · · ·	e reed chain for farmed animais				
	II.	Health inform	nation	II.a. Certificate reference No	II.b.				
		the European	Parliament and of the Cou	declare that I have read and understood I uncil (1a), and in particular Article 8(c) and 42/2011 (1b), and in particular Chapter II	Article 8(d) and Article 10 thereof,				
_	II.1.	the blood prod	lucts described above con	sist of blood products that satisfy the requi	rements below;				
ation	II.2.	they consist ex	xclusively of blood produc	ts not intended for human or animal consu	mption;				
Part II: Certification	II.3.	they have been prepared and stored in a plant supervised by the competent authority, exclusively with the following animal by-products:							
Part		nption in accordance with Union nercial reasons;]							
		(²) and/or	with Union legislation animals, derived fro	animals, which is rejected as unfit for hu, but which did not show any signs of dise m carcases that have been slaughtered man consumption following an ante-morter	ases communicable to humans or I in a slaughterhouse and were				
		(²) and/or [- blood of slaughtered animals, which did not show any signs of diseases communic humans or animals, obtained from animals that have been slaughtered in a slaughterhou having been considered fit for human consumption following an ante-mortem inspe- accordance with Union legislation;]							
		(²) and/or		ducts originating from live animals that d le through these products to humans or ar					
		(²) and/or	[- blood and blood possumption;]	roducts derived from the production o	f products intended for human				
		(²) and/or		which have been derived from animals whi in Article 1(2)(d) of Council Directive 96/2: b);]					
		(²) and/or	listed in Group B(3)	containing residues of other substances of Annex I to Directive 96/23/EC, if suc nion legislation or, in the absence thereof,	h residues exceed the permitted				
	II.4.	accordance w	ith Union legislation, in sl lection or from live anima	manufactured from was been collected aughterhouses approved and supervised als in facilities approved and supervised b	by the competent authority of the				
	(²) [II.5.	crossbreeds, of guaranteeing t	other than Suidae and Ta	ved from Artiodactyla, Perissodactyla a ayassuidae, the products have undergone of foot-and-mouth disease, vesicular stom gue:	one of the following treatments,				
		(²) either	[heat treatment at a check;]	temperature of 65 °C for at least three ho	urs, followed by an effectiveness				
		(²) and/or	[irradiation at 25 kGy	by gamma rays, followed by an effectivene	ess check;]				
		(²) and/or	[change in pH to pH t	5 for two hours, followed by an effectivenes	ss check;]				
		(²) and/or	[heat treatment of a check.]]	at least 80 °C throughout their substance	e, followed by an effectiveness				

COUNTRY

Treated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals

II.	Health information			II.a. Certificate reference No	II.b.			
(²) [II.6.	undergone one of and-mouth disea	of the following tre ase, vesicular sto	eatmer omatiti	m Suidae, Tayassuidae, poultry and other avints guaranteeing the absence of pathogens os, swine vesicular disease, classical swine cavian influenza, as appropriate to the specie	f the following diseases: foot- e fever, African swine fever,			
	(²) either	[heat treatment at a temperature of 65 °C for at least three hours, followed by an effectiveness check;]						
	(²) and/or	[irradiation at 25	5 kGy	by gamma rays, followed by an effectiveness	check;]			
	(²) and/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 the substance of the product, followed by an effectiveness check]].					
(²) [II.7.				rom species other than those listed in point ease specify):]	II.5 or II.6, the products have			
II.8.	The products wer	re:						
	(²) either	[packed in new	or ste	rilised 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;] and					
	the outer packaging or containers bear labels indicating 'NOT FOR HUMAN OR ANIMAL CONSUMPTION';							
II.9.	the products were	e stored in enclos	ed sto	rage;				
II.10.	all precautions w	ere taken to avoid	the c	ontamination of the products with pathogenic	agents after treatment;			
(²) [II.11.	The treated blood	d products describ	oed ab	ove				
	(²) either	[is derived from	other	ruminants than bovine, ovine or caprine anim	als.]]			
	(²) or	[is derived from	bovin	e, ovine or caprine animals and does not cont	ain and is not derived from:			
		, ,	contin	e, ovine and caprine materials other than tho uously reared and slaughtered in a country o ible BSE risk in accordance with Decision 200	r region classified as posing a			
		(²) or	[(a)	specified risk material as defined in point 1 o No 999/2001 of the European Parliament an				
		,	(b)	mechanically separated meat obtained from caprine animals, except from those animals reared and slaughtered in a country or negligible BSE risk in accordance to 2007/453/EC (4), in which there has been not been	that were born, continuously egion classified as posing a with Commission Decision			
			(c)	animal by-product or derived product obt caprine animals which have been killed, at the central nervous tissue by means construment introduced into the cranial cavity into the cranial cavity, except for thos continuously reared and slaughtered in a coposing a negligible BSE risk in accordance vi	iter stunning, by laceration of of an elongated rod-shaped , or by means of gas injected e animals that were born, ountry or region classified as			

COUNTRY

Treated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals

II.	Health information	II.a.	Certificate reference No	l	II.b.				
Not	es								
Part	Part I:								
_	 Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if it is a certificate for a commodity to be transited through the European Union; it may be filled in if the certificate is for a commodity to be imported into the European Union. 								
_	Box reference I.11 and I.12: Approval numb issued by the competent authority.	er: the	e registration number of	the establishm	ent or plant, which has been				
_	Box reference I.12: Place of destination: this in transit may only be stored in free zones, free				a transit commodity. Products				
_	Box reference I.15: Registration number (rails to be provided. In the case of unloading a entry into the European Union.								
_	Box I.19: use the appropriate Harmonized Sys	stem (I	HS) code under the follow	ving headings:	05.11, 30.02, 35.02 or 35.04.				
_	Box reference I.23: for bulk containers, the co	ntaine	r number and the seal nu	ımber (if applica	able) must be included.				
-	Box reference I.25: technical use: any use production or manufacturing of pet food.	other	than feeding of farmed	d animals, oth	er than fur animals, and the				
_	Box reference I.26 and I.27: fill in according to	whetl	ner it is a transit or an imp	oort certificate.					
-	Box reference I.28 in case of Species: sel Ruminantia or Suidae, Pesca, Reptilian.	ect fro	om the following: Aves,	Ruminantia, S	Suidae, Mammalia other than				
Part	t II:								
(^{1a})	OJ L 300, 14.11.2009, p. 1.								
(1b)	OJ L 54, 26.2.2011, p. 1.								
(2)	Delete as appropriate.								
(^{2a})	OJ L 125, 23.5.1996, p. 3.								
(2b)	OJ L 125, 23.5.1996, p. 10.								
(3)	OJ L 147, 31.5.2001, p. 1.								
(4)	OJ L 172, 30.6.2007, p. 84.								
_	The signature and the stamp must be in a diff	erent o	colour to that of the printing	ng.					
-	Note for the person responsible for the consignand must accompany the consignment until it								
Offic	cial veterinarian/Official inspector								
	Name (in capital letters):			Qualification a	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

(cou	NTR	Υ							Veterinary certifi	cate to EU
		l.1.	Consignor Name			1.2.	Certificate	reference No		1.2.a.	
			Address			1.3.	I.3. Central competent authority				
			Tel.	1.4.	Local con	npetent authorit	ty				
	'n	I.5.	Consignee			I.6.		esponsible for t	he loa	d in EU	
	gnme		Name Address				Name Address				
	consi		Postcode				Postcode				
	ched		Tel.				Tel.				
	of dispatched consignment	I.7.	Country of origin ISO	code I.8. Region of origin	Code	1.9.	Country of destination		ode	I.10. Region of destination	Code
	etails (1.11	11. Place of origin				I.12. Place of destination				
	Part I: Details		Name Address	Approval number			Name Address			tom warehouse roval number	
	Ps		Name Address	Approval number			Postcode				
			Name Address	Approval number							
		I.13. Place of loading				1.14.	Date of d	leparture			
		1.15	. Means of transport			I.16.	Entry BIP	in EU			
			. —	hip ☐ Railway wa ther ☐	gon 🔲	I.17. Number(s) of CITES					
			Identification	_							
		1.40	Documentation reference					I.19. Commo	dity oo	de (HS code)	
		1.18	. Description of commodit	ty				1.19. Commo	Ť		
		104	Tanananahana at anadash						1.20.	Quantity	
		1.21	. Temperature of product Ambient	Chilled		I.22. Number of packages					
		1.23	. Seal/Container No					1.24.	Type of packaging		
		1.25	. Commodities certified fo	or:					•		
			Animal feedingstuff	Technica	l use 🗌						
		1.26	. For transit through EU to Third country	o third country		1.27	. For impo	ort or admission	n into E	≣∪ [
		1.28	. Identification of the comm	modities							
			Species (Scientific name)	Appro	/al number Manufactu			s		Net weig	ht
		1									

COUNTRY Fresh or chilled hides and skins of ungulates II.a. Certificate reference No II.b. II. Health information I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Annex XIV, Chapter II thereof, and certify that the hides and skins described above: II.1. have been obtained from animals that: Certification (2) either [- were slaughtered and their carcases are fit for human consumption in accordance with Union legislation;] [- 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;] (²) or Part II: (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: 11.2. (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 has been free for at least 12 months before dispatch from foot-and-mouth disease and where, for 12 months before dispatch, (b) no vaccination has been carried out against foot-and-mouth disease (3); 11.3. have been obtained from: lanimals 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;] have undergone all precautions to avoid contamination with pathogenic agents. 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.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent — 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.

COUN	TRY	Fresh o	or chilled hides and skins of ungulates						
II.	Health information	II.a. Certificate reference No	II.b.						
— Вс	Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be given.								
— Во	Box reference I.25: technical use: any use other than for animal consumption.								
— Вс	— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.								
Part I	l:								
(^{1a}) C	J L 300, 14.11.2009, p. 1.								
(1b) C	U L 54, 26.2.2011, p. 1.								
(²) D	elete as appropriate.								
(3) D	elete diseases not applicable to the species concerned.								
— Th	e signature and the stamp must be in a different colour to that	of the printing.							
	ote for the person responsible for the consignment in the Eucompany the consignment until it reaches the border inspection		only for veterinary purposes and has to						
Officia	al veterinarian/Official inspector								
Nai	me (in capital letters):	Qualification a	nd title:						
Dat	te:	Signature:							
Sta	mp:								

CHAPTER 5(B)

Health certificate

For treated hides and skins of ungulates, intended for dispatch to or for transit through $(^2)$ the European Union

CO	UNIK	Υ	Veterinary certificate	to EL		
	1.1.	Consignor	I.2. Certificate reference No I.2.a.			
		Name Address	I.3. Central competent authority			
		Tel.	I.4. Local competent authority			
=	1.5.	Consignee	I.6. Person responsible for the load in EU			
l er		Name	Name			
l g		Address	Address			
] S			,			
8		Postcode	Postcode			
) ě		Tel.	Tel.			
of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO I.10. Region of Code destination	de		
8	-					
etai	1.11	. Place of origin	I.12. Place of destination			
Part I: Details		Name Approval number Address	Name Custom warehouse ☐ Address Approval number			
"		Name Approval number				
		Address	Postcode			
		Name Approval number Address				
	1.13	Place of loading	I.14. Date of departure			
	1.15	. Means of transport	I.16. Entry BIP in EU			
		Aeroplane ☐ Ship ☐ Railway wagon ☐				
		Road vehicle Other O	Latz Niumbay(a) of OITEO			
		Identification	I.17. Number(s) of CITES			
		Documentation references				
	110	Description of commodity	I.19. Commodity code (HS code)			
	1.10	. Description of commodity	1.19. Commodity code (HS code)			
			I.20. Quantity			
	1.21	. Temperature of product	I.22. Number of packages			
		Ambient ☐ Chilled ☐	Frozen			
	1.23	Seal/Container No	I.24. Type of packaging			
	1.25	. Commodities certified for:				
		Animal feedingstuff ☐ Technical use ☐				
		Anima reedingstan				
	1.26	. For transit through EU to third country	I.27. For import or admission into EU			
		Third country ISO code				
	1.28	Identification of the commodities				
		Species Approval number	of establishments Net weight			
		(Scientific name) Approval Hamber				
	1					

1	,	lealth in	formation	II.a. Certificate reference No II.b.
			Parliament	ersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the Europit and of the Council (1a) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 (1b), and Annex XIV, Chapter II thereof, and certify that the hides and skins described above:
		II.1.	have beer	n obtained from animals that:
			(²) either	[- were slaughtered and their carcases are fit for human consumption in accordance with Union legislation;]
			(²) or	[- were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were considered fit, a result of such inspection, for slaughter for human consumption in accordance with Union legislation:]
			(²) or	[- did not show any clinical signs of any disease communicable to humans or animals through the hide or skin, were not killed to eradicate any epizootic disease;]
(²)	either	[II.2.	part of a t	m animals originate from a third country or, in the case of regionalisation in accordance with Union legislation, fro third country listed in Part 1 of Annex II to Commission Regulation (EU) No 206/2010 (³) from which imports of fi he 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
			(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
(2)	or	[II.2.	part of a	m animals originate from a third country or, in the case of regionalisation in accordance with Union legislation, fro third country listed in Part 1 of Annex II to Regulation (EU) No 206/2010 from which imports of fresh meat of ading 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
			(²) or	[dried for 42 days at a temperature of at least 20 °C;]]
		II.3.		gnment has not been in contact with other animal products or with live animals presenting a risk of spreading a ser ible disease.
No	otes			
Pa	ırt I:			

COUNTRY	Trea	ted hides and skins of ungulates					
II. Health information	II.a. Certificate reference No	II.b.					
Box reference I.11 and I.12: Approval number: the registration number authority.	er of the establishment or plant, which	has been issued by the competent					
 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	1.03.						
Box reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should b	e given.					
Box reference I.25: technical use: any use other than for animal con	sumption.						
— Box reference I.26 and I.27: fill in according to whether it is a transit	t or an import certificate.						
Part II:							
(^{1a}) OJ L 300, 14.11.2009, p. 1.							
(^{1b}) OJ L 54, 26.2.2011, p. 1.							
(²) Delete as appropriate.							
(³) OJ L 73, 20.3.2010, p. 1.							
(4) OJ L 147, 31.5.2001, p. 1.							
- 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 Europ accompany the consignment until it reaches the border inspection polynomials.		or veterinary purposes and has to					
Official veterinarian/Official inspector							
Name (in capital letters):	Qualification and	d 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 (1) the European Union and have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation

NTR'	ľ					Veterinary certi	icate to Et	
1.1.	Consignor		I.2. Certi	ficate reference No)	1.2.a.		
	Name		I.3. Central competent authority					
	Address		<u> </u>					
	Tel.		I.4. Loca	l competent autho	rity			
1.5.	Consignee		I.6. Person responsible for the load in EU					
	Name		Nam	ie				
	Address		Addr	ress				
	Postcode		Post	code				
	Tel.		Tel.					
1.7.	Country of origin ISO code I.8. R	egion of origin Code	I.9. Cour	ntry of	ISO	I.10. Region of	Code	
	, ,	1			ode	destination	1	
1.11.	Place of origin		I.12. Plac	e of destination				
	Name Approva	I number	Nam			Custom warehouse]	
	Address		Addr	ress		Approval number		
	Name Approva Address	Inumber						
		I number	Post	code				
	Address							
I.13.	Place of loading		I.14. Date	of departure				
l.15.	Means of transport		I.16. Entry	y BIP in EU				
	Aeroplane Ship	Railway wagon 🗌						
	Road vehicle Other		I.17. Num	ber(s) of CITES				
	Identification							
	Documentation references							
I.18.	Description of commodity			I.19. Commo	dity cod	de (HS code)		
					1.20.	Quantity		
1.21.	Temperature of product				1.22.	Number of packages		
	Ambient Chilled	d 🔲	Frozen 🔲					
1.23.	Seal/Container No				1.24.	Type of packaging		
1.25.	Commodities certified for:							
	Animal feedingstuff	Technical use						
1.00	<u> </u>		1.07 5					
1.26.	For transit through EU to third country		1.27. For I	import or admissio	n into E	±U		
	Third country ISO coo	le 						
1.28.	Identification of the commodities							
	Species (Scientific name)	Approval num	ber of estat			Net v	veight	
		Manu	tacturing bia	INI				

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

COUNTRY

CUL	JNTRY				uninterrupted days before importa	ation
	II.	Healt	th informati	on	II.a. Certificate reference No	II.b.
			I, the unde	ersigned declare that the hides and skins	described above:	
		II.1.	have beer	obtained from animals that:		
			(1) either	[- were slaughtered and their carcase	s are fit for human consumption in	accordance with Union legislation;]
ation			(¹) or	[- were slaughtered in a slaughterhouse result of such inspection, for slaught	e, after undergoing ante-mortem inspe er for human consumption in accorda	
II: Certification			(¹) or	[- did not show any clinical signs of an and were not killed to eradicate any		or animals through the hide or skin,
Part II:		II.2.	have beer	1:		
ية			(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 wit	h the addition of 2 % of sodium carb	ponate;]
		II.3.		been in contact with other animal proble disease;	ducts or with live animals presenti	ng a risk or spreading a serious
	(²) either	[II.4.	have beer under poir	n kept separate immediately before dispatt II.2.]	atch for 21 days under official super	vision after the treatment described
	(²) or	[11.4.	following t	he declaration of the transporter, the dur	ation of the transport period is forese	en to be at least 21 days.]
	Notes					
	Part I:					
				esponsible for the consignment in the Eur in if the certificate is for import commodi		in only if it is a certificate for transit
	Box reference authority.	rence I.	11 and I.12:	Approval number: the registration number	er of the establishment or plant, which	has been issued by the competent
	Box refered be stored	rence I. d in free	12: Place of e zones, free	destination: this box is to be filled in only a warehouses and custom warehouses.	if it is a certificate for transit commod	dity. The products in transit can only
				tion number (railway wagons or containe oading and reloading.	r and lorries), flight number (aircraft)	or name (ship); information is to be
	— Box refe	rence I.	19: use the	appropriate HS code: 41.01; 41.02 or 4	1.03.	
	— Box refe	rence I.	23: for bulk	containers, the container number and th	e seal number (if applicable) should	be given.
	— Box refe	rence I.	25: technica	ll use: any use other than for animal con	sumption.	
	— Box refe	rence I.	26 and I.27:	fill in according to whether it is a transit	t or an import certificate.	
	Part II:					
	(1) Delete a	s appro	priate.			
	— The sign	ature a	nd the stam	p must be in a different colour to that of	the printing.	
				isible for the consignment in the Europe t until it reaches the border inspection po		or veterinary purposes and has to

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

COUNTRY	uninterrupted days before importation	010 101 2
II. Health information	II.a. Certificate reference No II.b.	
Official veterinarian/Official inspector		
Name (in capital letters):	Qualification and title:	
Date:	Signature:	
Stamp:		

▼<u>M4</u>

CHAPTER 6(A)

Health certificate

For treated game trophies and other preparations of birds and ungulates, consisting only of bones, horns, hooves, claws, antlers, teeth, hides or skins, for dispatch to or for transit through $(^2)$ the European Union

,014	TRY						vetermary ce	rtificate to EU
1.	.1.	Consignor Name		1.2.	Certificate re	ference No	1.2.a.	
		Address		1.3.	Central comp	petent authority		
		Tel.		1.4.	Local compe	tent authority		
	.5.	Consignee Name Address Postcode			Person respo Name Address	onsible for the loa	ad in EU	
		Tel.			Tel.			
1	.7.	Country of origin ISO code	I.8. Region of origin Code	1.9.	Country of destination	ISO code	I.10. Region of destination	Code
<u> </u>								
1.	.11.	Place of origin		1.12.	Place of des	tination		
		Name Address	Approval number		Name Address		stom warehouse proval number	
-		Name Address	Approval number		Postcode			
		Name Address	Approval number					
1.	.13.	Place of loading		1.14.	Date of depa	arture		
1.	.15.	Means of transport		I.16.	Entry BIP in	EU		
		Aeroplane Ship						
		Road vehicle Other		1.17.	Number(s) of	f CITES		
		Identification Documentation references			()			
1.	.18.	Description of commodity			1.19	. Commodity cod	de (HS code)	
							I.20. Quantity	
1.	.21.						I.22. Number of pack	ages
1.	.23.	Seal/Container No					I.24. Type of packagi	ng
1.	.25.	Commodities certified for:						
		Technical use						
1.	.26.	For transit through EU to third of	ountry	1.27.	or import or	admission into E	:U	
		Third country	ISO code					
1.	.28.	Identification of the commodities		-				
- 1		Species	Nature	_				of packages

▼ M4

Treated game trophies and other preparations of birds and ungulates, consisting only bones, horns, hooves, claws, antiers, teeth, bidge or skine

COUNTRY hides or skins Health information II.a. Certificate reference No II. I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Annex XIV, Chapter II thereof, and certify that the game trophies described above: II: Certification 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 []].2.1 in the case of game trophies or other preparations consisting only of hides or skin: Part (2) either [have been dried;] (2) and/or [have been dry-salted or wet-salted for a minimum of 14 days before dispatch;] minimum of 14 days salting before they reach the EU border inspection post;]] (2) and/or [II.2.2 in the case of game trophies or other preparations consisting only of bone, horns, hooves, claws, antiers 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 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.11 and I.12; Approval number: the registration number of the establishment or plant, which has been issued by the competent 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) is to be provided. In
case of unloading and reloading, the consignor must inform the BIP of entry into the EU. Box I.19: use the appropriate Harmonized System (HS) code under the following headings: 05.05, 05.06, 05.07 or 97.05. Box reference I.23; for bulk containers, the container number and the seal number (if applicable) should be included. Box reference I.25: technical use: any use other than for animal consumption. Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate. Box reference I.28: (a) for nature of commodity, select one or more of the following: [bones], [horns], [hooves], [claws], [antlers], [teeth], [hides] and/or [skins]; (b) in case of Species: select from the following: Aves, Equidae, Tapiridae, Rhinoceritidae, Antilocaparidae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamindae, Moschidae Suidae, Tayassuidae, Tragulidae and Elephantidae.

