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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:

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
► <u>M17</u>	Commission Implementing Regulation (EU) 2019/1177 of 10 July 2019	L 185	26	11.7.2019
► <u>M18</u>	Commission Delegated Regulation (EU) 2019/2122 of 10 October 2019	L 321	45	12.12.2019
► <u>M19</u>	Commission Delegated Regulation (EU) 2019/2124 of 10 October 2019	L 321	73	12.12.2019

#### Corrected by:

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

## 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)

## 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;

- (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>

- (i) 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.

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## 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.

## Article 6

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

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.

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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.

# ▼<u>M8</u>

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.

## ▼<u>M14</u>

## 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.

3. 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

2. 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;

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

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## Article 14

# Feeding of certain species in and outside feeding stations and in zoos

1. 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;

(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.

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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.

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#### 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.

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;

(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;
- (ix) 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.

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## 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.

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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;

(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.

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## 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 (<sup>1</sup>);
- (b) either entered in TRACES or accessible by means of TRACES as of 31 October 2021 at the latest.

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#### 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;

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<sup>(1)</sup> https://ec.europa.eu/food/sites/food/files/safety/docs/ fs-animal-products-app-est-technical spec 04032012 en.pdf

- (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.

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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.

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3. The competent authority of the Member State where an organic fertiliser or a soil improver, which has been produced from meat-andbone 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.

# ▼<u>M2</u>

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,

- 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.

## ▼B

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.

# ▼<u>M10</u>

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

## ▼<u>B</u>

#### 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:
  - (i) 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;

# ▼<u>M2</u>

- 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.

# ▼<u>M18</u>

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.

# ▼<u>B</u>

# 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.

▼<u>M19</u>

▼M5

#### Article 29a

#### Specific requirements for transit through Croatia of animal by-products 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:

# ▼<u>M5</u>

(a) the consignment is sealed with a serially numbered seal by the official veterinarian at the border inspection post of entry.

#### ▼<u>M19</u>

# ▼<u>B</u>

#### 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.

# ▼<u>M16</u>

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.

# 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.

# ▼<u>M16</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;
- (j) 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:

- 1. '**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;

# ▼<u>M11</u>

 '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 (<sup>1</sup>), and starfish of the species *Asterias rubens* which are harvested in a mollusc production area;

# ▼<u>B</u>

- 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

9. '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

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

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;

## ▼<u>B</u>

- 'apiculture by-products' means honey, beeswax, royal jelly, propolis or pollen not intended for human consumption;
- 11. '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;
- 13. 'greaves' means the protein-containing residue of rendering, after partial separation of fat and water;
- 14. '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;
- 16. 'canned petfood' means heat-processed petfood contained within a hermetically sealed container;
- 17. '**dogchews**' means products for pet animals to chew, produced from untanned hides and skins of ungulates or from other material of animal origin;
- 18. 'flavouring innards' means a liquid or dehydrated derived product of animal origin used to enhance the palatability values of petfood;

### ▼<u>M</u>4

- 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;
- 'raw petfood' means petfood containing certain Category 3 material which has not undergone any preserving process other than chilling or freezing;
- 22. 'catering waste' means all waste food, including used cooking oil originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens;



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

# ▼<u>M11</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  $^{\circ}\mathrm{C};$  or
- (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 °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;

- (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;

## ▼<u>B</u>

- 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;
- 34. '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:
    - (i) 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;

# ▼<u>B</u>

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;

# ▼<u>M2</u>

- 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>

- 'co-incineration' means the recovery or disposal of animal by-products or derived products, if they are waste, in a co-incineration plant;
- '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;
- '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;
- 49. 'processing methods' means the methods listed in Chapters III and IV of Annex IV;

- 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;
- 52. '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;
- '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

1. 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:

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(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:
    - 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**

- 1. 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.
- 3. 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.
- 6. 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

- 1. 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.
- 2. The approval issued by the competent authority, or conditions attached to it, shall lay down temperature measurement requirements.
- 3. The functioning of any automated monitoring equipment shall be subject to control and to an annual surveillance test.
- 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

- 1. Sites of high capacity plants, including associated storage areas for animal by-products, shall be designed in such a way as to prevent unauthorised and accidental release of any polluting substances into soil, surface water and groundwater.
- 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 ash.

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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.

- (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.
- 2. 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.
- 3. 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.
- 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.
- 5. 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.

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#### 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.
- 2. 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.

- 3. 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**

- 1. 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.
- 2. 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

- 1. 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.
- 2. 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.

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## 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/Nm<sup>3</sup> 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 <sup>3</sup>	
Sulphur dioxide	50	
Nitrogen oxides (as NO <sub>2</sub> )	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/m<sup>3</sup>, 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.