Part II:

 $(^{1a})\;\; OJ\;L\; 300,\; 14.11.2009,\; p.\;1.$

▼<u>M4</u>

Treated game trophies and other preparations of birds and ungulates, consisting only bones, horns, hooves, claws, antiers, teeth, hides or skins

COUNTRY	hides or skins						
II. Health information	II.a. Certificate reference No	II.b.					
(^{1b}) OJ L 54, 26.2.2011, p. 1							
(²) Delete as appropriate.							
- The signature and the stamp must be in a different colour to that o	the printing.						
Note for the person responsible for the consignment in the European the consignment until it reaches the border inspection post.	Union: this certificate is only for veterina	ry purposes and has to accompan					
Official veterinarian/Official inspector							
Name (in capital letters):	Qualifica	tion and title:					
Date:	Signature	ə:					
Stamp:							

CHAPTER 6(B)

Health certificate

For game trophies or other preparations of birds and ungulates consisting of entire parts which have not been treated, intended for dispatch to or for transit through $\binom{2}{1}$ the European Union

COL	JNTRY	′ :								Vete	erinary certifica	te to EU
	l.1.	Consignor					1.2.	Certificate referen	nce No	1.2	2.a.	
		Name					1.3.	Central competer	nt authority			
		Address					1.4.	Local competent	authority			
		Tel.										
	1.5.	Consigned					1.6.	Person responsib	ole for the lo	ad in E	U	
Ę		Name						Name				
gnme		Address						Address				
consi		Postcode						Postcode				
ped		Tel.						Tel.				
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code	I.8.	Region of origin	Code	1.9.	Country of destination	ISO code	I.10.	Region of destination	Code
Details	l.11.	Place of o	rigin				I.12.	Place of destinati	on			
=======================================		Name Approval number Address								Cue	tom warehouse	
Pa							Name Approval number					
		Name		Appro	val number			Address		, , , pp	TOVAL HAITIDO	
		Address		• •								
		Name		Appro	val number			Postcode				
		Address										
	I.13.	Place of lo	ading				I.14.	Date of departure)			
	l.15.	Means of t	transport				I.16.	Entry BIP in EU				
		Aeroplane	☐ Ship	п	Railway wa	agon \square						
		Road vehi			riaminaj me	.go <u>—</u>	1.17.	Number(s) of CIT	ES			
		Identificati										
		Document	ation referen	ces								
	l.18.	Description	n of commod	ity					I.19. Comr	nodity	code (HS code)	
								L		1.20	. Quantity	
	l.21.									1.22	. Number of pa	ckages
	1.23.	Seal/Conta	ainer No							1.24	. Type of packa	ging

1.25.	Commodities certified for:				
	Technical use □				
1.26.	For transit through EU to third	country	1.27.	For import or admission into EU	
	Third country	ISO code			
1.28.	Identification of the commoditi	ies			
	Species (Scientific name)			Number of packages	

COUNTRY

Game trophies or other preparations of birds and ungulates consisting of entire parts which have not been treated

	II.	Health info	ormatio	on		II.a.	Certifica	ite referer	nce No		II.b.	
		the Europe	ean Pai	rliament		Counc	il (^{1a}), ar	d Comm	ission Reg	ulation (Ě	U) No 142/20	No 1069/2009 of 011 (^{1b}), and in
	(²) either	[II.1.	with re	spect to	game trophie	es or ot	her prepa	arations o	f cloven-ho	ofed anima	als, excluding	swine:
Part III: Certification			(a)	a perio		eding 1	2 months					nd rinderpest for nst any of those
≅			(b)	the ga	me trophies or	other	preparati	ons desci	ribed above) :		
Pa				(i)	authorised fo susceptible of	r the e lomest een no	xportation ic specie animal h	n to the E s and wh nealth res	iuropean U nere, during	nion of fre the perio	sh meat of the	region, which is e corresponding ceding 60 days, ses to which the
				(ii)	of another thi	rd cou	ntry or pa	ırt of a thi	rd country	not authori		rom the borders untreated game n;]
	(²) or	[II.1.	with re	spect to	game trophic	es or ot	her prepa	arations o	f wild swine) :		
			(a)	classic porcine	cal swine feve	r, Afric enceph	an swine almiyeliti	fever, sw (Tesche	vine vesicul en disease)	ar disease and no va	, foot-and-mo accinations ha	s, was free from uth disease and we been carried
			(b)	the ga	me trophies or	other	preparati	ons desci	ribed above) :		
				(i)	exportation to	to the ecies a nal he	Europea and wher	n Union e, during	of fresh r	neat of th of the pr	e correspondeceding 60 d	uthorised for the ling susceptible ays, there have th the swine are
				(ii)		ird cou	ntry or pa	art of a thi	ird country			rom the borders untreated game
	(²) or	[II.1.	describ	bed abo								ner preparations of the exporting
	(²) or	[II.1.	with re	spect to	game trophie	es or ot	her prepa	arations o	f game bird	ls:		
			(a)	diseas		(r	egion) is	free from	ı highly pat	hogenic a	vian influenza	and Newcastle
			(b)	that we	ere killed in th no animal he	at regi	on and w	here duri	ng the peri	od of the p	preceding 30	wild game birds days there have e wild birds are
	II.2.		f anima	l origin	likely to conta							ontact with other s so as to avoid

COUNTRY

Game trophies or other preparations of birds and ungulates consisting of entire parts which have not been treated

							treated
II.	Health in	formation		II.a.	Certificate reference No	II.b.	
(²) [II.3.	The game	trophies or o	ther preparat	ions des	cribed above		
	(²) either	[are derived	from other r	uminants	than bovine, ovine or caprine anima	ls.]]	
	(²) or	[are derived	from bovine	, ovine o	caprine animals and does not conta	iin and is not deriv	ved from:
		(²) either	continuo	isly rear	nd caprine materials other than the ed and slaughtered in a country of in accordance with Decision 2007/4	or region classifi	
		(²) or			risk material as defined in point 1 01 of the European Parliament and c		Regulation (EC)
			aı sl ad	nimals, e aughtere ccordanc	ally separated meat obtained from the except from those animals that were din a country or region classified as with Commission Decision 2007/49 ous BSE case,	re born, continuo as posing a negli	ously reared and gible BSE risk in
(c) animal by-product or derived product obtained from bovine, ovine or ca animals which have been killed, after stunning, by laceration of the ce nervous tissue by means of an elongated rod-shaped instrument introduced the cranial cavity, or by means of gas injected into the cranial cavity, except those animals that were born, continuously reared and slaughtered in a co or region classified as posing a negligible BSE risk in accordance with Dec 2007/453/EC.]]]							
Notes							
Part I:							
it is	a certificate		dity to be tra	ansited th	gnment in the European Union: this rough the European Union; it may		
		.11 and I.12: empetent auth		ımber: th	e registration number of the establ	ishment or plant,	which has been
					to be filled in only if it is a certificate louses and custom warehouses.	for transit commo	odity. Products in
					ragons or container and lorries), fligh nd reloading in the European Union.		t) or name (ship);
— Вох	reference I.	19: use the ap	opropriate HS	S code: 0	5.05; 05.06, 05.07, 05.11; 96.01 or 9	7.05.	
— Вох	reference I.	23: for bulk co	ontainers, the	containe	er number and the seal number (if ap	plicable) must be	included.

Box reference I.25: technical use: any use other than for animal consumption.

Elephantidae.

Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

Box reference I.28: Species: select from the following: Aves, Equidae, Tapiridae, Rhinoceritidae, Antilocaparidae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamindae, Moschidae Suidae, Tayassuidae, Tragulidae and

COUNTRY

Game trophies or other preparations of birds and ungulates consisting of entire parts which have not been treated

II.	Health information	II.a. Certificate reference No		II.b.
Part	t II:			
(^{1a})	OJ L 300, 14.11.2009, p. 1.			
(1b)	OJ L 54, 26.2.2011, p. 1.			
(2)	Delete as appropriate.			
(3)	OJ L 147, 31.5.2001, p. 1.			
(4)	OJ L 172, 30.6.2007, p. 84.			
_	The signature and the stamp must be in a dif	fferent colour to that of the printir	ng.	
_	Note for the person responsible for the cons and must accompany the consignment until Union.			
Offic	cial veterinarian/Official inspector			
	Name (in capital letters):		Qualification a	nd 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

Consignor Name					1.2.	Cortifica	ate reference	NI-	- I.,	٠	
Name					1.2.	Certifica	ate reference	INO	1.5	2.a	
					1.3.	Central	competent a	uthority			
Address											
Tel.					1.4.	Local c	ompetent au	thority			
Consignee					1.6.	Person	responsible	for the loa	ad in E	€U	
Name						Name					
Address						Addres	s				
Postoode						Postoor	40				
Tel.						Tel.	10				
Country of origin	ISO code	I.8. Regi	ion of origin	Code	1.9.	Country	/ of	ISO	1.10.	Region of	Code
country or origin	1		on on ong	1				code		destination	1
. Place of origin					1.12.	Place o	of destination				
Name		Approval n	umber			Name]
		Ammunial in				Addres	S		Apı	oroval number	
Address		Approvai n	umber								
Name Address		Approval n	umber			Postco	de				
. Place of loading					l.14.	Date of	departure				
. Means of transport	t .				I.16.	Entry B	IP in EU				
Aeroplane	Ship 🔲	Ra	ilway wagon [
	Other 🗌				1.17.						
	erences										
							I 19 Com	modity co	de (HS	S code)	
. Booding aon or oom	imounty						1.10. 0011	05.02	uo (110	, 0000)	
								1.20.	Quant	tity	
. Temperature of pro	oduct							1.22.	Numb	er of packages	
Ambient		Chilled [Frozer	, 🗆					
. Seal/Container No								1.24.	Туре	of packaging	
. Commodities certif	ied for:										
Animal feedingstuff	· 🗆		Technical us	se 🗌							
. For transit through	EU to third	country			1.27.	For imp	ort or admis	sion into I	≣U]
Third country		ISO code									
. Identification of the	commoditie	es			1						
		ents		Nu	mber of	packag	jes			Net v	weight
	Tel. Consignee Name Address Postcode Tel. Country of origin Place of origin Name Address Name Address Name Address Place of loading Means of transport Aeroplane Road vehicle Identification Documentation refe Description of com Temperature of pro Ambient Seal/Container No Commodities certif Animal feedingstuff For transit through Third country Identification of the Approval number of	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code Place of origin Name Address Name Address Name Address Name Address Place of loading Means of transport Aeroplane Ship Road vehicle Other Identification Documentation references Description of commodity Temperature of product Ambient Seal/Container No Commodities certified for: Animal feedingstuff Services For transit through EU to third Third country Identification of the commodities	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Reg Postcode Tel. Country of origin ISO code I.8. Reg Postcode Tel. Country of origin ISO code I.8. Reg Place of origin Name Approval in Address Name Approval in Address Name Approval in Address Place of loading Means of transport Aeroplane Ship Ra Road vehicle Other Identification Documentation references Description of commodity Temperature of product Ambient Chilled I Seal/Container No Commodities certified for: Animal feedingstuff For transit through EU to third country Third country ISO code Identification of the commodities Approval number of establishments	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Region of origin Place of origin Name Approval number Address Name Approval number Address Name Approval number Address Place of loading Means of transport Aeroplane Ship Railway wagon Road vehicle Other Identification Documentation references Description of commodity Temperature of product Ambient Chilled Seal/Container No Commodities certified for: Animal feedingstuff Technical us For transit through EU to third country Third country ISO code Identification of the commodities Approval number of establishments	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Region of origin Code Place of origin Name Address Name Approval number Address Name Approval number Address Name Approval number Address Place of loading Means of transport Aeroplane Ship Railway wagon Documentation references Description of commodity Temperature of product Ambient Chilled Documentation references Commodities certified for: Animal feedingstuff Technical use Documentation of the commodities Approval number Iso code Identification Iso code Identification Iso code	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Region of origin Code I.9. Place of origin Name Approval number Address Place of loading I.14. Means of transport Aeroplane Ship Railway wagon Indentification Documentation references Description of commodity Temperature of product Ambient Chilled Frozer Seal/Container No Commodities certified for: Animal feedingstuff Technical use Indentification I.27. Third country ISO code I.27. Identification of the commodities Approval number of establishments Number of	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Region of origin Code I.9. Country destina Place of origin ISO code I.8. Region of origin Code I.9. Country destina Place of origin Approval number Address Name Approval number Address Name Approval number Address Postcod Name Approval number of packag Number of packag Number of packag	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Region of origin Code I.9. Country of destination Place of origin Name Address Approval number Address Name Address Name Approval number Address Name Address Name Approval number Address Name Address Name Approval number Address Name Address Name Approval number Address Name Approval number Address Name Approval number Address Postcode I.14. Date of departure I.16. Entry BIP in EU I.17. I.17. I.19. Com III9. Com II9. Com III9. Com I	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Region of origin Code Place of origin Name Address Approval number Address Postcode Tel. Country of origin ISO code I.8. Region of origin Code Place of origin Name Address Approval number Address Name Address Approval number Address Postcode Postcode Postcode Postcode I.12. Place of destination Name Address Name Address Postcode I.14. Date of departure I.16. Entry BIP in EU I.17. I.19. Commodity coors Ostoze I.20. Temperature of product Ambient Chilled Frozen I.24. Commodities certified for: Animal feedingstuff Technical use I.27. For import or admission into I Indentification Into I I.27. For import or admission into I I.28. Seal/Container No I.29. I.29. I.20. I.20. I.20. I.20. I.21. For transit through EU to third country III III III III III III III III III I	Tel. Consignee Name Address Postcode Tel. Country of origin ISO code I.8. Region of origin Code I.9. Country of destination Place of origin Name Address Approval number Address Postcode Tel. 1.12. Place of destination Name Address Approval number Address Approval number Address Postcode Place of origin Name Approval number Address Approval number Address Postcode 1.14. Date of departure I.16. Entry BIP in EU I.17. I.19. Commodity code (HS 05.02 I.20. Quant Temperature of product Ambient Chilled Frozen I.22. Numb Technical use I.25. For import or admission into EU I.16. Entry Import or admission into EU I.17. For transit through EU to third country Iso code I.28. Number of packages	Tel. Consignee Name Address Postcode Postcode Tel. Country of origin ISO code I.8. Region of origin Code I.1. Place of destination Place of origin Name Address Approval number Address Name Address Approval number Address Name Address Approval number Address Name Approval number Postcode Address I.14. Date of departure I.16. Entry BIP in EU I.17. I.19. Commodity code (HS code) 05.02 I.20. Quantity I.20. Quantity I.21. Type of packages Approval number of packages Commodities certified for: Animal feedingstuff

Pig bristles from third countries or regions thereof that are free from

COUNTRY African swine fever Health information II.a. Certificate reference No II.b. I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and in particular Article 10(b)(iv) thereof, and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Annex XIV, Chapter 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 Certification 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; Part II: 11.4. the pig bristles are dry and securely enclosed in packaging. 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.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent 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.25: technical use: any use other than for animal consumption. 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 L 300, 14.11.2009, p. 1. (1b) OJ L 54, 26.2.2011, p. 1. (2) Delete as appropriate. The signature and the stamp must be in a different colour to that of the printing. Note for the person responsible for the consignment in 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/Official inspector 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

cou	NTR	1							Veterinary cert	ificate to EU
	l.1.	Consignor			1.2.	Certificat	e reference	No No	1.2.a.	
		Name			1.3.	Central o	ompetent a	authority		
		Address			14	Local co	mpetent au	thority		
		Tel.			1.4.	Local co	inpetent at	unonty		
ent	1.5.	Consignee			1.6.	Person r	esponsible	for the loa	ad in EU	
nu		Name				Name				
nsiç		Address				Address				
o p		Postcode				Postcode	Э			
dispatched consignment		Tel.	T			Tel.			T	
lispa	1.7.	Country of origin ISO code	I.8. Region of origin	Code	1.9.	Country destinati		ISO code	I.10. Region of destination	Code
o						dootinati		0000	dodination	
etails	l.11.	Place of origin			l.12.	Place of	destination	1		'
Part I: Details		Name Address	Approval number			Name Address			Custom warehouse Approval number	
д		Name Address	Approval number			Postcode	9			
		Name Address	Approval number			1 001000				
	I.13.	Place of loading			l.14.	Date of	departure			
	l.15.	Means of transport			I.16.	Entry BII	o in EU			
		Aeroplane	Railway wagon]						
		Road vehicle Other	1		l.17.					
		Identification Documentation references								
	1.18.	Description of commodity					I.19. Com	modity co	de (HS code)	
								05.02		
								1.20.	Quantity	
	1.21.	Temperature of product						1.22.	Number of packages	
		Ambient	Chilled		Froze	r 🗆				
	1.23.	Seal/Container No						1.24.	Type of packaging	
	1.25.	Commodities certified for:								
		Animal feedingstuff	Technical use	e 🗆						
	1.26.	For transit through EU to third	I country		1.27.	For impo	ort or admis	ssion into	EU	
		Third country	ISO code							
	1.28.	Identification of the commodit	ies							
		Approval number of establish Manufacturing plant	ments	Num	nber of	package	s		Ne	et weight

COUNTRY

Pig bristles from third countries or regions thereof that are not free from African swine fever

Health information II.a. Certificate reference No II.b. I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and in particular Article 10(b)(iv) thereof, and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Annex XIV, Chapter 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; Certification 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; 11.2. II.3. the pig bristles mentioned above have been: ≝ Part (2) either [boiled;] (2) or [dyed;] (2) or [bleached;] the pig bristles are dry and securely enclosed in packaging. 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.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent 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.25: technical use: any use other than for animal consumption. 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 L 300, 14.11.2009, p. 1. (1b) OJ L 54, 26.2.2011, p. 1. (2) Delete as appropriate. The signature and the stamp must be in a different colour to that of the printing. - Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

▼<u>B</u>

COUNTRY Pig bristles from third countries or regions thereof that are not free from African swine fever II. Health information II.a. Certificate reference No II.b. Official veterinarian/Official inspector Name (in capital letters): Date: Stamp:

CHAPTER 8

Health certificate

For animal by-products to be used for purposes outside the feed chain or for trade samples $(^2)$, intended for dispatch to or for transit through $(^2)$ the European Union

COL	JNTRY	′ :				Veterinary certifica	te to EU	
	l.1.	Consignor	1.2.	Certificate referer	nce No	I.2.a.		
		Name	1.3.	Central competer	nt authority			
		Address	1.4.	Local competent	authority			
		Tel.						
	1.5.	Consignee	1.6.	Person responsib	le for the lo	ad in EU		
ueut		Name		Name				
ignn		Address		Address				
Part I : Details of dispatched consignment		Dantasda		Destanda				
ed c		Postcode		Postcode				
atch	1.7.	Tel. Country ISO code I.8. Region of Code	1.9.	Tel. Country of	ISO	I.10. Region of	Code	
disp	1.7.	of origin origin	1.9.	destination	code	destination	Code	
s of								
etails	I.11.	Place of origin	1.12	. Place of destinati	on			
ă ă								
art		Name Approval number				Custom warehouse		
L		Address		Name Approval number				
		Name Approval number		Address				
		Address						
		Name Approval number		Postcode				
		Address						
	I.13.	Place of loading	1.14	. Date of departure	•			
	I.15.	Means of transport	1.16	. Entry BIP in EU				
		Aeroplane Ship Railway wagon Railway						
		Road vehicle Other	1.17					
		Identification						
		Documentation references						
	I.18.	Description of commodity			I.19. Comr	modity code (HS code)		
						T		
						I.20. Quantity		
	1.21.	Temperature of product		_		I.22. Number of page	ckages	
		Ambient Chilled Chilled		Frozen \square				
	1.23.	Seal/Container No				I.24. Type of packa	ging	

1.25.	Commodities cert	ified for:				
	Technical use \square					
1.26.	For transit through	n EU to third country		I.27. For import or a	dmission into EU	
	Third country	ISO code	е			
1.28.	Identification of th	e commodities	A	-ft-bli-b		
			Approval number	or establishments		
(Sci	Species entific name)	Nature of commodity	Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples (2)

	II.	Health information	ı	II.a. C	ertificate reference No		II.b.					
		of the European Pa	rliament and of the	Council (nat I have read and und ^{1a}), and Commission R ertify that the animal by	egulation (El	J) No 142/20	111 (^{1b}), and in				
ion		referred to	in the definition of	f trade sa	imal by-products intenc mples in point 39 of Ar IOT FOR HUMAN CON	nnex I to Reg	julation (EU)					
Part II: Certification		(²) or [satisfy the	e animal health req	uirements	set out in point II.1.];							
ë ë	II.1.	The animal by prod	ucts described abo	ve								
Pa	II.1.1.	have been	have been									
					imported from a (³) authorised to expo	third coul ort fresh mea						
			2) and/or [(b) obtained in the exporting third country, territory or part thereof:									
		eith	either:									
		(i)	(i) have remained in that third country, territory or part thereof eligible to export fresh meat to the European Union since birth or for a period of at least the preceding three months before the date of slaughter; and/or									
		(ii)	(ii) were killed in the wild in that third country, territory or part thereof (4);]									
			rived from eggs, n ertebrates;]	nilk, rodei	nts, lagomorphs, or ac	quatic anima	ls or terrest	rial or aquatic				
	(²) [II.1.2.				derived from eggs, mi es and unprocessed fu							
		(²) either [(a) cor	ning from holdings:									
		(i)	(i) where, for the following diseases for which the animals are susceptible, ther not been any case/outbreak of rinderpest, swine vesicular disease, New disease or highly pathogenic avian influenza during the period of the prec 30 days, nor of classical or African swine fever during the period of the prec 40 days; nor in the holdings situated in their vicinity within a 10 km radius, of the period of the preceding 30 days; and									
		(ii)	period of the	he preced	been any case/outbrea ing 60 days, nor in the ng the period of the pre	holdings site	uated in their					
		(b) wh	ich:									
		(i)	were not ki	illed to era	adicate any epizootic di	sease;						
		(ii)	(ii) remained on their holdings of origin for a period of at least 40 days before the of departure and which were transported directly to the slaughterhouse w contact with other animals which did not comply with the same health condition									
		(iii)	(iii) at the slaughterhouse, passed the ante-mortem health inspection during the period of 24 hours before the time of slaughter and showed no evidence of the diseases referred to above for which the animals are susceptible; and									
		(iv)	accordance requiremen	e with the	slaughterhouse before e relevant provisions of t equivalent to those la 1099/2009 (⁵)]	of Union legi	slation and	complied with				

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples (2)

									the fee	ed chai	n or foi	trade sa	amples (²)
II.	Health inf	orma	tion		II.a.	Certific	ate refe	rence l	No		II.b.		
	(²) or	[(a)	captured an	nd killed in t	he wilc	d in an a	rea:				_		
			1	where withing distribution of the contraction of the period of the period of the contraction of the contract	seases Newca le prec	s for whi astle dis ceding 3	ch the a sease o 0 days	animals or highl nor of o	are sus	ceptible genic a	e: foot-a vian in	ind-mout fluenza (h disease, during the
			· í	that is situa another terr dates for the	ritory o	of a third	country	or par	t thereo	f, which	is not a	authorise	
		(b)	which after centre and establishme	I immediate									
(²) [II.1.3.	obtained in diseases r 30 days on exportation	n an referre r, in t n to tl	naterials othe establishme ed to in poir the event of ne Europear of the estab	nt around want II.1.2 for a case/ou o Union was	which, which tbreak s auth	within a the an of one orised o	radius imals a of thos nly afte	of 10 re susc e disea r the re	km, the ceptible ases, the emoval c	re has during e prepa of all m	been no a period aration	o case/o d of the of raw m	utbreak of preceding naterial for
II.1.4.			ained and pred above, a										
II.1.5.	disinfected sealed un PRODUCT	d befo nder t TS Of	ed in new pa ore use and, the respons NLY FOR TH name and a	in the cas ibility of the IE MANUFA	se of con ne con ACTUR	consignn mpetent RE OF D	nents sl authori ERIVEI	nipped ty, bea D PROI	other the aring the DUCTS	an via e label FOR U	parcel indica SES OU	post, in ting 'ANI JTSIDE T	containers IMAL BY-
II.1.6.	consist onl	ly of t	he following	animal by-p	roduct	ts:							
	(²) either	[-	carcases ar killed which irreversibly	were deem	ned fit f	for huma	an cons	umption	n in acco	rdance	with Ur		
	(²) and/or	[-	carcases and slaughterhod ante-morter human cons	ouse and w m inspectio	rere co	onsidere oodies a	d fit for nd the	slaugh followir	nter for lang parts	human	consun	nption fol	llowing an
			``	carcases or consumptio signs of disc	n in a	ccordan	ce with	Union	legislat	ion, bu			
			(ii)	heads of po	ultry;								
			` ´	hides and s the phalang bones;									
			(iv)	pig bristles;									
			(v)	feathers;]									
	(²) and/or	[-	animal by-p Article 1(3) Council (^{2a}),	(d) of Reg	ulation	1 (EC)	No 853	/2004	of the E	Europea	an Parli	ament a	nd of the
	(²) and/or	[-	blood of an humans or after having mortem insp	animals, ob g been cor	btained nsidere	d from a ed fit fo	nimals slaugh	that ha	ve been human	slaugh	ntered in	n a slaug	hterhouse

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples (²)

				1110 1004 0114	in or for trade samples (²)
II.	Health inf	orma	ation	II.a. Certificate reference No	II.b.
	(²) and/or	[-		sing from the production of products intendone, greaves and centrifuge or separator slu	
	(²) and/or	[-	longer intended for h	igin, or foodstuffs containing products of a uman consumption for commercial reaso aging defects or other defects from which	ns or due to problems of
	(²) and/or	[-	derived products, which	uffs of animal origin, or feedingstuffs contains are no longer intended for feeding for coluring or packaging defects or other defects;]	mmercial reasons or due to
	(²) and/or	[-		, feathers, hair, horns, hoof cuts and raw low signs of any disease communicable thro	
	(²) and/or	[-		parts of such animals, except sea mamma municable to humans or animals;]	ls, which did not show any
	(²) and/or	[-		from aquatic animals originating from s for human consumption;]	establishments or plants
	(²) and/or	[-		originating from animals which did not s that material to humans or animals:	how any signs of disease
			(i) shells from	shellfish with soft tissue or flesh;	
			(ii) the following	g originating from terrestrial animals:	
			— hatche	ery by-products;	
			— eggs;		
			— egg by	y-products, including egg shells;	
			(iii) day-old chi	cks killed for commercial reasons;]	
	(²) and/or	[-	animal by-products fro humans or animals;]	m aquatic or terrestrial invertebrates, other	than species pathogenic to
	(²) and/or	[-	Category 1 material	ereof of the zoological orders of Rodentia as referred to in Article 8(a)(iii), (iv) an tegory 2 material as referred to in Article 9(a	id (v) of Regulation (EC)
	(²) and/or	[-		dead animals that did not show clinic that product to humans or animals;]	cal signs of any disease
II.1.7.		in s	ich a way that they will	f origin or have been preserved in accord not spoil between the time of dispatch and	
(²) (⁶) [II.1.8.					
(²) (⁷)					
either [II.1.8.1.	territory or	par	t thereof referred to in	gnment come from animals that have bee point II.1.1, where vaccination programm ficially controlled in domestic bovine animals	es against foot-and-mouth

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples (²)

				the feed chain or for trade samples (²)							
II.	Health info	ormation		II.a. Certificate reference No	II.b.						
(2) (8)											
and/or [II.1.8.2.	The anima meat.]]	l by-products	in this consig	gnment consist of animal by-products de	erived from offal or deboned						
(²) [II.1.9.	the animal	by-products o	lescribed above	e							
	(²) either	[are derived	are derived from other ruminants than bovine, ovine or caprine animals.]]								
	(²) or	[are derived	e derived from bovine, ovine or caprine animals and does not contain and is not derived from:								
		(²) either	either [bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC.]]								
		(²) or	[(a) specified risk material as defined in point 1 of Annex V to Regulati No 999/2001 of the European Parliament and of the Council (9);								
			animals, slaughte accorda	cally separated meat obtained from bone except from those animals that were bred in a country or region classified as pace with Commission Decision 2007/453 indigenous BSE case,	orn, continuously reared and osing a negligible BSE risk in						
			animals nervous into the for those country	by-product or derived product obtained f which have been killed, after stunning, tissue by means of an elongated rod- cranial cavity, or by means of gas injected e animals that were born, continuously or region classified as posing a negligible 12007/453/EC.]]]	by laceration of the central shaped instrument introduced into the cranial cavity, except reared and slaughtered in a						
II.1.10	the animal	by-products o	lescribed above	9 :							
	(²) either		ain milk or milk als, other than	products of ovine or caprine animal origin fur animals.]	or is not intended for feed for						
	(²) or			cts of ovine or caprine animal origin and inals, and the milk or milk products:	s intended for feed for farmed						
				and caprine animals which have been kellowing conditions are fulfilled:	ept continuously since birth in						
		(i)	classical sc	rapie is compulsorily notifiable;							
		(ii)	an awarene	ess, surveillance and monitoring system is	in place for classical scrapie;						
		(iii)		rictions apply to holdings of ovine or cap f TSE or the confirmation of classical scra							
		(iv)	ovine and o	aprine animals affected with classical scr	apie are killed and destroyed;						
		(v)	defined in t Health (OIE	to ovine and caprine animals of meat-a ne Terrestrial Animal Health Code of the E), of ruminant origin has been banned a try for a period of at least the preceding s	World Organisation for Animal and effectively enforced in the						
		(b) originate	e from holdings	where no official restrictions are imposed	I due to a suspicion of TSE;						
		` '	of the precedir	s where no case of classical scrapie hang seven years or, following the confirm	0						

▼M15

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples (2)

II.	Health information		II.a. Certificate reference No II.b.							
	(²) either	slaughtered carrying at	nd caprine animals on the holding have been killed and destroyed or i, except for breeding rams of the ARR/ARR genotype, breeding ewes least one ARR allele and no VRQ allele and other ovine animals least one ARR allele;]							
	(²) or	destroyed, a since the da monitoring, accordance Annex X to	in which classical scrapie was confirmed have been killed and and the holding has been subjected for a period of at least two years ate of confirmation of the last classical scrapie case to intensified TSE including testing with negative results for the presence of TSE in with the laboratory methods set out in point 3.2 of Chapter C of Regulation (EC) No 999/2001, of all of the following animals which are e of 18 months, except ovine animals of the ARR/ARR genotype:							
		— animal	s which have been slaughtered for huma	n consumption; and						
			s which have died or been killed on then the framework of a disease eradication	•						

Notes

Part I:

- Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if
 it is a certificate for a commodity to be transited through the European Union; it may be filled in if the certificate is for a
 commodity to be imported into the European Union.
- Box reference I.11: In the case of consignments for trade samples or analyses: indicate the name and address of the establishment only.
- Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority.
- Box reference I.12: Place of destination: this box is to be filled in:
 - products for the manufacture of derived products for uses outside the feed chain: only if it is a certificate for a transit commodity. Products in transit may only be stored in free zones, free warehouses and custom warehouses.
 - products for trade samples or analyses: the plant in the European Union indicated in the authorisation of the competent authority where appropriate.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In the case of unloading and reloading in the European Union, the consignor must inform the border inspection point of the point of entry into the European Union.
- Box reference I.19: use the appropriate Harmonized System (HS) code under the following headings: 04.01; 04.02; 04.03; 04.04; 04.08; 05.05; 05.06, 05.07; 05.11.91; 05.11.99, 23.01 or 30.01.
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be included.
- Box reference I.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the
 production or manufacturing of pet food.
- Box reference I.25: for the purposes of the certificate, 'technical use' includes use as a trade sample.
- Box reference I.26 and I.27: except for trade samples, which are not sent in transit, fill in according to whether it is a transit or an import certificate.
- Box reference I.28:
 - products for the manufacture of derived products for uses outside the feed chain: Manufacturing plant: provide the veterinary control number of the approved establishment.
 - products for the particular technological studies or analyses: the plant in the European Union indicated in the authorisation of the competent authority where appropriate.
 - Species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or Suidae, Pesca, Mollusca, Crustacea, invertebrates other than Mollusca and Crustacea.

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples (²)

II.	Health information	II.a. Certificate reference	No	II.b.						
Pari	t II:									
(^{1a})	OJ L 300, 14.11.2009, p. 1.									
(1b)	OJ L 54, 26.2.2011, p. 1.									
(2)	Delete as appropriate.									
(^{2a})	OJ L 139, 30.4.2004, p. 55.									
(3)	The name and ISO code number of the exporting country as laid down in:									
_	Part 1 of Annex II to Commission Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010, p. 1);									
_	Annex I to Commission Regulation (EC) No 798	3/2008 (OJ L 226, 23.8.2008,	p. 1), and							
_	Annex I to Commission Regulation (EC) No 119	9/2009 (OJ L 39, 10.2.2009, p	. 12).							
	In addition the ISO code of territories and parts thereof referred to in the Annexes to Regulations (EU) No 206/2010, (EC) No 798/2008 and (EC) No 119/2009 referred to in this note (where applicable for the susceptible species concerned) must be included where applicable.									
(4)	Only for countries from where the game meat intended for human consumption of the same animal species is authorised for importation into the European Union.									
(⁵)	OJ L 303, 18.11.2009, p. 1.									
(⁶)	Supplementary guarantees to be provided where 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 deboned fresh meat of domestic ruminants for human consumption is authorised for exportation to the European Union. The whole masseter muscles of bovine animals, incised in accordance with the requirements of Part B.1 of Chapter I of Section IV of Annex Ito Regulation (EC) No 854/2004 of the European Parliament and of the Council (OJ L 139 30.4.2004, p. 206), are also permitted.									
(⁷)	Only for certain South American countries.									
(8)	Only for certain South American and South Africa	can countries.								
(⁹)	OJ L 147, 31.5.2001, p. 1.									
(10)	OJ L 172, 30.6.2007, p. 84.									
-	The signature and the stamp must be in a differ	ent colour to that of the printi	ng.							
_	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 point of entry into the European Union.									
Offic	Official veterinarian/Official inspector									
	Name (in capital letters):		Qualification an	d 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

cou	COUNTRY Veterinary certificate to EU												
	1.1.	Consignor				1.2.	Certificat	e reference	No	1.2.a.			
		Name Address				I.3. Central competent authority							
						I.4. Local competent authority							
	l	Tel.											
eut	1.5.	Consignee				I.6. Person responsible for the load in EU							
ਵ		Name				Name							
nsig		Address					Address						
8		Postcode					Postcode	e					
dispatched consignment		Tel.					Tel.						
pat	1.7.	Country of origin Is	SO code	I.8. Region of origin	Code	1.9.	Country	of	ISO	I.10. Region	of	Code	
흥		ĺ			ı		destinati	on I	code	destinati	on I		
s of													
Part I: Details	1.11.	. Place of origin					Place of	destination					
<u>:</u>		Name		Approval number			Name			Custom war]	
- Jar		Address					Address			Approval nu	mber		
-		Name Address		Approval number									
		Name		Approval number			Postcode	е					
		Address											
	1.13.	Place of loading		I.14. Date of departure									
	l.15.	. Means of transport					I.16. Entry BIP in EU						
		Aeroplane	Ship 🔲	Railway wagon [
		Road vehicle	Other 🔲			1.17.							
		Identification											
		Documentation refere	ences										
	I.18.	Description of commo	odity			I.19. Commodity code (HS code)							
									1.20.	Quantity			
	1.21.	Temperature of produ	uct			I.22. Number of packages							
		Ambient		Chilled		Froze	n 🔲						
	1.23.	Seal/Container No							1.24.	I.24. Type of packaging			
	1.25.	Commodities certified	d for:										
		Animal feedingstuff	7	Technical us	e 🗆								
		Attinual localitystan [] Teoliilloal dee []											
	1.26.	For transit through El	U to third	, –		1.27.	For impo	ort or admis	sion into	EU]	
		Third country		ISO code									
	1.28.	Identification of the co	ommoditie	s									
		Nature of commodity	Арр	proval number of establis Manufacturing plant	hments	ı	Number o	f packages		Net weight	Batch	number	

Fish oil not intended for human consumption to be used as feed

c	COUNTRY					material or for purposes outside the feed chain					
ſ		II.	Health inf	orma	ation	II.a. Certificate reference No	II.b.				
			and of the	Cour	ned official veterinarian, declare that I have read an noil (1a) and in particular Article 10 thereof, and Coof, and certify that the fish oil described above:	ommission Regulation (EU) No 142/20					
		II.1.	consists of	fish	oil that satisfies the health requirements below;						
	tion	II.2.	contains e	xclus	sively fish oil not intended for human consumptio	n;					
	Part II: Certification	II.3.			ared and stored in a dedicated fish plant approved egulation (EC) No 1069/2009;	d, validated and supervised by the com	petent authority in accordance with				
	= II.4. has been prepared exclusively with the following animal by-products:										
	g.		(2) either	[-	animal by-products arising from the production	of products intended for human consu	umption;]				
			are no longer intended for human ging defects or other defects from								
			(2) and/or	[-	aquatic animals, and parts of such animals, explicable to humans or animals;]	cept sea mammals, which did not sh	ow any signs of diseases commu-				
L			(2) and/or	[-	animal by-products from aquatic animals origin consumption;]	nating from plants or establishments	manufacturing products for human				
		II.5.	the fish oil	:							
 (a) has been subjected to processing in accordance with Annex X, Chap order to kill pathogenic agents; 							of Regulation (EU) No 142/2011, in				
				(b)	has not been in contact with other types of o	ils including rendered fats from any	species of terrestrial animals, and				
			(2) either	[(c)	is packaged in new containers or in containers to contamination and all precautions taken to prevent the contamination of the containers		e been cleaned and disinfected if necessary for the prevention of r contamination,]				
			(²) or	[(c)		as and bulk tanks and any other bulk container or bulk road tanker used in acturing plant either directly on to the ship or into shore tanks or directly to ean before use.]					
			and	(d)	which bear labels indicating 'NOT FOR HUMAN	N CONSUMPTION'.					
		Notes									
		Part I:									
					erson responsible for the consignment in the Eur be filled in if the certificate is for import commodi		n only if it is a certificate for transit				
					Place of destination: this box is to be filled in only nes, free warehouses and custom warehouses.	r if it is a certificate for transit commod	ity. The products in transit can only				
		— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to provided in case of unloading and reloading.									
		— Box reference I.19: use the appropriate HS code: 15.04 or 15.18.									
		— Вох	reference I	.23: 1	for bulk containers, the container number and the	e seal number (if applicable) should b	pe included.				
		— Вох	reference I	.25: 1	technical use: any use other than for animal con	sumption.					
		— Вох	reference I	.26 a	and I.27: fill in according to whether it is a transit	t or an import certificate.					

Box reference I.28: Manufacturing plant: provide the registration number of the treatment/processing establishment.

COUNTRY	Fish oil not intended for human consumption to be used as fee material or for purposes outside the feed chain					
II. Health information	II.a. Certificate reference No	II.b.				
Part II:						
(^{1a}) OJ L 300, 14.11.2009, p. 1.						
(^{1b}) OJ L 54, 26.2.2011, p. 1.						
(²) Delete as appropriate.						
- The signature and the stamp must be in a different colour to that of	the printing.					
Note for the person responsible for the consignment in the Europaccompany the consignment until it reaches the border inspection personal content of the consignment and the consignment of the consig		r veterinary purposes and has to				
Official veterinarian/Official inspector						
Name (in capital letters):	Qualification an	d title:				
Date:	Signature:					
Stamp:						

CHAPTER 10(A)

Health certificate

For rendered fats not intended for human consumption to be used as feed material, intended for dispatch to or for transit through $(^2)$ the European Union

COL	JNTRY	′ :								Veterinary certifica	te to EU		
	1.1.	Consignor					1.2.	Certificate refere	nce No	I.2.a.			
		Name					1.3.	Central compete	nt authority				
		Address					1.4.	Local competent	authority				
		Tel.											
	1.5.	Consignee					1.6.	Person responsi	ble for the lo	ad in EU			
nent		Name						Name					
ignr		Address						Address					
suos		Postcode						Postcode					
ped (Tel.						Postcode Tel.					
atch	1.7.		ISO code	1.8.	Region of	Code	1.9.	Country of	ISO	I.10. Region of	Code		
dish		of origin			origin	1		destination	code	destination			
ls of													
Part I : Details of dispatched consignment	l.11.	Place of original	in				I.12.	Place of destination	tion				
=======================================		Name		A =====	ممطحين مامير					Overte en voere bevere			
Parl		Name Approval number Address						Name		Custom warehouse	ш		
		Name		Annro	val number			Address		Approval number			
		Name Approval number Address					Address						
		Name Approval number						Postcode					
		Address						1 0010000					
	I.13.	Place of loading						I.14. Date of departure					
	l.15.	Means of tra	nsport				I.16.	Entry BIP in EU					
		Aeroplane 🗆] Ship	П	Railway wa								
		Road vehicle	_ '		Railway wa	agon 🗀	1.17.						
		Identification		71 🗀			1.17.						
		Documentati		ces									
	I.18. Description of commodity						I.19. Comr	modity code (HS code)					
	,								- , ,				
							ı		I.20. Quantity				
	1.21.	Temperature	of product	t						I.22. Number of pa	ckages		
		Ambient ☐ Chilled ☐						Frozen C]				
	I.23. Seal/Container No									I.24. Type of packa	aging		

1.25.	Commodities cer	tified for:								
	Animal feedingst	uff 🗖	Manufactu	Manufacture of petfood ☐ Technical use ☐						
1.26.	For transit throug	h EU to third count	ry 🗆	I.27. For import or a	admission into EU					
	Third country	ISO c	ode							
1.28.	Identification of th	ne commodities	A	of and all Pales and a						
			Approval number	of establishments						
(Sci	Species entific name)	Nature of commodity	Manufacturing plant	Number of packages	Net weight	Batch number				

COUNTRY

	II. Health information			II.a. Certificate reference No	II.b.								
		the European Pa	ırliame	nt and of the C	declare that I have read and understood Regouncil (^{1a}), and in particular Article 10 thereof Chapter II of Annex XIV thereto, and certify th	, and Commission Regulation							
_	II.1.	consist of rendere	ed fats	that satisfy the	health requirements below;								
ficatio	II.2.	consist of rendere	ed fats	not intended for	human consumption;								
Part II: Certification	II.3.	Article 24 of Reg	ulatior	(EC) No 1069/	ant approved and supervised by the competer 2009 or in accordance with Article 4(2) of Reuncil (3), in order to kill pathogenic agents;								
ă	II.4.	have been prepar	red ex	clusively with the	e following animal by-products:								
		(²) either	(²) either [- 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;]										
		(²) and/or	[-	slaughtered ir consumption f	the following parts originating either from animals that have been a slaughterhouse and were considered fit for slaughter for human ollowing an ante-mortem inspection or bodies and the following parts of ame killed for human consumption in accordance with Union legislation:								
				cor	cases or bodies and parts of animals which are rejected as unfit for human sumption in accordance with Union legislation, but which did not show any is of disease communicable to humans or animals;								
				(ii) hea	ads of poultry;								
				incl	es and skins, including trimmings and splitting thereof, horns and feet, luding the phalanges and the carpus and metacarpus bones, tarsus and statarsus bones;								
				(iv) pig	p bristles;								
				(v) fear	athers;]								
		(²) and/or	[-	humans or ani	als which did not show any signs of disease communicable through blood to imals, obtained from animals that have been slaughtered in a slaughterhouse been considered fit for slaughter for human consumption following an antection in accordance with Union legislation;]								
		(²) and/or	[-		ducts arising from the production of pr ncluding degreased bone, greaves and centri g;]								
		(²) and/or	[-	longer intende	imal origin, or foodstuffs containing products d for human consumption for commercial re or packaging defects or other defects from wl	asons or due to problems of							
		(²) and/or	[-	or derived pro- due to problem	edingstuffs of animal origin, or feedingstuffs ducts, which are no longer intended for feedi ns of manufacturing or packaging defects or ot mal health arises;]	ng for commercial reasons or							
		(²) and/or	[-		a, wool, feathers, hair, horns, hoof cuts and lid not show signs of any disease communi mals;]								

COUNTRY

			used as feed material
II.	Health informa	ation	II.a. Certificate reference No 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.	(²) either	[-	in the case of material of porcine origin, come from a country or part of the territory of a country free from foot-and-mouth disease for the period of the preceding 24 months and free from classical swine fever and African swine fever for the period of the preceding 12 months;]
	(²) and/or	[-	in the case of material of poultry origin, come from a country or part of a territory of a country free from Newcastle disease and avian influenza for a period of the preceding 6 months;]
	(²) and/or	[-	in the case of material of ruminant origin, come from a country or part of a territory of a country free from foot-and-mouth disease for the period of the preceding 24 months and free from rinderpest for the period of the preceding 12 months;]
	(²) and/or	[-	where there has been an outbreak of one of the diseases referred to in point II.5. during the relevant period referred to in point II.5, and where the rendered fats derived from a susceptible species, have been subjected to a heat treatment for at least 70 °C for 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.]
II.6.			nt animals, were purified in such way that the maximum levels of remaining total insoluble eed 0.15% in weight;
II.7.	the rendered fa	ts:	
		(a)	have been subjected to processing in accordance with the requirements of Section 3 of Chapter II of Annex X to Regulation (EU) No 142/2011, or a treatment in accordance with Section XII of Annex III to Regulation (EC) No 853/2004, in order to kill pathogenic agents; and
	(²) either	[(b)	are packaged in new containers or in containers that have been cleaned and disinfected if necessary for the prevention of contamination, and all precautions have been 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 directly to plants have been checked under the responsibility of the competent authority and found to be clean before use;]
	and which bear	labels i	ndicating 'NOT FOR HUMAN CONSUMPTION';

COUNTRY

								used as reed material
II.	Health info	ormation		H.	а.	Certificate reference No		II.b.
(²) [II.8.	the rendere	ed fats descr	ribed above					
	(²) either	[is derived	d from other	ruminan	ts t	han bovine, ovine or caprine anima	als.]]	
	(²) or	[is derived	d from bovine	e, ovine	or o	caprine animals and does not conta	ain ai	nd is not derived from:
		(²) either			derived from animals born, assified as posing a negligible			
		(²) or	[(a)			risk material as defined in point 01 of the European Parliament and		
			(b)	animals slaught accorda	s, e ere anc	ally separated meat obtained from xcept from those animals that w d in a country or region classified e with Commission Decision 200 digenous BSE case,	ere b as p	porn, continuously reared and posing a negligible BSE risk in
			(c)	animals nervous into the for thos country	s w s ti cra se or	product or derived product obtain hich have been killed, after stun ssue by means of an elongated anial cavity, or by means of gas inju animals that were born, continuo region classified as posing a negl 007/453/EC.]]]	ning rod-s ected ously	, by laceration of the central shaped instrument introduced d into the cranial cavity, except reared and slaughtered in a
II.9.	the rendere	ed fats descr	ribed above:					
	(²) either		contain milk nimals, other			oducts of ovine or caprine animal c imals.]	origin	or is not intended for feed for
	(²) or					f ovine or caprine animal origin a and the milk or milk products:	ınd is	s intended for feed for farmed
		(a)				e and caprine animals which have following conditions are fulfilled:	beer	n kept continuously since birth
			(i)	classica	al s	crapie is compulsorily notifiable;		
			(ii)	an awa		ness, surveillance and monitoring	g sys	stem is in place for classical
			(iii)			trictions apply to holdings of ovine of TSE or the confirmation of classi		
			(iv)	ovine a		caprine animals affected with	clas	sical scrapie are killed and
			(v)	defined Animal	l in He	g to ovine and caprine animals of n the Terrestrial Animal Health Co ealth (OIE), of ruminant origin h n the whole country for a period	ode d nas l	of the World Organisation for been banned and effectively
		(b)	originate fi	rom hold	dinç	gs where no official restrictions a	re im	nposed due to a suspicion of
		(c)				s where no case of classical scra s or, following the confirmation of a		

COUNTRY

		1		used as reed material				
II. Health information		II.a.	Certificate reference No	II.b.				
(²) ei	slau ewe	ughtere es cari	and caprine animals on the holding haved, except for breeding rams of the Arying at least one ARR allele and no arrying at least one ARR allele;]	ARR/ARR genotype, breeding				
(²) oı	des sind TSI in a Anr are	all animals in which classical scrapie was confirmed have been killed and estroyed, and the holding has been subjected for period of at least two years not the date of confirmation of the last classical scrapie case to intensified SE monitoring, including testing with negative results for the presence of TSE accordance with the laboratory methods set out in point 3.2 of Chapter C of nnex X to Regulation (EC) No 999/2001, of all of the following animals which re over the age of 18 months, except ovine animals of the ARR/ARR enotype:						
	_	anim	als which have been slaughtered for hu	uman consumption; and				
	-		als which have died or been killed on t d in the framework of a disease eradicat					
Nator								
Notes Part I:								
raiti.								
 Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if it is a certificate for a commodity to be transited through the European Union; it may be filled in if the certificate is for a commodity to be imported into the European Union. 								
 Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. Products in transit may only be stored in free zones, free warehouses and custom warehouses. 								
			gons or container and lorries), flight nu g and reloading in the European Union.	mber (aircraft) or name (ship);				
Box reference I.19: use the appropr	iate HS co	de: 04	.05; 15.01; 15.02; 15.03; 15.04; 15.05;	15.06; 15.16.10 or 15.18.				
Box reference I.23: for bulk contains	ers, the co	ntainer	number and the seal number (if applica	able) must be included.				
Box reference I.25: technical use: a and the production or manufacturing			an feeding of farmed animals, other th	an fur animals or pet animals,				
Box reference I.26 and I.27: fill in actions	ccording to	wheth	er it is a transit or an import certificate.					
— Box reference I.28:								
Species: select from the following: F	Ruminantia	a, other	than Ruminantia					
	gistration r	number	of the treatment/processing establishm	ent.				
Part II:								
(^{1a}) OJ L 300, 14.11.2009, p. 1.								
(^{1b}) OJ L 54, 26.2.2011, p. 1.								
(²) Delete as appropriate.								
(³) OJ L 139, 30.4.2004, p. 55.								

COUNTRY

II.	Health information	II.a.	Certificate reference N	0	II.b.					
(4)	OJ L 147, 31.5.2001, p. 1.									
(5)	OJ L 172, 30.6.2007, p. 84.									
-	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.									
Offi	cial veterinarian/Official inspector									
	Name (in capital letters):			Qualification a	and title:					
	Date:			Signature:						
	Stamp:									
1										

CHAPTER 10(B)

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

CO	JNTR	/ :								Vete	erinary certifica	te to EU	
	l.1.	Consignor					1.2.	Certificate refere	nce No	1.2	2.a.		
		Name					1.3.	Central compete	nt authority				
		Address					1.4.	Local competent	authority				
		Tel.											
	1.5.	Consignee					1.6.	Person responsi	ble for the loa	ad in E	U		
nen		Name						Name					
signı		Address						Address					
cons		Postcode						Postcode					
hed		Tel.						Tel.					
Part I : Details of dispatched consignment	1.7.	.7. Country ISO code I.8. Region of Code of origin				1.9.	Country of destination	ISO code	I.10.	Region of destination	Code		
ails	111	Place of orig	nin				112	Place of destinat	tion				
Det		1 1000 01 011	9111				1.12.	ridoo or dootiria					
Į,		Name Approval number Address								Cus	tom warehouse		
a.								Name		Арр	roval number		
		Name Approval number					Address						
		Address											
		Name		Appro	oval number			Postcode					
		Address											
	I.13.	Place of loa	iding				l.14.	Date of departur	е				
	I.15.	Means of tra	ansport				I.16. Entry BIP in EU						
		Aeroplane [•		Railway wa	agon 🗖							
		Road vehicl		er 📙			l.17.						
	Identification Documentation references I.18. Description of commodity												
								I 10 Comr	ma ditu	nodo (HC nodo)			
								1.19. Comr	noulty (code (HS code)			
							L		1.20	. Quantity			
	1.21.	Temperatur	e of product	t						1.22	. Number of page	ckages	
		Ambient \square			Chilled]		Frozen C]				
	I.23. Seal/Container No									1.24	. Type of packa	ging	

1.25.	Commodities certifie	ed for:								
	Technical use □									
1.26.	For transit through E		I.27. For import or admission into EU							
	Third country	ISO code								
1.28.										
		Appr	oval number	of establishment	s					
(S	Species Manufacturing plant (Scientific name)		Number of packages		Net weight	Batch number				

COUNTRY

Rendered fats not intended for human consumption for certain purposes outside the feed chain

	II.	Health informati	on		II.a. Certificate reference No	II.b.				
		European Parliar	ment a	and of the Cou	declare that I have read and understood Regul uncil (^{1a}), and in particular Articles 8, 9 and in particular Chapter II of Annex XIV thereto, a	10 thereof, and Commission				
_	II.1.	consist of rendere	ed fats	not intended fo	r human consumption that satisfy the health red	quirements below;				
ficatio	II.2.	have been prepar	red ex	clusively with th	e following animal by-products:					
Part II: Certification	(²) [II.2.1.		egulat	ion (EU) No 14	e production of renewable fuels referred to in po 2/2011, biodiesel or oleochemical products, ar No 1069/2009;]					
ď	(²) [II.2.2.	of Annex IV to Re	egulati	on (EU) No 142	e production of renewable fuels referred to in po /2011, the materials have been prepared exclu ation (EC) No 1069/2009;]					
	(²) [II.2.3.	in the case of n materials have be			purposes other than cosmetics, pharmaceu ely from:	ticals or medical devices, the				
		(²) either	[-		oducts containing residues of authorised permitted levels referred to in Article 15(3) of C					
		(²) and/or	[-		imal origin which have been declared unfit for reign bodies in those products;]	human consumption due to the				
		(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	[-	animals killed	d parts of animals slaughtered or, in the cas , and which are fit for human consumption are not intended for human consumption for ca	on in accordance with Union				
		(²) and/or	[-	in a slaughter an ante-morte	I the following parts originating either from anim nouse and were considered fit for slaughter fo m inspection or bodies and the following parts nption in accordance with Union legislation:	r human consumption following				
				consun	ses or bodies and parts of animals which are nption in accordance with Union legislation, but ase communicable to humans or animals;					
				(ii) heads	of poultry;					
					and skins, including trimmings and splitting the langes and the carpus and metacarpus bones,					
				(iv) pig bris	tles;					
				(v) feather						
		(²) and/or	[-	humans or an after having b	als which did not show any signs of disease of imals obtained from animals that have been steen considered fit for slaughter for human of tion in accordance with Union legislation;]	laughtered in a slaughterhouse				
		(²) and/or	[-		oducts arising from the production of princluding degreased bone, greaves and centrig:]					

COUNTRY

Rendered fats not intended for human consumption for certain purposes outside the feed chain

II.	Health inform	ation	II.a. Certificate reference No II.b.	
	(²) and/or	products of animal origin, or foodstuffs containing products of animal origin, which are longer intended for human consumption for commercial reasons or due to problem manufacturing or packaging defects or other defects from which no risk to public or an health arises;]	is c	
	(²) and/or	[-	petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-prod or derived products, which are no longer intended for feeding for commercial reasons or to problems of manufacturing or packaging defects or other defects from which no ris public or animal health arises;]	· du
	(²) and/or	[-	blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from animals that did not show signs of any disease communicable through that product humans or animals;]	
	(²) and/or	[-	aquatic animals, and parts of such animals, except sea mammals, which did not show signs of diseases communicable to humans or animals;]	an
	(²) and/or	[-	animal by-products from aquatic animals originating from plants or establishm manufacturing products for human consumption;]	ent
	(²) and/or	[-	the following material originating from animals which did not show any signs of discommunicable through that material to humans or animals:	eas
			(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	[-	aquatic and terrestrial invertebrates other than species pathogenic to humans or animals	s;]
	(²) and/or	[-	animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, ex Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) of Regulation No 1069/2009and Category 2 material as referred to in Article 9(a) to (g) of that Regulation	(EĊ
	(²) and/or	[-	hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead anii that did not show any signs of disease communicable through that product to human animals;]	
	(²) and/or	[-	adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-moinspection in accordance with Union legislation;]]	/hic
(²) [II.2.4.			is destined for purposes other than the production of organic fertilisers or soil improval or medical devices:	vers
	(²) either	[-	specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 of European Parliament and of the Council $(^{2b})$;	f th
	(²) and/or	[-	entire bodies or parts of dead animals containing specified risk material as define Article 3(1)(g) of Regulation (EC) No 999/2001 at the time of disposal;]	ed i
	(²) and/or	[-	animal by-products which have been derived from animals which have been submitte illegal treatment as defined in Article 1(2)(d) of Council Directive 96/22/EC (2c) or Article of Council Directive 96/23/EC;	

COUNTRY

Rendered fats not intended for human consumption for certain purposes outside the feed chain

II.	Health int	formation	II.a. Certificate reference No	II.b.							
	(²) and/or	contamina the permit	r-products containing residues of othe tts listed in Group B(3) of Annex I to Directi ed levels laid down by Union legislation or, ber State of importation;]]	ive 96/23/EC, if such residues exceed							
II.3.	the render	red fats:									
	me		essing in accordance with method oter III of Annex IV to Regulation (EU) No								
			shipment to the European Union with gly entration of at least 250 mg GTH per kilogra								
	(c) in the case of rendered fats of ruminant origin, insoluble impurities in excess of 0,15% in weight have been removed,										
	(d) have been transported under conditions which prevent their contamination, and										
	(e) be	ar labels on the packagir	g or container indicating "NOT FOR HUMAN	OR ANIMAL CONSUMPTION";							
(²) [II.4.	in the case of materials destined for organic fertilisers, cosmetics, pharmaceuticals, medical devices or soil improvers the rendered fats described above										
	(²) either	[are derived from othe	ruminants than bovine, ovine or caprine an	imals.]							
	(²) or	[are derived from bovi	e, ovine or caprine animals and does not co	ontain and is not derived from:							
		continuou	vine and caprine materials other than ly reared and slaughtered in a country or re accordance with Decision 2007/453/EC.]								
			cified risk material as defined in point 999/2001 of the European Parliament and o								
		ani sla acc	chanically separated meat obtained from nals, except from those animals that w ghtered in a country or region classified ordance with Commission Decision 2007/45 genous BSE case,	vere born, continuously reared and as posing a negligible BSE risk in							
		wh me by boi	nal by-product or derived product obtained in the have been killed, after stunning, by lacer and of an elongated rod-shaped instrument means of gas injected into the cranial cavity, continuously reared and slaughtered in a regligible BSE risk in accordance with Decision	ration of the central nervous tissue by introduced into the cranial cavity, or y, except for those animals that were country or region classified as posing							
Notes											

Part I:

- Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if it is a certificate for a commodity to be transited through the European Union; it may be filled in if the certificate is for a commodity to be imported into the European Union.
- Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority.

COUNTRY

Rendered fats not intended for human consumption for certain purposes outside the feed chain

II.	Health information	II.a.	(Certificate reference No		II.b.		
_	Box reference I.12: Place of destination: this transit may only be stored in free zones, free					transit commodity. Products in		
_	Box reference I.15: Registration number (rail to be provided. In the case of unloading a inspection post of the point of entry into the E	nd rela	oa	ding in the European				
_	Box I.19: use the appropriate Harmonized 15.04; 15.05; 15.06; 15.16 or 15.18.	System	n (HS) code under the fo	llowing heading	gs: 04.05; 15.01, 15.02; 15.03;		
_	Box reference I.23: for bulk containers, the containers	ontaine	er	number and the seal nu	mber (if applica	ble) must be included.		
_	Box reference I.25: technical use: any use of the production or manufacturing of pet food.	her tha	an	feeding of farmed anim	als, other than	fur animals or pet animals, and		
_	Box reference I.26 and I.27: fill in according to	o whet	the	er it is a transit or an imp	ort certificate.			
_	Box reference I.28:							
	Species: select from the following: Ruminant	ia, othe	er	than Ruminantia				
	Manufacturing plant: provide the registration	numbe	er	of the treatment/process	sing establishm	ent.		
Par	t II:							
(^{1a})	OJ L 300, 14.11.2009, p. 1.							
(1b)	OJ L 54, 26.2.2011, p. 1.							
(2)	Delete as appropriate.							
(^{2a})	OJ L 125, 23.5.1996, p. 10.							
(2b)	OJ L 147, 31.5.2001, p. 1.							
(2c)	OJ L 125, 23.5.1996, p. 3.							
(3)	OJ L 147, 31.5.2001, p. 1.							
(4)	OJ L 172, 30.6.2007, p. 84.							
_	The signature and the stamp must be in a dif	ferent o	CC	lour to that of the printin	ıg.			
_	Note for the person responsible for the cons and must accompany the consignment until Union.							
Offic	cial veterinarian/Official inspector							
	Name (in capital letters):				Qualification a	nd 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 $\binom{2}{}$ the European Union

COL	JNTRY	r :								Vete	rinary certifica	te to EU
	l.1.	Consignor					1.2.	Certificate refere	nce No	1.2	2.a	
		Name					1.3.	Central compete	nt authority			
		Address					1.4.	Local competent	authority			
		Tel.										
	1.5.	Consignee)				I.6. Person responsible for the load in EU					
ent		Name						Name				
ignm		Address						Address				
d cons		Postcode						Postcode				
chec		Tel.						Tel.				
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code	I.8. 	Region of origin	Code	1.9.	Country of destination	ISO code	I.10.	Region of destination	Code
Details	l.11.	Place of or	rigin				I.12.	Place of destinat	ion			
<u> </u>		Name Approval number					Cust	om warehouse				
2		Address					Name		Аррі	roval number		
		Name		Appro	val number			Address				
		Address										
		Name		Appro	Approval number			Postcode				
		Address										
	I.13.	Place of lo	ading				I.14.	Date of departure	Э			
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU				
		Aeroplane	☐ Ship		Railway wa	agon 🗖						
		Road vehi					1.17.					
	Identification											
		Document	ation referen	ces								
	I.18.	I.18. Description of commodity					I.19. Comr	modity (code (HS code)			
								L		1.20	Quantity	
	1.21.	Temperatu	ire of product	t						1.22	Number of pa	ckages
		Ambient 🗖]		Chilled C]		Frozen C]			
	122	Sool/Contr	ninor No							124	Type of pecks	aina

1.25.	Commodities certifie	ed for:								
	Animal feedingstuff	Manufacture of petfood ☐			Technical u	Technical use 🛘				
1.26.	. For transit through EU to third country			I.27. For import or admission into EU						
	Third country	ISO code								
I.28.	8. Identification of the commodities Approval number of establishments									
(8	Species Manufacturing plant (Scientific name)		Number of packages		ges N	let 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

							chain
	II.	Health informat	tion		II.a.	Certificate reference No	II.b.
		the European	Parliame 2011 (^{1b})	ent and o	of the Council	te that I have read and understood F (1 a), and in particular Article 10 ther pter I of Annex XIV thereto, and cer	eof, and Commission Regulation
	II.1.	consists of gel	atine/col	agen (²)	that satisfy the	e health requirements below;	
ation	II.2.	consist exclusi	ively of g	elatine/c	ollagen (²) not	intended for human consumption;	
Part II: Certification	II.3.					proved and supervised by the compe n order to kill pathogenic agents;	tent authority in accordance with
art II:	II.4.	has been prep	ared exc	lusively \	with the follow	ng animal by-products:	
ď		(²) either	of animals slaughtered or, in the ca which are fit for human consump of intended for human consumption for	tion in accordance with Union			
		(²) and/or	[-	slaugh consur	tered in a s nption followir	following parts originating either laughterhouse and were considering an ante-mortem inspection or builled for human consumption in accor	ed fit for slaughter for human odies and the following parts of
				(i)	consumption	bodies and parts of animals which in accordance with Union legislatic ase communicable to humans or anim	on, but which did not show any
				(ii)	heads of pou	Itry;	
				(iii)		ns, including trimmings and splitting es and the carpus and metacarpus	
				(iv)	pig bristles;		
				(v)	feathers;]		
		(²) and/or	[-	consur		arising from the production of ng degreased bone, greaves and ce	
		(²) and/or	[-	longer manufa	intended for	rigin, or foodstuffs containing produc human consumption for commercial ckaging defects or other defects from	reasons or due to problems of
		(²) and/or	[-	or deri	ved products,	stuffs of animal origin, or feedingstuf which are no longer intended for fe nanufacturing or packaging defects or palth arises;]	eding for commercial reasons or
		(²) and/or	[-			parts of such animals, except sea mmunicable to humans or animals;]	ammals, which did not show any
		(²) and/or	[-			from aquatic animals originating cts for human consumption;]	from plants or establishments
	II.5.	the gelatine/co	ollagen (2):			
			(a)	and in	particular wi	aged, stored and transported under apping and packaging took place ed under Union legislation were used	in a dedicated room, and only

COUNTRY

Gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed chain

						chain
II.	Health info	rmation		II.a.	Certificate reference No	II.b.
					packages containing gelatine/collag AGEN(2) SUITABLE FOR ANIMAL CONS	
	(²) either	[(b)	Category 3 more rinse	materia es, invol i, followe	elatine, was produced by a process that was subjected to a treatment with acid ving pH adjustment, extraction by heated by purification by means of filtration at a light control of the c	I or alkali, followed by one or ting one or several times in
	(²) or	[(b)	Category 3	materia kali follo	llagen, was produced by a process that was subjected to a treatment involving wed by one or more rinses, filtration a	washing, pH adjustment using
(²) [II.6.	in the case	e of gelatine/o	collagen (2) fr	om mate	erials other than hides and skins	
	(²) either	[is derived t	rom other ru	minants	than bovine, ovine or caprine animals.]]	
	(²) or	[is derived t	rom bovine,	ovine or	caprine animals and does not contain and	d is not derived from:
		(²) either	continuous	ly reared	d caprine materials other than those d and slaughtered in a country or region cl ance with Decision 2007/453/EC.]]	
		(²) or			sk material as defined in point 1 of A 1 of the European Parliament and of the C	
			ani slav acc	mals, ex ughtered ordance	ly separated meat obtained from bones cept from those animals that were bot in a country or region classified as pot with Commission Decision 2007/453/EC us BSE case,	orn, continuously reared and sing a negligible BSE risk in
			ani tiss cav tha clas	mals wh ue by m ity, or by t were	product or derived product obtained from the control of the contro	ceration of the central nervous ent introduced into the cranial avity, except for those animals ered in a country or region
II.7.	in the case	e of gelatine/o	collagen (²) fr	om mate	erials other than hides and skins described	d above:
	(²) either		ontain milk onals, other th		roducts of ovine or caprine animal origin nimals.]	or is not intended for feed for
	(²) or				of ovine or caprine animal origin and is and the milk or milk products:	intended for feed for farmed
					nd caprine animals which were kept contin itions are fulfilled:	uously since birth in a country
		(i)	clas	ssical sc	rapie is compulsorily notifiable;	
		(ii)	an	awarene	ess, surveillance and monitoring system is	in place for classical scrapie;
		(iii)			rictions apply to holdings of ovine or cap f TSE or the confirmation of classical scra	

▼M15

COUNTRY

Gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed

II.	Health information		II.a.	Certificate reference No	II.b.			
	(iv) ov	ne and c	aprine animals affected with classical so	crapie are killed and destroyed;			
	(de He	fined in that alth (OIE	to ovine and caprine animals of mea ne Terrestrial Animal Health Code of th i), of ruminant origin has been banned try for a period of at least the preceding	e World Organisation for Anima I and effectively enforced in the			
	(b) c	originate from ho	oldings w	here no official restrictions are imposed	due to a suspicion of TSE;			
			holdings where no case of classical scrapie has been diagnosed during the period ng seven years or, following the confirmation of a case of classical scrapie:					
	(sla ca	[all ovine and caprine animals on the holding have been killed and destroyed or slaughtered, except for breeding rams of the ARR/ARR genotype, breeding ewes carrying at least one ARR allele and no VRQ allele and other ovine animals carrying at least one ARR allele;]					
	(de sir mo ac An						
		_	anima	ls which have been slaughtered for hun	nan consumption; and			
		_		ls which have died or been killed on n the framework of a disease eradication				

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 a commodity to be transited through the European Union; it may be filled in if the certificate is for a
 commodity to be imported into the European Union.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. Products in transit may 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) is to be provided. In the case of unloading and reloading in the European Union, the consignor must inform the border inspection post of the point of entry into the European Union.
- Box I.19: use the appropriate Harmonized System (HS) code under the following headings: 35.03 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.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the
 production or manufacturing of pet food.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
- Box reference I.28: Species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or Suidae, Pesca.

COUNTRY

Gelatine and collagen not intended for human consumption to be used as feed material or for purposes outside the feed chain

	II.	Health information	II.a.	Certificate reference N	0	II.b.
	Part	II:				
	(^{1a})	OJ L 300, 14.11.2009, p. 1.				
	(1b)	OJ L 54, 26.2.2011, p. 1.				
	(²)	Delete as appropriate.				
	(3)	OJ L 147, 31.5.2001, p. 1.				
	(⁴)	OJ L 172, 30.6.2007, p. 84.				
	_	The signature and the stamp must be in a d	lifferent c	olour to that of the printir	ng.	
	_	Note for the person responsible for the conand must accompany the consignment until				s only for veterinary purposes
	Offic	cial veterinarian/Official inspector				
		Name (in capital letters):			Qualification a	nd title:
		Date:			Signature:	
		Stamp:				
Į						

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

COL	JNTRY	/ :			Veterinary certificate to EU				
	l.1.	Consignor	1.2.	Certificate reference No	I.2.a.				
		Name	1.3.	Central competent author	ity				
		Address	1.4.	Local competent authority					
		Tel.							
	1.5.	Consignee	1.6.	I.6. Person responsible for the load in EU					
nent		Name		Name					
ign		Address		Address					
sous		Postcode		Postcode					
ped (Tel.		Tel.					
Part I : Details of dispatched consignment	1.7.	Country ISO code I.8. Region of Code	1.9.	Country of ISO	I.10. Region of Code				
dist		of origin origin		destination code	destination				
ls of									
Detai	l.11.	Place of origin	1.12	. Place of destination					
=					о				
Par		Name Approval number		Nama	Custom warehouse				
	Address			Name	Approval number				
		Name Approval number Address		Address					
		Name Approval number		Postcode					
		Address		1 Ostcode					
	I.13.	Place of loading	1.14	. Date of departure					
				<u> </u>					
	I.15.	Means of transport	I.16	. Entry BIP in EU					
		Aeroplane ☐ Ship ☐ Railway wagon ☐							
		Road vehicle Other O	1.17						
		Identification	1.17						
	Documentation references								
	I.18.	Description of commodity		I.19. Co	ommodity code (HS code)				
	,				•				
					I.20. Quantity				
	I.21.	Temperature of product			I.22. Number of packages				
		Ambient ☐ Chilled ☐		Frozen 🗖					
	1.23.	Seal/Container No			I.24. Type of packaging				

1.25.	Commodities certi	fied for:							
	Animal feedingstu	ff 🗆	Manufactu	re of petfood \square	Technical use	cal use 🗆			
1.26.	For transit through	EU to third country	, 🗆	I.27. For import or	admission into EU				
	Third country	ISO co	de						
I.28.	.28. Identification of the commodities Approval number of establishments								
(Sci	Species entific name)	Nature of commodity	Manufacturing plant	Number of packages	Net weight	Batch number			

COUNTRY

					used as feed filaterial of for uses outside the feed chair							
	II.	Health inf	ormation			II.a. Certificate reference No		II.b.				
		the Europe (EU) No	ean Parliamen 142/2011 (^{1b}),	t and of th , and in p	ie Čo partic	eclare that I have read and under uncil (¹a), and in particular Article ılar Chapter I of Annex XIV th losphate (²) described above:	10 thereof	f, and Commission Regulation				
uo	II.1.	consists o below;	f hydrolysed p	orotein/dica	alciun	phosphate/tricalcium phosphate	(²) that sa	atisfy the health requirements				
ertificati	II.2.	consists e		nydrolysed	prot	in/dicalcium phosphate/tricalcium	phosphat	e (²) not intended for human				
Part II: Certification	II.3.					approved and supervised by the 09, in order to kill pathogenic agen		nt authority in accordance with				
Δ.	II.4.	has been p	orepared exclu	sively with	the f	llowing animal by-products:						
		(²) either	slaughtered of	or, in the in accord	case	nosphate derived from defatted of game, bodies or parts of anim with Union legislation, but are no	nals killed,	and which are fit for human				
		(²) or	[in the case o	of other ma	terial	:						
			(²) either	of Un	[- carcases and parts of animals slaughtered or, in the case of game, bodies of of animals killed, and which are fit for human consumption in accordanc Union legislation, but are not intended for human consumption for comr reasons;]]							
			(²) and/or	sla cor of	carcases and the following parts originating either from animals that I slaughtered in a slaughterhouse and were considered fit for slaughter consumption following an ante-mortem inspection or bodies and the follo of animals from game killed for human consumption in accordance viegislation:							
				(i)	co	cases or bodies and parts of anima sumption in accordance with Unio ns of disease communicable to hur	n legislatio	on, but which did not show any				
				(ii)	he	ids of poultry;						
				(iii)	inc	es and skins, including trimmings uding the phalanges and the car tatarsus bones;						
				(iv)) pig	bristles;						
				(v)	fea	thers;]]						
			(²) and/or	blo sla cor	od to ughte	animals which did not show any humans or animals obtained from rhouse after having been con tion following an ante-mortem n;]]	animals the	nat have been slaughtered in a rit for slaughter for human				
			(²) and/or	cor	ารนฑ	by-products arising from the production, including degreased bone, om milk processing;]]		•				
			(²) and/or	are	no l	of animal origin, or foodstuffs cor onger intended for human consum s of manufacturing or packaging de or animal health arise;]]	nption for	commercial reasons or due to				

COUNTRY

				used as feed material or for uses outside the feed chain							
II.	Health inf	formation	1	II.a. Certificate reference No II.b.							
		(²) and/d	or [-	petfood and feedingstuffs of animal origin, or feedingstuffs 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/d	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/0	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/0	or [-	animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]]							
		(²) and/0	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 hydrol	ysed prot	ein/dicalciur	m phosphate/tricalcium phosphate (²):							
		F (CONSUMP oarticular th	ed and packaged in packaging which bear labels indicating 'NOT FOR HUMAN FION' and was stored and transported under satisfactory hygiene conditions, and in e wrapping and packaging took place in a dedicated room, and only preservatives inder Union legislation were used; and							
	(²) either			of hydrolysed protein, was produced by a process involving appropriate measures to ntamination of raw Category 3 material.							
		r i	roduced in	of hydrolysed proteins entirely or partly derived from ruminants hides and skins, was a processing plant dedicated only to hydrolysed proteins production, using a process preparation of the raw Category 3 material by brining, liming and intensive washing							
		(tem	exposure of the material to a pH of more than 11 for more than 3 hours at a perature of more than 80 °C and subsequently by heat treatment at a temperature of a than 140 °C for 30 minutes at more than 3,6 bar; or							
		(exposure of the material to a pH of 1 to 2, followed by a pH of more than 11, followed heat treatment at a temperature of more than 140 °C for 30 minutes at 3 bar.]							
	(²) or	[(b) i	n the case o	of dicalcium phosphate, was produced by a process that:							
		(and	ares that all Category 3 bone-material is finely crushed and degreased with hot water treated with dilute hydrochloric acid (at a minimum concentration of 4 $\%$ and a pH of than 1,5) over a period of at least two days,							
		(wed by a treatment of the obtained phosphoric liquor with lime, resulting in a ipitate of dicalcium phosphate at pH 4 to 7, and							

COUNTRY

							4000	. 40 1004			ises outside the feed chain
II.	Health inf	ormati	on		II.a.	Cert	ificate ref	ference N	0		II.b.
			(iii)	finally air-di temperature					t temperature	of	65 °C to 325 °C and an end
	(²) or	[(b)	in the	case of trical	cium pho	spha	te, was p	roduced t	y a process e	ens	uring:
			(i)	that all Cate water (bone					ushed and de	egre	eased in counter-flow with hot
			(ii)	the continue	ous cool	king w	ith steam	at 145 °0	C during 30 m	ninu	tes at 4 bars,
			(iii)	the separat		he pr	otein bro	th from t	he hydroxyar	pati	te (tricalcium phosphate) by
			(iv)	the granula 200 °C.]	ition of	the tr	icalcium	phosphat	e after drying	g ir	n a fluidised bed with air at
(²) [II.6.	the hydrol	ysed pr	otein/dic	alcium phos	ohate/tri	calciu	m phosph	nate (²) de	escribed abov	e	
	(²) either	[is de	rived fro	m other rumi	nants tha	an bov	vine, ovin	ie or capr	ne animals.]]		
	(²) or	[is de	rived fro	m bovine, ov	ine or ca	prine	animals :	and does	not contain a	nd	is not derived from:
		(²) eit	her	continuousl	y reared	d and	l slaught	ered in		re	derived from animals born, gion classified as posing a C.]]
		(²) or							n point 1 of ent and of the		nnex V to Regulation (EC) puncil (3);
				anima slaugl accor	als, exce ntered in	ept front a co vith Co	om those ountry or ommissio	e animals region o	s that were lassified as p	bor pos	of bovine, ovine or caprine n, continuously reared and ing a negligible BSE risk in (4), in which there has been
				anima tissue cavity that v classi	als which by mea , or by r were bo	n have ins of neans irn, c posi	been kil an elong of gas ir ontinuous	led, after lated rod- njected in sly reare	stunning, by I shaped instru to the cranial d and slaugl	lace ime cav	m bovine, ovine or caprine eration of the central nervous nt introduced into the cranial vity, except for those animals red in a country or region accordance with Decision
II.7.	the hydrol	ysed pr	otein/dic	alcium phos	ohate/tri	calciu	m phosph	nate (²) de	escribed abov	e:	
	(²) either			tain milk or i ls, other thar			of ovine	or caprin	e animal origi	in o	r is not intended for feed for
	(²) or			or milk pro than fur anii						is i	ntended for feed for farmed
		(a)		rived from ov y where the f					have been ke	ept	continuously since birth in a
			(i)	classical sc	rapie is	comp	ulsorily no	otifiable;			
			(ii)	an awarene	ess, surv	eilland	ce and m	onitoring	system is in p	olac	e for classical scrapie;
			(iii)	official restr of TSE or th						nim	als in the case of a suspicion

▼M15

COUNTRY

					usea as r	eed material or for	uses outside the feed chain
II.	Health informatio	n		II.a.	Certificate referen	ce No	II.b.
l		(iv) ov	vine and cap	orine ar	nimals affected with	n classical scrapie a	re killed and destroyed;
		in of	the Terrest ruminant o	rial An rigin h	imal Health Code o	of the World Organis and effectively enfor	e meal or greaves, as defined sation for Animal Health (OIE), ced in the whole country for a
l	(b)	originate t	rom holding	gs wher	e no official restrict	tions are imposed d	ue to a suspicion of TSE;
l							en diagnosed during the period se of classical scrapie:
		(²) either	slaughtere	ed, exc t least	cept for breeding rone ARR allele an	ams of the ARR/A	been killed and destroyed or RR genotype, breeding ewes d other ovine animals carrying
		(²) or	and the ho confirmation testing we laboratory No 999/20	olding hon of the ith neground of the ith neground of the ith of t	nas been subjected ne last classical scr gative results for ods set out in point	for a period of at le rapie case to intensi the presence of 3.2 of Chapter C of g animals which are	ave been killed and destroyed, ast two years since the date of ified TSE monitoring, including TSE in accordance with the of Annex X to Regulation (EC) e over the age of 18 months,
l			— anima	ıls whic	h have been slaug	htered for human co	onsumption; and
						n killed on the holdi dication campaign.]]	ing but which were not killed in
Notes							
Part I:							

- Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if
 it is a certificate for a commodity to be transited through the European Union; it may be filled in if the certificate is for a
 commodity to be imported into the European Union.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. 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: 05.08, 28.35.25; 28.35.26, 29.22; 35.02; 35.03 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.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the
 production or manufacturing of pet food.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
- Box reference I.28:
 - Species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or Suidae, Pesca, Mollusca, Crustacea, invertebrates other than Mollusca and Crustacea.

COUNTRY

II.	Health information	II.a. Certificate reference No	II.b.
	Nature of commodity: specify if hydrolys	sed protein, dicalcium phosphate	or tricalcium phosphate.
	Manufacturing plant: provide the registra	ation number of treatment/proce	ssing establishment.
Part	II:		
(^{1a})	OJ L 300, 14.11.2009, p. 1.		
(1b)	OJ L 54, 26.2.2011, p. 1.		
(2)	Delete as appropriate.		
(3)	OJ L 147, 31.5.2001, p. 1.		
(4)	OJ L 94, 1.4.2006, p. 28.		
_	The signature and the stamp must be in a diffe	erent colour to that of the printin	g.
_	Note for the person responsible for the consignand must accompany the consignment until i Union.		
Offic	sial veterinarian/Official inspector		
	Name (in capital letters):		Qualification and title:
	Date:		Signature:
	Stamp:		

CHAPTER 13

Health certificate

For apiculture by-products intended exclusively for use in apiculture, intended for dispatch to or for transit through $\binom{2}{2}$ the European Union

COL	MIK	γ								Veterinary cei	rtificate to EU			
	1.1.	Consignor				1.2.	Certificat	e reference	No No	1.2.a.				
		Name Address				1.3.	Central c	ompetent a	authority					
		Tel.				1.4.	Local co	mpetent au	thority					
=	1.5.	Consignee				I.6. Person responsible for the load in EU								
Ē		Name					Name							
dispatched consignment		Address				Address								
00		Postcode					Postcode	_						
þed		Tel.					Tel.							
patc	1.7.	Country of origin	ISO code	I.8. Region of orig	in Code	1.9.	I.9. Country of ISO code I.10. Region of Code							
7		ocamity or origin		nor ringion or one			destinati			destination				
Part I: Details	l.11.	Place of origin	I			l.12.	Place of	destination	1		_			
art I: [Name Address		Approval number			Name Address			Custom warehouse Approval number	; 			
-		Name Address		Approval number										
		Name Address		Approval number			Postcode	9						
	I.13.	Place of loading				l.14.	Date of	departure						
	1.15.	Means of transport	:			1.16.	Entry BII	o in EU						
		Aeroplane	Ship [] Railway v	wagon 🔲									
		Road vehicle	Other [1.17.								
		Identification Documentation refe												
	110	Description of com				I.19. Commodity code (HS code)								
	1.10.	Description of com	mounty					1.19. Com	iniounty co	de (H3 code)				
									1.20.	Quantity				
	1.21.	Temperature of pro	oduct						1.22.	Number of packages				
		Ambient		Chilled		Froze	n 🗌							
	1.23.	Seal/Container No							1.24.	Type of packaging				
	1.25.	Commodities certifi	ied for:											
		Technical use												
	1.26.	For transit through	EU to third	country		1.27.	For impo	ort or admis	ssion into I	EU [
		Third country		ISO code										
	1.28.	Identification of the	commoditie	es		-								
		Species (Scientific name)	1	Nature of commodity		Appr		er of estab acturing pla		Net	weight			

COUNTRY Apiculture by-products intended exclusively for use in apiculture II.a. Certificate reference No II.b. Health information I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Annex XIV, Chapter 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 (a) American foulbrood (Paenibacillus larvae larvae); II: Certification (b) Acariosis (Acarapis woodi (Rennie)); (c) Small hive beetle (Aethina tumida); and (d) Tropilaelaps mites (Tropilaelaps spp.); Part 11.2. have been (2) either [subjected to a temperature of - 12 °C or lower for at least 24 hours.] [in the case of wax refined or processed in accordance with processing method 1-2-3-4-5-7 $(^2)$ as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011] (2) or 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.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority. - 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.25: technical use: any use other than for animal consumption. - 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; (1a) OJ L 300, 14.11.2009, p. 1. (1b) OJ L 54, 26.2.2011, p. 1. (2) Delete as appropriate. The signature and the stamp must be in a different colour to that of the printing. — Note for the person responsible for the consignment in 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/Official inspector Name (in capital letters): Qualification and title: Date: Signature: Stamp:

▼<u>M4</u>

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 $\binom{2}{2}$ the European Union

	ΓRY								vetermary c	ertificate to El		
1.1		Consignor Name				1.2.	Certificate re	ference No	1.2.a.			
		Address				1.3.	Central com	petent authority				
		Tel.				I.4. Local competent authority						
1.5	5.	Consignee Name Address				1.6.	Person responsible for the load in EU Name Address					
		Postcode Tel.					Postcode Tel.					
1.7	7.	Country of origin	ISO code	I.8. Region of origin	Code	1.9.	Country of destination	ISO code	I.10. Region of destination	Code		
1.1	11.	Place of origin				1.12.	Place of des	tination	1			
		Name Approval number Address					Name Address		stom warehouse proval number			
		Name Address		Approval num	nber		Postcode					
		Name Address		Approval num	nber							
1.1	13.	Place of loading				1.14.	Date of depa	arture				
1.1	15.	i. Means of transport					Entry BIP in	EU				
		Aeroplane Road vehicle	Ship Other		wagon 🗌							
		Identification Documentation refe				1.17.						
1.1	18.	Description of com	modity				l.19	. Commodity co	de (HS code)			
									I.20. Quantity			
1.2	21.	Temperature of pro	duct						I.22. Number of pac	kages		
		Ambient		Chilled			Fro	zen 🗌				
1.2	23.	Seal/Container No							I.24. Type of packag	ging		
1.2	25.	Commodities certifi	ed for:									
		Technical use										
1.2	26.	For transit through	EU to third of	ountry		1.27.	For import or	admission into E	U			
		Third country		ISO code								
1.2	28.	Identification of the	commodities	i								
		Species (Scientific name)	Appro	oval number of establish Manufacturing plant	nments	Num	ber of packag	jes Net	weight E	atch number		

Fat derivatives not intended for human consumption to be used

▼<u>M4</u>

			Cato	de the feed chain						
II.	Health info	rma	tion II.a.	Certificate reference No	II.b.					
	and of the	Cour	ncil (^{1a}) and in particular Article 10 thereof, and Commi	ssion Regulation (EÙ) No 142/.						
II.1.	consist of fa	t de	erivatives that satisfy the health requirements below;							
II.2.	consist of fa	at de	erivatives intended for purposes outside the feed chair	n, other than in cosmetics, ph	narmaceuticals and medical devices;					
II.3.				ervised by the competent auth	nority in accordance with Article 24 of					
II.4.	have been p	orep	ared from rendered fats exclusively produced from the	e following materials:						
II.4.1.					ertilisers, soil improvers, cosmetics,					
	(²) either [- the following material:									
			(i) specified risk material;							
			(ii) entire bodies or parts of dead animals containing	specified risk material at the	time of disposal;]					
	(²) and/or	[-			tted to illegal treatment as defined in					
	(²) and/or	[-	Annex I to Directive 96/23/EC, if such residues exc	eed the permitted levels laid						
II.4.2.					outside the feed chain, other than in					
	(²) either	[-	animal by-products containing residues of authorised to in Article 15(3) of Directive 96/23/EC;]	substances or contaminants ex	cceeding the permitted levels referred					
	(²) and/or	[-	products of animal origin which have been declared u those products;]	nfit for human consumption due	e to the presence of foreign bodies in					
	(²) and/or	[-								
II.4.3.	the following	g Ca	stegory 3 materials:							
	(²) either	[-								
	(²) and/or	[-	considered fit for slaughter for human consumption fo	llowing an ante-mortem inspec	tion or bodies and the following parts					
			(ii) heads of poultry;							
					ng the phalanges and the carpus and					
			(iv) pig bristles;							
			(v) feathers;]							
	(²) and/or	[-	from animals that have been slaughtered in a slaugh	nterhouse after having been co	onsidered fit for slaughter for human					
	(²) and/or	[-			sumption, including degreased bone,					
	II.1. II.2. II.3. II.4. II.4.1.	I, the unders and of the of Annex XI II.1. consist of fa II.2. consist of fa II.3. have been p Regulation (II.4. have been p Headlation (II.4.1. in case the pharmaceuti (2) either (2) and/or (2) and/or (3) either (4) and/or (5) either (6) and/or (7) and/or (8) and/or (9) and/or (11.4.3. the following (1) either (9) and/or (11.4.3. the following (1) either (1) and/or	I, the undersign and of the Cou of Annex XIV th consist of fat de II.2. consist of fat de II.2. consist of fat de II.3. have been prep Regulation (EC) II.4. have been prep II.4.1. in case the fat pharmaceuticals (2) either [- (2) and/or [- (2) and/or [- (2) and/or [- (2) and/or [- (3) and/or [- (4) and/or [- (5) either [- (6) and/or [- (7) either [- (8) and/or [- (9) and/or [- (11.4.3. the following Ca (1) either [- (2) and/or [- (3) and/or [- (4) and/or [- (5) either [- (6) and/or [- (7) either [- (8) either [- (9) and/or [- (1) either [- (2) and/or [- (3) either [- (4) either [- (5) either [- (6) either [- (7) either [- (8) either [- (9) either [- (1) either [- (1) either [- (1) either [- (2) either [- (3) either [- (4) either [- (5) either [- (6) either [- (7) either [- (8) either [- (9) either [- (9) either [- (1) either [- (2) either [- (3) either [- (4) either [- (5) either [- (6) either [- (7) either [- (8) either [- (9) either [- (9) either [- (1) either [- (2) either [- (3) either [- (4) either [- (5) either [- (6) either [- (8) either [- (9) e	I, the undersigned official veterinarian, declare that I have read and une and of the Council (19) and in particular Article 10 thereof, and Commi of Annex XIV thereto, and certify that the fat derivatives described ab consist of fat derivatives that satisfy the health requirements below; II.2. consist of fat derivatives intended for purposes outside the feed chail have been prepared and stored in a plant approved, validated and sup Regulation (EC) No 1069/2009, in order to kill pathogenic agents; II.4. have been prepared from rendered fats exclusively produced from the in case the fat derivatives are intended for uses outside the feed pharmaceuticals and medical devices, the following Category 1 mater (2) either [- the following material: (i) specified risk material; (ii) entire bodies or parts of dead animals containing ehither sub Annex I to Directive 96/22/EC or Article 2(b) or Article 12(b) of Directive 96/22/EC or Article 2(b) or Annex I to Directive 96/22/EC, if such residues exclusively products containing residues of other sub Annex I to Directive 96/22/EC, if such residues exclusives, pharmaceuticals and medical devices, the following Category animal by-products containing residues of authorised to in Article 15(3) of Directive 96/23/EC.] (2) either [- animal by-products containing residues of authorised to in Article 15(3) of Directive 96/23/EC.] (3) and/or [- animal by-products containing residues of authorised to in Article 15(3) of Directive 96/23/EC.] (4) and/or [- carcases and parts of animals, other than those referre other than being slaughtered or killed for human consumption in accordance with Union legisli reasons;] (5) and/or [- carcases and parts of animals slaughtered or, in the chuman consumption in accordance with Union legisli reasons;] (6) and/or [- carcases and the following parts originating either from considered fit for slaughter for human consumption for animals from game killed for human consumption for animals from game killed for human consumption for animals from ga	I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1 and of the Council (*) and in particular Article 10 thereof, and Commission Regulation (EU) No 142 of Annex XIV thereto, 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 intended for purposes outside the feed chain, other than in cosmetics, pl II.3. have been prepared and stored in a plant approved, validated and supervised by the competent auth Regulation (EC) No 1089/2009, in order to kill pathogenic agents; III.4. have been prepared from rendered fats exclusively produced from the following materials: III.4. in case the fat derivatives are intended for uses outside the feed chain, other than in organic 1 pharmaceuticals and medical devices, the following Category 1 materials: (i) sepcified risk material; (ii) entire bodies or parts of dead animals containing specified risk material at the (*) and/or [- animal by-products which have been derived from animals which have been submit Article 1(2)(d) of Directive 99(2)2EC or Article 2(b) of Directive 96(2)2EC] (*) and/or [- animal by-products containing residues of other substances and environmental or Annex 1 to Directive 99(2)2EC or Article 2(b) or Directive 99(2)2EC animal substances or contaminants every to in Article 15(3) of Directive 99(2)2EC.] (*) and/or [- animal by-products containing residues of authorised substances or contaminants every to in Article 15(3) of Directive 99(2)2EC.] (*) and/or [- animal by-products containing residues of authorised substances or contaminants every to in Article 15(3) of Directive 98(2)2EC.] (*) and/or [- animal by-products containing residues of authorised substances or contaminants every to in Article 15(3) of Directive 98(2)2EC.] (*) and/or [- animal by-products of animals of animals of the full and the products.] (*) and/or [- animal by-products of animal origin which have been declared unfit					

▼<u>M4</u>

COUNTRY

Fat derivatives not intended for human consumption to be used outside the feed chain

COUNT	H Y				outside the feed chain						
II.	Health inform	nati	on		II.a. Certificate reference No	II.b.					
	(²) and/or	[-	consumption for com		ining products of animal origin, which to problems of manufacturing or pack s;]						
	(²) and/or	[-	no longer intended for		eedingstuffs containing animal by-prod al reasons or due to problems of ma animal health arises;]						
	(²) and/or	[-			oof cuts and raw milk originating from oduct to humans or animals;]	live animals that did not show signs					
	(²) and/or	[-	aquatic animals, and communicable to hur		s, except sea mammals, which did	not show any signs of diseases					
	(²) and/or	[-	animal by-products fr consumption;]	rom aquatic animals orig	inating from plants or establishments	manufacturing products for human					
	(²) and/or	[-	the following materia material to humans o		s which did not show any signs of	disease communicable through that					
			(i) shells from shellf	ish with soft tissue or fle	sh;						
			(ii) the following orig	inating from terrestrial ar	al animals:						
			— hatchery by-p	roducts,							
			— eggs,								
			— egg by-produ	cts, including egg shells;	ills;						
			(iii) day-old chicks ki	lled for commercial reason	ons;]						
II.5.	in case of fat	der	ivatives produced from	n animal by-products refe	erred to in point II.4.1 and point II.4.2	:					
	(a) have been	n pr	oduced using the follo	owing methods:							
	(²) either		[transesterification or acids and esters)]	hydrolysis at least 200 °C	c, under corresponding appropriate pre	essure, for 20 minutes (glycerol, fatty					
	(²) or		[saponification with N	IaOH 12M (glycerol and	soap):						
			(2) either [in a b	eatch process at 95 °C fo	or three hours;]						
			(2) or [in a c	ontinuous process at 14	0 °C, 2 bars (2000 hPa) for eight min	nutes;]]					
	(²) or		[hydrogenation at 160	0°C at 12 bars (12000 h	Pa) pressure for 20 minutes;]						
				in containers that have FOR HUMAN OR ANIMA	been cleaned, and all precautions and L CONSUMPTION";	e taken to prevent its contamination					
II.6.	in case of fat with one of the	deri he	vatives produced from processing methods [animal by-products refer 1]-[2]-[3]-[4]-[5]-[6]-[7] (²)	red to in point II.4.3, the fat derivatives referred to in Chapter III of Annex I	have been produced in accordance V to Regulation (EU) No 142/2011.					
Notes											

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) is to be provided. In
 case of unloading and reloading, the consignor must inform the BIP of entry into the EU.
- Box I.19: use the appropriate Harmonized System (HS) code under the following headings: 15.16 or 15.08.

Fat derivatives not intended for human consumption to be used

▼<u>M4</u>

Stamp:

COUNTRY outside the feed chain II. Health information II.a. Certificate reference No II.b. — Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included. — Box reference I.25: technical use: any use other than for animal consumption. Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate. Box reference I.28: Species: select from the following: Ruminantia, Other; Manufacturing plant: provide the registration number of treatment/processing establishment. Part II: (1a) OJ L 300, 14.11.2009, p. 1. (^{1b}) OJ L 54, 26.2.2011, p. 1. (2) Delete as appropriate. The signature and the stamp must be in a different colour to that of the printing. Note for the person responsible for the consignment in 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/Official inspector Name (in capital letters): Qualification and title: Date: Signature:

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

οU	NTR	1									Veter	rinary certifi	cate to El	
	1.1.	Consignor					1.2.	Certificat	e referen	ce No	1.2.a.			
		Name					1.3.	Central c	ompeten	t authority				
		Address							•					
		Tel.					I.4. Local competent authority							
ent	1.5.	Consignee					1.6.	I.6. Person responsible for the load in EU						
muf		Name					Name							
isic		Address						Address						
200		Postcode						Postcode	_					
cne		Tel.						Tel.	3					
alspatcnea consignment			100 1							100 1				
<u>as</u>	1.7.	Country of origin	ISO code	I.8. Reg	jion of origin	Code	1.9.	Country destination		ISO code	I.10. Regio	on of nation	Code	
s or														
rarr I : Details	l.11.	Place of origin					l.12.	Place of	destinati	on				
-		Name		Approval r	number			Name				varehouse 🗆]	
าสต		Address						Address			Approval	number		
-		Name Address		Approval r	number			5						
		Name		Approval r	number			Postcode	9					
		Address		. 1-1										
	I.13.	Place of loading					l.14.	Date of	departure					
	l.15.	5. Means of transport						Entry BII	o in EU					
		Aeroplane	Ship 🔲	Ra	ailway wagon [
		Road vehicle	Other 🔲		, ,		1.17.							
		Identification					1.17.							
		Documentation refe	erences											
	I.18.	Description of com	modity						I.19. Co	mmodity co	de (HS code)		
										15.16.10				
										1.20.	Quantity			
	1.21.	Temperature of pro	oduct							1.22.	Number of p	oackages		
		Ambient		Chilled			Froze	n 🗆				-		
	1.23.	Seal/Container No								1.24.	Type of pac	kaging		
	1.25.	Commodities certif	ied for:											
		Animal feedingstuff	· 🗆		Technical L	ıse 🗌								
	1.26.	For transit through	EU to third	country			1.27.	For impo	ort or adn	nission into	ΞU]	
		Third country		ISO code										
	1.28.	Identification of the	commoditie	es			1							
		Species	Nature of	f commodit	ty Approva	I number of	f estab	lishments		mber of	Net weight	Batch	number	
		(Scientific name)				Manufacturi	ng pla	nt	pa	ckages				

Fat derivatives not intended for human consumption to be used as COUNTRY feed or outside the feed chain Health information II.a. Certificate reference No II.b. I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (1a) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011 (1b), and in particular Annex XIV, Chapter II thereof, and certify that the fat derivatives described above: II.1. consist of fat derivatives that satisfy the health requirements below: II: Certification 112 consist of fat derivatives not intended for human consumption: 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; 11.3. Part II.4. have been prepared from rendered fats exclusively produced from the following Category 3 materials: (2) either [- 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 (2) and/or [- 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) carcases 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 intended 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 feedingstuffs of animal origin, or feedingstuffs 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:1 (2) and/or [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for human (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;

Fat derivatives not intended for human consumption to be used as COUNTRY feed or outside the feed chain Health information II.a. Certificate reference No II.b. (ii) the following originating from terrestrial animals: - hatchery by-products. eaas. - egg by-products, including egg shells; (iii) day-old chicks killed for commercial reasons;] are packaged in new containers or in containers which bear labels indicating 'NOT FOR HUMAN CONSUMPTION', that have been cleaned, and all precautions are taken to prevent its contamination. II.5. 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.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority. - 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.25: technical use: any use other than for animal consumption. 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: (1a) OJ L 300, 14.11.2009, p. 1. (1b) OJ L 54, 26.2.2011, p. 1. (2) Delete as appropriate. The signature and the stamp must be in a different colour to that of the printing. — Note for the person responsible for the consignment in 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/Official inspector Name (in capital letters): Qualification and title: Date: Signature: Stamp:

▼<u>M4</u>

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 $\binom{2}{1}$ the European Union

JNTR	I						vetermary cer	tificate to E
l.1.	Consignor Name			1.2.	Certificate refe	erence No	I.2.a.	
	Address			1.3.	Central compo	etent authority		
	Tel.			1.4.	Local compet	ent authority		
1.5.	Consignee Name Address				Person responsive Name Address	nsible for the lo	ad in EU	
	Postcode Tel.				Postcode Tel.			
1.7.	Country of origin ISO code I	.8. Region of origin	Code		Country of destination	ISO code	I.10. Region of destination	Code
111	Place of origin			112	Place of desti	nation		1
	Name Address	Approval numb	per		Name	Cu	stom warehouse	
	Name Address	Approval numb	per		Address Postcode	Ар	proval number	
	Name Address	Approval numb	oer		7 5515545			
I.13.	Place of loading			l.14.	Date of depar	ture		
l.15.	Means of transport			I.16.	Entry BIP in E	EU		
	Aeroplane Ship Ship Road vehicle Other	•	agon 🗌					
	Identification Documentation references	_		1.17.				
l.18.	Description of commodity				I.19.	Commodity cod	de (HS code)	
							I.20. Quantity	
I.21.	Temperature of product	Oh III a 1 🗖			F		I.22. Number of packa	ages
1.23.	Ambient Seal/Container No	Chilled			Froze		I.24. Type of packagin	ng
1.25.	Commodities certified for:							
20	Animal feedingstuff		Technical ı	use 🔲				
1.26.	For transit through EU to third cou	untry [1.27. F	For import or a	admission into E	:U	
	Third country	ISO code						
1.28.	Identification of the commodities			I				
1	Approval number of establishment	te Mur	nber of pa			Net weight		tch number

▼<u>M4</u>

JNTRY			used as feed	
II.	Health info	rmation	II.a. Certificate reference No	II.b.
	and of the C	signed official veterinarian, declare that I ha Souncil (^{1a}) and in particular Article 10 there thereto, and certify that the egg products o	ve read and understood Regulation (EC) No of, and Commission Regulation (EU) No 14: lescribed above:	o 1069/2009 of the European Parliame 2/2011 (^{1b}), and in particular Chapter I
II.1.	consist of eq	gg products that satisfy the health require	ments below;	
II.2.	consist exclu	usively of egg products not intended for h	uman consumption;	
II.3.		EC) No 1069/2009 or Article 4(2) of Regula	alidated and supervised by the competent a tion (EC) No 853/2004 of the European Par	
II.4.	have been p	prepared (derived) exclusively with the following	owing animal by-products:	
	(²) either	[- animal by-products arising from the p	production of products intended for human	consumption;]
	(²) and/or		ffs containing products of animal origin, w or due to problems of manufacturing or p lith arise;]	
	(²) and/or	[- the following material originating from that material to humans or animals:	terrestrial animals which did not show any	signs of disease communicable through
		 hatchery by-products, 		
		— eggs,		
		- egg by-products, including egg sh	nells;]	
II.5.	have been s	subjected to processing:		
	(²) either	[in accordance with processing method No 142/2011;]	(4) as set out in Ch	napter III of Annex IV to Regulation (E
	(²) or	[in accordance to a method and parame out in Chapter I of Annex X, to Regulat	eters which ensure that the products compl ion (EU) No 142/2011;]	y with the microbiological standards s
	(²) or	[in accordance with Section X, Chapters	I and II of Annex III to Regulation (EC) N	o 853/2004;]
II.6.	have been e following sta		g a random sample immediately prior to d	ispatch and found it to comply with t
	Salmonella:	absence in 25g: $n = 5$, $c = 0$, m	= 0, M = 0,	
	Enterobacter	riaceae: n = 5, c = 2, m = 10, M = 300 i	n 1 gram;	
II.7.		standards on residues of substances that a dangerous or harmful to animal health;	are harmful or might alter the organoleptic o	characteristics of the product or make
II.8.	the end prod	duct was:		
	(²) either	[packed in new or sterilised bags,]		
	(²) or	[transported in bulk in containers or othe approved by the competent authority be	means of transport that were thoroughly clofore use,]	eaned and disinfected with a disinfecta
	and which b	pear labels indicating "NOT FOR HUMAN	CONSUMPTION";	
II.9.	the end prod	duct was stored in enclosed storage;		
II.10.	the product	has undergone all precautions to avoid co	ntamination with pathogenic agents after tr	reatment.
Notes				
Part I:				

▼<u>M4</u>

cou	UNTRY	Egg products not intended for human consumption that could be used as feed				
II.	Health information	II.a. Certificate reference No	II.b.			
	Box reference I.12: Place of destination: this box is to be filled in only be stored in free zones, free warehouses and custom warehouses.	y if it is a certificate for transit commodi	ity. The products in transit can only			
	 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 BIP of entry into the EU. 					
-	— Box I.19: use the appropriate Harmonized System (HS) code under the following headings: 04.08, 23.09 or 35.02.					
-	Box reference I.23: for bulk containers, the container number and th	e seal number (if applicable) should be	e included.			
-	Box reference I.25: technical use: any use other than for animal con	sumption.				
-	Box reference I.26 and I.27: fill in according to whether it is a transit	t or an import certificate.				
Pai	rt II:					
(^{1a})	OJ L 300, 14.11.2009, p. 1.					
(1b)	OJ L 54, 26.2.2011, p. 1.					
(2)	Delete as appropriate.					
(3)	OJ L 139, 30.4.2004, p. 55.					
(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 consid m;	ered satisfactory if the number of bacte	eria in all samples does not exceed			
	M = maximum value for the number of bacteria; the result is consider or more; and	lered unsatisfactory if the number of ba	cteria in one or more samples is M			
	c = number of samples the bacterial count of which may be betwee count of the other samples is m or less.	een m and M, the sample still being co	nsidered acceptable if the bacterial			
-	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 $\mbox{\it l}$ the consignment until it reaches the border inspection post.	Jnion: this certificate is only for veterina	ry purposes and has to accompany			
Offi	icial veterinarian/Official inspector					
	Name (in capital letters):	Qualificat	tion 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 hom 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

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 fertilisers or soil improvers and will be conveyed directly for the purpose of further processing or treatment to:

Name:	Address:
	I is not derived from specified risk material as defined in Annex rated meat obtained from bones of bovine, ovine or caprine
The importer:	
Name:	Address:
Done at	on

Reference number as indicated on the Common Veterinary Entry Document (CVED) provided for in Annex III to Commission Regulation (EC) No 136/2004:

Official stamp of the border inspection post of entry into the EU (2)

Signature:

(Signature of the official veterinarian of the border inspection post) $(^2)$

Name: (Name in capital letters)

reaches the border inspection post.

Signature

⁽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, derived products from processed manure and guano from bats intended for dispatch to or for transit through $(^2)$ the European Union

CC	UNTR	Υ					Veterinary cer	tificate to EU
	1.1.	Consignor	1.2.	Certificate	e reference N	0	I.2.a.	
		Name	I.3. Central competent authority					
		Address						
		Tel.	1.4.	Local co	mpetent autho	rity		
1	1.5.	Consignee	1.6.	Person r	esponsible for	the loa	ad in EU	
8		Name		Name				
1.5	5	Address		Address				
8	3	Post of a		D				
3	3	Postcode Tel.		Postcode Tel.	9			
1 2	į	0	1.0			100		
1 2	1.7.	Country of origin ISO code I.8. Region of origin Code	1.9.	Country destination		ISO code	I.10. Region of destination	Code
1	5							
Dart I. Details of discontahed consistences	1.11	. Place of origin	I.12.	Place of	destination			_
غ ا	<u>.</u>	Name Approval number		Name			Custom warehouse	П
7		Name Approval number Address		Address			Approval number	_
٩	-	Name Approval number						
		Address		Postcode	е			
		Name Approval number Address						
	1.13	. Place of loading	l.14.	Date of	departure			
L	1.15	. Means of transport	I.16.	Entry BIF	P in EU			
		Aeroplane ☐ Ship ☐ Railway wagon ☐						
		Road vehicle Other O						
		Identification	1.17.					
		Documentation references						
	1.18	. Description of commodity			I.19. Commo	dity cod	de (HS code)	
				,		1.20.	Quantity	
	1.21	. Temperature of product				1.22.	Number of packages	
		Ambient ☐ Chilled ☐	Froze	n 🔲				
	1.23	. Seal/Container No				1.24.	Type of packaging	
	1.25	. Commodities certified for:		-				
		Technical use □						
		recinical use						
	1.26	. For transit through EU to third country	1.27.	For impo	ort or admissio	n into E	≣U	
		Third country ISO code						
	1.28	. Identification of the commodities						
		Species Nature of commodity			al number of e		ments	Net weight
		(Scientific name)			Manufacturing	plant		

Processed manure, derived products from processed manure and

COUNTRY guano from bats Health information II.a. Certificate reference No II.b. I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and in particular Article 9 thereof, and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Annex XIV, Chapter II thereof, and certify that the processed manure, the derived products from processed manure and the guano from bats described come from a plant for the manufacture of products for 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 142/2011; II.1. Certification 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 authorised by the importing Member State in accordance with the specific conditions laid down in Regulation (EC) No 1069/2009 and in Regulation (EU) No 142/2011 as follows: Part 11.3. are: (a) free from Salmonella (no salmonella in 25 g treated product); (b) free from Escherichia coli or from Enterobacteriaceae (based on the aerobic count: less than 1 000 cfu per gram of treated product); have been subjected to reduction in spore-forming bacteria and toxin formation; 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 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.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority. - 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.25: technical use: any use other than for animal consumption. 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, derived products from processed manure or guano from bats. (1a) OJ L 300, 14.11.2009, p. 1. (1b) OJ L 54, 26.2.2011, p. 1.

COUNTRY	Processed manure, derived pro guano from bats	Processed manure, derived products from processed manure and guano from bats				
II. Health information	II.a. Certificate reference No	II.b.				
(²) Delete as appropriate.						
The signature and the stamp must be in a d	ferent 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/Official inspector						
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 fertilisers or soil improvers intended for dispatch to or for transit through (2) the European Union

COL	JNTR	/ :	Veterinary certificate to EU					
	l.1.	Consignor	1.2.	Certificate reference No	1.2.a.			
		Name	1.3.	I.3. Central competent authority				
		Address	1.4.	Local competent authorit	у			
		Tel.	-					
	1.5.	Consignee	1.6.	I.6. Person responsible for the load in EU				
men		Name Address		Name Address				
sign		Address		Address				
CO		Postcode		Postcode				
hed		Tel.		Tel.				
spatc	1.7.	Country ISO code I.8. Region of Code	1.9.	Country of ISO	I.10. Region of Code			
) dis		of origin origin		destination code	destination			
ails	111	Place of origin	112	. Place of destination				
Det	1.11.	T. Tidde of origin		Those of destination				
Part I : Details of dispatched consignment		Name Approval number			Custom warehouse			
a.		Address		Name	Approval number			
		Name Approval number		Address				
		Address						
		Name Approval number		Postcode				
		Address						
	I.13.	Place of loading	1.14	. Date of departure				
	I.15.	Means of transport	1.16	6. Entry BIP in EU				
		Aeroplane Ship Railway wagon Railway						
		Road vehicle Other	1.17	. Number(s) of CITES				
		Identification						
		Documentation references						
	I.18.	Description of commodity		I.19. C	commodity code (HS code)			
					05.07			
	101	To an anathur of another			I.20. Quantity			
	1.21.	Temperature of product Ambient □ Chilled □		Frozen 🗖	I.22. Number of packages			
	122	Seal/Container No		Frozen 🗀	I.24. Type of packaging			
	1.23.	Jean Container NO			1.24. Type of packaging			

Commodities certified for:					
Further process \square	Techn	ical use 🗆			
For transit through EU to third	d country	I.27. For import or admission into EU			
Third country	ISO code				
8. Identification of the commodities Approval number of establishments					
Species (Scientific name)	Manufacturing plant	Net weight	Batch number		
	Further process For transit through EU to third Third country Identification of the commodit Species	Further process Techn For transit through EU to third country Third country ISO code Identification of the commodities Approval num Species Manufacturing plant	Further process Technical use For transit through EU to third country ISO code Identification of the commodities Approval number of establishments Species Manufacturing plant Net weight		

COUNTRY

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

	II.	Health in	formation		II.a. Certificate reference No	II.b.				
		the Europ	I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2005 the European Parliament and of the Council (¹a), and Commission Regulation (EU) No 142/2011 (¹b), and particular Chapter II of Annex XIV thereto, and certify that the horns and horn products, excluding horn meal, a hooves and hoof products, excluding hoof meal (²) described above							
_	II.1.	originate f	rom animals							
tificatio	(²) either [that were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were f result of such inspection, for slaughter for human consumption;]									
Part II: Certification		(²) or	[that did no animals;]	ot show clinical	signs of any disease communicable through	that product to humans or				
Pa	II.2.	horns, horn products, hooves and hoof products must have undergone a heat treatment for one hour at a core temperature of at least $80 ^{\circ}\text{C}$;								
	II.3.	horns mus	st have been	removed without	opening the cranial cavity;					
	II.4.		at any stage of processing, storage or transport every precaution must have been taken to avoid cross-contamination.							
	II.5.	the horns packed:	the horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, were packed:							
		(²) either	[in new pac	kaging or contai	ners;]					
		(²) or	[in vehicles authority;]	or bulk contain	ers disinfected prior to loading using a product	approved by the competent				
			'NOT FOR H		arked so as to indicate the type of the animal by IIMAL CONSUMPTION' and the name and addi					
	(²)[II.6.	The horns	and horn pr	oducts, excludin	g horn meal, and hooves and hoof products, exc	cluding hoof meal described				
		(²) either	[is derived f	rom other rumin	ants than bovine, ovine or caprine animals.]]					
		(²) or	[is derived f	rom bovine, ovir	e or caprine animals and does not contain and is	s not derived from:				
			(²) either	continuously re	e and caprine materials other than those deared and slaughtered in a country or region class cordance with Decision 2007/453/EC.]					
			(²) or		ed risk material as defined in point 1 of An //2001 of the European Parliament and of the Co					
				animal slaugh accord	nically separated meat obtained from bones of s, except from those animals that were born ered in a country or region classified as posi- ance with Commission Decision 2007/453/EC (genous BSE case,	n, continuously reared and ng a negligible BSE risk in				
				animal tissue cavity, that w classifi	by-product or derived product obtained from s which have been killed, after stunning, by laced by means of an elongated rod-shaped instrumer or by means of gas injected into the cranial caviere born, continuously reared and slaughtered as posing a negligible BSE risk in a 53/EC.]]]	ration of the central nervous nt introduced into the cranial ity, except for those animals ed in a country or region				

COUNTRY

Health information

II.

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

II.b.

Not	es	
Part	th:	
_	Box reference I.6: Person responsible for the consignment in the European Unit is a certificate for a commodity to be transited through the European Union commodity to be imported into the European Union.	
_	Box reference I.11 and I.12: Approval number: the registration number of issued by the competent authority.	the establishment or plant, which has been
_	Box reference I.12: Place of destination: this box is to be filled in only if it is in transit must only be stored in free zones, free warehouses and custom war	
_	Box reference I.15: Registration number (railway wagons or container and loinformation is to be provided in the event of unloading and reloading in the Ed	
_	Box reference I.23: for bulk containers, the container number and the seal number and	umber (if applicable) must be given.
_	Box reference I.25: technical use: any use other than for animal consumption	1.
_	Box reference I.26 and I.27: fill in according to whether it is a transit or an important of the second sec	port certificate.
_	Box reference I.28: Nature of commodity.	
Part	: II:	
(^{1a})	OJ L 300, 14.11.2009, p. 1.	
(^{1b})	OJ L 54, 26.2.2011, p. 1.	
(2)	Delete as appropriate.	
(3)	Type of product: horns, horn products, hooves, hoof products.	
(4)	OJ L 147, 31.5.2001, p. 1.	
(⁵)	OJ L 172, 30.6.2007, p. 84.	
_	The signature and the stamp must be in a different colour to that of the printing	ng.
_	Note for the person responsible for the consignment in the European Union: and must accompany the consignment until it reaches the border inspection Union.	
Offic	cial veterinarian/Official inspector	
	Name (in capital letters):	Qualification and title:
	Date:	Signature:
	Stamp:	

II.a. Certificate reference No

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

000	MIK		veterinary certificate to EU				
	1.1.	Consignor	I.2. Certificate reference No I.2.a.				
		Name Address	I.3. Central competent authority				
		Tel.	I.4. Local competent authority				
 =	1.5.	Consignee	I.6. Person responsible for the load in EU				
Je		Name	Name				
l g		Address	Address				
l SE							
8		Postcode	Postcode				
dispatched consignment		Tel.	Tel.				
patc							
5	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of				
Part I: Details	l.11.	Place of origin	I.12. Place of destination				
Part I:		Name Approval number Address	Name Custom warehouse ☐ Address Approval number				
		Name Approval number	7,44,55				
		Address	Postcode				
		Name Approval number Address					
	I.13.	Place of loading	I.14. Date of departure				
	l.15.	Means of transport	I.16. Entry BIP in EU				
		Aeroplane Ship Railway wagon					
		Road vehicle Other	I.17. Number(s) of CITES				
		Identification	1.17. Number(3) of Office				
		Documentation references					
	I.18.	Description of commodity	I.19. Commodity code (HS code) 35.03				
			I.20. Quantity				
			·				
	1.21.	Temperature of product	I.22. Number of packages				
		Ambient Chilled Chilled	Frozen				
	1.23.	Seal/container No	I.24. Type of packaging				
	1.25.	Commodities certified for:	•				
		Technical use					
	1.26.		I.27. For import or admission into EU				
	1.28.	Identification of the commodities	I				
		Species Approval number of establishm (Scientific name) Manufacturing plant	ents Net weight Batch number				

Gelatine not intended for human consumption to be used by the COUNTRY photographic industry Health information II.a. Certificate reference No II.b. I, the undersigned official, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council (^{1a}) and in particular Articles 8 and 10 thereof, and Commission Regulation (EU) No 142/2011 (^{1b}), and in particular Annex XIV, Chapter 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;

Certification Part

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 does 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;
- has been wrapped, packaged in new containers, stored and transported in sealed, leak-proof labelled containers in a vehicle under satisfactory hygiene conditions; 11.4.
- II.5. has been produced by a process ensuring that the raw material is:
 - (3) either treated by pressure sterilisation as referred to in definition No 19 of Article 3 of Regulation (EC) No 1069/2009 (2);
 - (3) or 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 'PHOTOGRAPHIC 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, the Netherlands or the United Kingdom.
- Box reference I.9: Country of destination: only applicable for the Czech Republic, the Netherlands or the United Kingdom.
- Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent
- 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.
- Box reference I.25: technical use: any use other than for animal consumption.

Part II:

- (1a) OJ L 300, 14.11.2009, p. 1.
- (1b) OJ L 54, 26.2.2011, p. 1.
- (2) Pressure sterilisation (method 1) is also referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011 as follows:

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.

COUNTRY

Gelatine not intended for human consumption to be used by the photographic industry

II. Health information	II.a. Certificate reference No	0 []	I.b.				
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 contin	3. The processing may be carried out in batch or continuous systems.'						
(3) 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 load in the Europei consignment until it reaches the factory of destination from		erinary purp	oses and has to accompany the				
Official veterinarian/Official inspector							
Name (in capital letters):	Qualif	ication and	title:				
Date: Signature:							
Stamp:							

CHAPTER 20

Model declaration

Declaration for the import from third countries and for the transit through (2) the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products

COL	JNTR	/ :								Vete	erinary certifica	te to EU	
	l.1.	Consignor					1.2.	Certificate refere	ence No	1.2	2.a.		
		Name						I.3. Central competent authority					
		Address					I.4. Local competent authority						
		Tel.											
	1.5.	Consignee	,				1.6.	I.6. Person responsible for the load in EU					
Ę		Name					Name						
Jume		Address						Address					
onsiç													
ğ		Postcode						Postcode					
tche		Tel.						Tel.					
Part I : Details of dispatched consignment	1.7.	Country of origin	ISO code	1.8.	Region of origin	Code	1.9.	Country of destination	ISO code	I.10.	Region of destination	Code	
ls of													
etai	I.11.	Place of origin						Place of destination	stination				
												_	
Part		Name		Appro	oval number					Cus	tom warehouse		
_		Address						Name		Арр	roval number		
		Name	Approval number					Address					
		Address											
	Name Approval number							Postcode					
		Address						ļ.,, <u>2</u>					
	I.13.	Place of lo	ading				1.14.	Date of departur	re				
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU					
		Aeroplane	☐ Ship	П	Railway wa	agon \square							
		Road vehic	`		rtanway we	agon —	1.17.						
		Identification											
		Documentation references											
	I.18.	Description	n of commod	ity			1	I.19. Commodity code (HS code					
										1.20	. Quantity		
	1.21.	Temperatu	re of produc	t						1.22	. Number of pa	ckages	
		Ambient 🗆]		Chilled]	Frozen□						
	1.23.	Seal/Conta	ainer No							1.24	. Type of packa	ging	

1.25.	Commodities certified for:							
	Technical use \square							
1.26.	For transit through EU to third	I country	I.27. For import or admission into EU					
	Third country	ISO code						
1.28.	Identification of the commodities Approval number of establishments							
	Species (Scientific name)	Manufacturing plant	Net weight	Batch number				

COUNTRY

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

					ve	terinary purposes, laborator	ry reagents,	and cosmetic products				
	II.	Health	h infoi	rmation	II.a.	Certificate reference No		II.b.				
	DEC	CLARATION										
	tran	he undersigned, declare that the intermediate product referred to above is intended to be imported by me into or to be insited through the European Union and satisfies the definition of an intermediate product provided for in point 35 of Annex Commission Regulation (EU) No 142/2011 (^{1a}), and in particular that:										
tion	(1)	it is intended	ed for the manufacture of:									
tifica		(²) either	[-	medicinal products,]								
Part II: Certification		(²) and/or										
Part		(²) and/or	[-	medical devices for medical and veterinary purposes,]								
		(²) and/or	[-	active implantable medical d	levices]						
		(²) and/or	[-	in vitro diagnostic medical de	evices	for medical and veterinary pur	poses,]					
		(²) and/or	[-	laboratory reagents,]								
		(²) and/or	[-	cosmetic products;]								
	(2) its design, transformation and manufacturing stages have been sufficiently completed in order to qualify the directly or as a component of a product intended for that purpose, except for the fact that it requires further manuf or transformation such as mixing, coating, assembling or packaging to make it suitable for placing on the market or into service as a medicinal product, veterinary medicinal product, medical device for medical and veterinary purpor active implantable medical devices, an in vitro diagnostic medical device for medical and veterinary purpos cosmetic product in accordance with the European Union legislation (1b) applicable to those products or as a lal reagent;						res further manufacturing g on the market or putting d veterinary purposes, an veterinary purposes or a					
	(3)	it has been o	derive	d from:								
		(²) either	[-			ed from animals submitted t 96/22/EC (^{2a}) or in Article 2(b)						
		(²) and/or	[-		consun	ightered or, in the case of gan nption in accordance with Unid I reasons;]						
(²) and/or [- carcases and the following parts originating either from animals that slaughterhouse and were considered fit for slaughter for human co mortem inspection or bodies and the following parts of animals to consumption in accordance with Union legislation:						man consum	ption following an ante-					
						s of animals which are rejecte ution, but which did not show a						
				(ii) heads of poultry;								
						trimmings and splitting thei nd metacarpus bones, tarsu:						
				(iv) pig bristles;								

(v) feathers;]

COUNTRY

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

				veterinary purposes, laboratory rea	gents, and cosmetic products					
II.	Healt	h info	rmation	II.a. Certificate reference No	II.b.					
	(²) and/or	[-	animals obtained from animal	ot show any signs of disease communicable through blood to humans or is other than ruminants that have been slaughtered in a slaughterhouse d fit for slaughter for human consumption following an ante-mortem Union legislation;]						
	(²) and/or	[-	animal by-products arising from the production of products intended for human consumption, in 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 intended for human consumption for commercial reasons or due to problems of manufactur packaging defects or other defects from which no risk to public or animal health arise;]							
	(²) and/or	[-	petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or deriv products, which are no longer intended for feeding for commercial reasons or due to problems manufacturing or packaging defects or other defects from which no risk to public or animal hearises;]							
	(²) and/or	[-		s, hair, horns, hoof cuts and raw milk o ase communicable through that product						
	(²) and/or	[-	aquatic animals, and parts of diseases communicable to hu	such animals, except sea mammals, w mans or animals;]	hich did not show any signs of					
	(²) and/or	[-	animal by-products from aqu products for human consumpti	atic animals originating from plants or on;]	establishments manufacturing					
	(²) and/or	[-	the following material originating through that material to human	ng from animals which did not show any is or animals:	signs of disease communicable					
			(i) shells from shellfish with	soft tissue or flesh;						
			(ii) the following originating	from terrestrial animals:						
			 hatchery by-product 	ets,						
			— eggs,							
			egg by-products, in	cluding egg shells;						
			(iii) day-old chicks killed for o	commercial reasons;]						
	(²) and/or	[-	animal by-products from aqua or animals;]	tic or terrestrial invertebrates other than	species pathogenic to humans					
	(²) and/or	[-		the zoological orders of Rodentia and L ticle 8(a)(iii), (iv) and (v) and Categor n (EC) No 1069/2009;]						
	(²) and/or	[-	products derived from or gene	rated by:						
			 aquatic animals, and par of disease communicable 	ts of such animals, except sea mammal e to humans or animals,	s, which did not show any signs					
			 aquatic or terrestrial invented 	rtebrates other than species pathogenic	to humans or animals,					
			Category 1 material as	eof of the zoological orders of Rode referred to in Article 8(a)(iii), (iv) and (to (g) of Regulation (EC) No 1069/2009;	(v) and Category 2 material as					

COUNTRY

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

								•	
II.	Health information			II.a.	Certificate reference I	No	II.b.		
	(²) and/or	²) and/or [- animals and parts of animals No 1069/2009,			s, other than those referred to in Article 8 or Article 10 of Regulation (EC				
		((i)	that died other than b	y being slaughtered or killed for human consumption, including animals ol purposes;				
		((ii)	foetuses;					
		((iii)	oocytes, embryos and	semer	which are not destine	d for breeding purp	oses; and	
		((iv)	dead-in-shell poultry;]					
	(²) and/or	[- 8	anim	al by-products other tha	n Cate	egory 1 material or Cate	egory 3 material;]		
(4)	its outer packaging is labelled 'FOR MEDICINAL PRODUCTS / VETERINARY MEDICINAL PRODUCTS / MEDICA DEVICES FOR MEDICAL AND VETERINARY PURPOSES / ACTIVE IMPLANTABLE MEDICAL DEVICES / IN VITRO DIAGNOSTIC MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES / LABORATORY REAGENTS COSMETIC PRODUCTS ONLY' and it is not intended to be diverted at any stage within the European Union for any other use;							AL DEVICES / IN VITRO DRATORY REAGENTS /	
(5)	the consignm point I.12 of th				o the	place of destination	n the European l	Jnion as indicated under	
	(²) either	devic medi	n establishment or plant for the production of medicinal products, veterinary medicinal products, medical vices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic idical devices for medical and veterinary purposes, laboratory reagents or cosmetic products, which has en registered in accordance with Article 23 of Regulation (EC) No 1069/2009],						
	(²) or	No 1	069/					24(1)(i) of Regulation (EC) or plant referred to in the	
Note	es								
_	2007/275/EC	of 17 /	April		f anima	als and products to be	subject to controls	th Commission Decision at border inspection posts	
_	Box reference	1.25: 1	techr	nical use: any use other	than f	or animal consumption			
(^{1a})	OJ L 54, 26.2.	2011,	p. 1						
(^{1b})	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 31: 28.11.2001, p. 67), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 127.1993, p. and Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59), as appropriate.								
(2)	Delete as appropriate.								
(^{2a})	OJ L 125, 23.5.1996, p. 3.								
(^{2b})	OJ L 125, 23.	5.1996	S, p.	10.					
The	importer								
	Name (in capi	tal lett	ers):				Address:		
	Date:						Signature:		

CHAPTER 21

Model declaration

Declaration by the importer of untreated wool and hair referred to in Article 25(2)(e) for import to the European Union

COL	JNTR	Υ:					
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.				
		Address	I.3. Central competent authority				
=		Tel.	I.4. Local competent authority				
Part I: Details of dispatched consignment	1.5.	Consignee Name Address Country Tel.	I.6. Person responsible for the load in EU Name Address Postcode Tel.				
	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of destination ISO code l.10. Region of Code destination				
	1.11.	Place of origin	I.12. Place of destination				
Part		Name Approval number Address	Name Approval number Address				
		Country	Postal code / Region				
	I.13.	Place of loading Address	I.14. Date of departure				
	l.15.	Means of transport	I.16. Entry BIP in EU Name Unit no				
		Aeroplane Ship Railway wagon Under U	I.17. No(s) of CITES				
	1.18.	Description of commodity	I.19. Commodity code (HS code)				
			I.20. Quantity				
	1.21.	Temperature of product Ambient	I.22. Number of packages				
	1.23.	Seal/Container No	I.24. Type of packaging				
	1.25.	Commodities certified for:	,				
		Further process					
	1.26.	For transit through EU to third country Third country ISO code	I.27. For import or admission into EU				
	1.28.	Identification of the commodities	1				
		Nature of commodity	Net weight				

▼ M2

Wool and hair referred to in Article 25(2)(e) of Regulation (EU) No 142/2011COUNTRY: II.a. Certificate reference No Health information II.b. **DECLARATION** I, the undersigned, declare that the untreated wool (1) and/or hair (1) is produced from animals other than those of the porcine species: Part II: Certification (a) at least 21 days before the date of entry into the Union; (b) in a third country or region thereof as listed in Part 1 of Annex II to Regulation (EU) No 206/2010 and authorised for imports into the Union of fresh meat of ruminants not subject to supplementary guarantees A and F mentioned therein; and (c) from animals kept in the third country or region thereof referred to in point (b) free of foot-and-mouth disease and, in the case of wool and hair from sheep and goats, of sheep pox and goat pox in accordance with the basic general criteria listed in Annex II to Directive This declaration is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post and must be issued 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. Box reference I.11 & I.12: Approval number: the registration number of the esatblishment or plant, which has been issued by the comptent authority. Use the appropriate Harmonised System (HS) code of the World Customs Organisation of the following headings: 5101 or 5102 Box reference I.19: Box reference I.20: Quantity: indicate the total gross and net weight in kg - Box reference I.28: Nature of commodity: Indicate wool and hair Part II: (1) Delete as appropriate. (2) The signature must be in colour different to that of the printing. The importer Name (in capital letters): Address: Date: Signature: Place:

ANNEX XVI

OFFICIAL CONTROLS

CHAPTER I

OFFICIAL CONTROLS IN PROCESSING PLANTS

Section 1

Supervision of the production

 The competent authority shall supervise processing plants to ensure compliance with the requirements of Regulation (EC) No 1069/2009 and with this Regulation.

It shall, in particular:

- (a) check:
 - the general conditions of hygiene of the premises, equipment and staff;
 - (ii) the efficacy of the own checks carried out by the operator of the processing plant, in accordance with Article 28 of Regulation (EC) No 1069/2009; such checks must include an examination of the results of those checks and if necessary, the taking of samples;
 - (iii) the effective implementation of the permanent written procedure based on the HACCP principles in accordance with Article 29(1) of Regulation (EC) No 1069/2009; such checks must include an examination of the results of this implementation and if necessary, the taking of samples;
 - (iv) 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 no such methods are laid down in Union legislation, in accordance with recognised international standards or, in their absence, national standards; and
 - (v) the storage conditions;
- (b) take any samples required for laboratory tests; and
- (c) make any other checks it considers necessary to ensure compliance with Regulation (EC) No 1069/2009 and with this Regulation.
- To allow it to carry out its responsibilities under point 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.

Section 2

Validation procedures

- 1. Prior to issuing an approval for a processing plant, as provided for in Article 44(1) of Regulation (EC) No 1069/2009, 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) a description of the process by a process flow diagram;
 - (b) an identification of critical control points (CCPs) including the material process rate for continuous systems;
 - (c) the compliance with the specific process requirements laid down by this Regulation; and

- (d) the achievement of the following requirements:
 - particle size for batch-pressure and continuous processes, defined by the mincer hole or the anvil gap size;
 - (ii) temperature, pressure, processing time and, in the case of continuous processing systems, the material processing rate, as specified in points 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 must be used at defined positions throughout the process system in such a way that temperature and pressure comply with the required conditions inside the whole continuous system or in a section of it; the temperature and pressure must be plotted against real time;
 - (b) measurement of the minimum transit time inside the whole relevant part of the continuous system where the temperature and pressure comply with the required conditions, must be provided to the competent authorities, using insoluble markers, such as manganese dioxide, or a method which offers equivalent guarantees.

Accurate measurement and control of the material process rate is essential and must be measured during the validation test in relation to a CCP that can be continuously monitored such as:

- (i) feed screw revolutions per minute (rev./min.);
- (ii) the electric power (amps at given voltage);
- (iii) the evaporation/condensation rate; or
- (iv) the 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 when it considers it necessary, and in any case each time any significant alterations are made to the process, such as modifications of the machinery or changes of raw materials.

CHAPTER II

LISTS OF REGISTERED AND APPROVED ESTABLISHMENTS, PLANTS AND OPERATORS

 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 point 2(a).

▼<u>B</u>

- 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 all registered and approved establishments, plants and operators on 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.
- The layout, including the relevant information and codes, of master lists shall follow the technical specifications which are published by the Commission on its website.

CHAPTER III

SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS

Section 1

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 Chapter V of Annex VIII to this Regulation 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.

Section 2

Official controls in low-capacity incineration plants

The competent authority shall inspect a low-capacity incineration plant for incineration of specified risk materials before approval, and at least once a year to monitor compliance with Regulation (EC) No 1069/2009 and with this Regulation.

Section 3

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 Regulation (EC) No 1069/2009, the competent authority shall monitor regularly the areas categorised as remote areas to ensure that those areas and the disposal operations are properly controlled.

Section 4

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 meat-and-bone meal or other products which have been processed in accordance with the processing methods set out in Chapter III of Annex IV and which are derived from the bodies or parts of bodies of animals of the same species;

▼B

- (b) that the animals are fed with the feed referred to in point (a), including:
 - (i) strict supervision of the health status of those animals; and
 - (ii) appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.
- The samples referred to in point 1(b)(ii) shall include samples taken from animals showing neurological symptoms and from older breeding animals.

Section 5

Official controls regarding collection centres

- 1. The competent authority shall:
 - (a) include collection centres into the list drawn up in accordance with Article 47(1) of Regulation (EC) No 1069/2009;
 - (b) assign an official number to each collection centre; and
 - (c) update the list of collection centres and make it available together with the list drawn up in accordance with Article 47(1) of Regulation (EC) No 1069/2009.
- 2. The competent authority shall carry out official controls at collection centres in order to verify compliance with this Regulation.

▼ M4

Section 6

Official controls regarding the feeding of wild animals and certain zoo animals with Category 1 material

The competent authority shall monitor the health status of the farmed animals in the region where feeding is carried out as referred to in Sections 2, 3 and 4 of Chapter II of Annex VI and shall carry out appropriate TSE surveillance involving regular sampling and laboratory examination for TSEs.

Those samples shall include samples taken from suspected animals and from older breeding animals.

▼B

Section 7

Official controls regarding the application of certain organic fertilisers and soil improvers

The competent authority shall carry out controls along the entire chain of production and use of organic fertilisers and soil improvers subject to the restrictions referred to in Chapter II of Annex II.

Those controls shall include checks on the mixing with a component referred to in point 2 of Section 1 of Chapter II of Annex XI, and checks on the stocks of such products kept on farm and the records kept in accordance with Regulation (EC) No 1069/2009 and with this Regulation.

Section 8

Official controls regarding approved photographic factories

The competent authority shall carry out documentary checks in approved photographic factories referred to in Table 3 of point 1 of Section 11 of Chapter II of Annex XIV 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.

Section 9

Official controls regarding certain imported rendered fats

The competent authority shall carry out documentary checks in registered establishments or plants receiving rendered fats which have been imported in accordance with Section 9 of Chapter II of Annex XIV on the channelling chain from the border inspection posts of first entry to the registered establishment or plant for the purpose of reconciliation of the quantities of products imported, used and disposed of.

▼<u>M16</u>

Section 10

Standard format for applications for certain authorisations in intra-Union trade

Operators shall inform the competent authority of the Member State of origin and apply to the competent authority of the Member State of destination for the authorisation of the dispatch of animal by-products and derived products referred to in Article 48(1) of Regulation (EC) No 1069/2009, and fish oil or fishmeal of Category 3 materials intended for detoxification in accordance with the following format in TRACES:

Reference number:	PAGE 1/2							
APPLICATION FOR THE AUTHORISATION OF THE DISPATCH OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS TO ANOTHER MEMBER STATE (ARTICLE 48 OF REGULATION (EC) No 1069/2009)								
Name and address of applicant	Approval or registration number (2)							
Name and address of place(s) of origin	Approval or registration number(s) (²)							
Name and address of consignor (1)	Approval or registration number (²)							
Name and address of place(s) of destination(s) (3)	Approval or registration number(s) (³)							
Animal by-products/derived products (4)	Intended use (4)							
☐ Category 1 material consisting of:	☐ Disposal as a waste							
(nature of the material) Category 2 material consisting of: (nature of the material) Meat-and-bone meal derived from Category 1 material Rendered fats derived from Category 1 material Meat-and-bone meal derived from Category 2 material Rendered fats derived from Category 2 material Rendered fats derived from Category 2 material Fish oil or fishmeal with excessive level(s) of dioxins and/or PCBs in accordance with Annex I to Directive 2002/32/EC destined for detoxification in an approved establishment	☐ Processing ☐ Combustion ☐ Incineration or co-incineration in ABP approved establishments or plants ☐ Application to land ☐ Transformation into biogas ☐ Composting ☐ Establishment for intermediate activities ☐ Petfood (⁵) ☐ Production of biodiesel or other biofuels ☐ For feeding to (⁶): ☐ For the manufacture of the following derived products (⁷) (²): ☐ Destined for detoxification in an approved establishment (²)							

Reference number:	PAGE 2/2						
APPLICATION FOR THE AUTHORISATION OF THE DISPATCH OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS TO ANOTHER MEMBER STATE (ARTICLE 48 OF REGULATION (EC) No 1069/2009)							
In case of meat-and-bone meal and rendered fats:	Species of origin (information should correspond to						
The materials have been processed according to the following method (9):	indication of species in DOCOM/CD (12)):						
The materials have been marked with GTH.							
In the case of fish oil intended for detoxification, processing metho	d:						
I, the undersigned, declare that the above information is factu	ally correct.						
(Signature: name, date, contact details: telephone, fax (if applicable	le), e-mail)						
Decision by the competent authority of the Member State of d	estination (10):						
The dispatch of the consignment is:							
☐ refused.							
☐ accepted.							
\square accepted subject to the application of pressure sterilisation (me	ethod 1) to the materials and GTH marking.						
☐ accepted subject to the following conditions for the dispatch (²)):						
This authorisation is valid until	(11)						
(Date, stamp and signature of the competent authority)							
Notes:							
Complete the document in BLOCK capitals. (¹) Fill in, if consignor is different from applicant.							
(2) Fill in, if appropriate.							
	blicant is responsible for providing the LVU with all the details of the various all required data. The number of multiple places of destination is subject to tination						
(4) Tick as appropriate.							
(°) In the case of petrood produced with Category 1 material, importe 1069/2009.	ed from third countries, referred to in Article 8(c) of Regulation (EC) No						
(6) Specify in accordance with Article 18 of Regulation (EC) No 1069/2009 (7) Specify intended uses, such as for the manufacture of fur, organic fertile							
(8) Specify. In case of dead equidae indicate the number of the transpon	der (microchip), if available, or the unique life number as defined in Article						
2(o) of Commission Regulation (EU) 2015/262 as indicated in the ident (*) Specify one of the processing methods referred to in Chapter III or Cha							
(10) For the competent authority: tick as appropriate.	. , ,						
(*) Insert date of expiration of authorisation. (12) DOCOM: commercial document in TRACES form/CD: commercial doc	ument.						

Section 11

Official controls regarding hydrolysis with subsequent disposal

The competent authority shall carry out controls at sites where hydrolysis with subsequent disposal is carried out in accordance with point B of Section 2 of Chapter V of Annex IX.

Such controls shall, for the purpose of reconciliation of the quantities of hydrolysed materials dispatched and disposed of, include documentary checks:

- (a) of the amount of materials which are hydrolysed at the site;
- (b) in the establishments or plants where the hydrolysed materials are disposed of.

Controls shall be carried out regularly on the basis of a risk assessment.

During the period of the first 12 months of operation, a control visit to a site, where a container for the hydrolysis is located, shall be carried out every time hydrolysed material is collected from the container.

Following the period of the first 12 months of operation, a control visit to such sites shall be carried out every time the container is emptied and checked for the absence of corrosion and leaking in accordance with point B(3)(j) of Section 2 of Chapter V of Annex IX.

▼ <u>M14</u>

Section 12

Official controls regarding plants approved for the combustion of animal by-products

The competent authority shall carry out documentary checks in accordance with the procedures referred to in Article 6(7) and (8) in approved plants referred to in Chapter V of Annex III.