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#### ANNEX IV

## PROCESSING

## CHAPTER I

## REQUIREMENTS FOR PROCESSING PLANTS AND CERTAIN OTHER PLANTS AND ESTABLISHMENTS

#### Section 1

#### **General conditions**

- 1. 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 slaughterhouses or other establishments which have been approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004, unless the risks to public and animal health resulting from the processing of animal by-products, which originate from such slaughterhouses or other establishments, are mitigated by compliance with at least the following conditions:
    - (i) the processing plant must be physically separated from the slaughterhouse or other establishment, where appropriate by locating the processing plant in a building that is completely separated from the slaughterhouse or other establishment;
    - (ii) the following must be installed and operated 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;

- (b) The processing plant must have a clean and unclean sector, adequately separated. The unclean sector must have a covered place to receive animal by-products and must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid in such a way as to facilitate the draining of liquids;
- (c) The processing plant must have adequate facilities including lavatories, changing rooms and washbasins for staff;
- (d) The processing plant must have sufficient production capacity for hot water and steam for the processing of animal by-products;
- (e) The unclean sector must, if appropriate, contain equipment to reduce the size of animal by-products and equipment for loading the crushed animal by-products into the processing unit;
- (f) Where heat treatment is required, all installations must be equipped with:
  - (i) measuring equipment to monitor temperature against time and, if applicable for the processing method used, pressure at critical points;
  - (ii) recording devices to record continuously the results of these measurements in a way so that they remain accessible for the purpose of checks and official controls;
  - (iii) an adequate safety system to prevent insufficient heating;
- (g) To prevent recontamination of the derived product by the introduction of animal by-products, there must be a clear separation between the area of the plant where incoming material for processing is unloaded and the areas set aside for the processing of that product and the storage of the derived product.
- 2. The processing plant must have adequate facilities for cleaning and disinfecting the containers or receptacles in which animal by-products are received and the 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

1. 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:

- 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

- 1. The critical control points that determine the extent of the heat treatments applied in processing shall include for each processing method as specified in 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

 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

 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

- 1. 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.

- 3. 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**

# ▼<u>M1</u>

1. 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;

# ▼<u>M13</u>

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

# ▼<u>B</u>

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

#### 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  $(H_2SO_4)$  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:
  - 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 °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;

- (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>

# ▼<u>M1</u>

- 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 (<sup>1</sup>) 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 (<sup>2</sup>).

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.

<sup>&</sup>lt;sup>(1)</sup> BS EN 12880:2000, Characterization of sludges. Determination of dry residue and water content. European Committee for Standardisation,

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

- (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:
      - (i) 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.

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(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:
  - (i) 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  $^{\circ}$ C for at least 20 minutes.

# ▼<u>M9</u>

- 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.

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

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 (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;

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

# ▼<u>M13</u>

(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:
    - (i) 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 (<sup>1</sup>);
- (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:
  - (i) 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;

<sup>(1)</sup> OJ L 135, 30.5.1991, p. 40.

- (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.

## ▼<u>M9</u>

## ANNEX V

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

# CHAPTER I

# **REQUIREMENTS APPLICABLE TO PLANTS**

#### Section 1

#### **Biogas** plants

- 1. 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  $^{\circ}$ 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;

## ▼<u>M4</u>

(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**

- 1. 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.

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.
- 2. 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.
- 7. 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

- 1. 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

- 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;

(viii) eggs;

(ix) egg products;

#### ▼ M9

- (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.

## ▼B

- 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.

# ▼<u>B</u>

- 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:

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

or

Enterococcaceae: n = 5, c = 1,  $m = 1\ 000$ ,  $M = 5\ 000$  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:

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

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;

- 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 (<sup>1</sup>) 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.
- 5. Users that handle research and diagnostic samples shall keep a register of consignments of such samples.

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.

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**

## ▼<u>M4</u>

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.
- 2. 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.

- 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

- 1. 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:

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

Country	Member State	Animal species	
code		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

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Country code	Member State	Animal species	
		Local name	Latin name
ES	Spain	bearded vulture	Gypaetus barbatus
		black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
		golden eagle	Aquila chrysaetos
		Spanish imperial eagle	Aquila adalberti
		black kite	Milvus migrans
		red kite	Milvus milvus
FR	France	bearded vulture	Gypaetus barbatus
		black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
		golden eagle	Aquila chrysaetos
		white-tailed eagle	Haliaeetus albicilla
		black kite	Milvus migrans
		red kite	Milvus milvus
HR	Croatia	bearded vulture	Gypaetus barbatus
III	Cround	black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
IT	Italy	bearded vulture	Gypaetus barbatus
11	Italy	black vulture	
			Aegypius monachus
		Egyptian vulture	Neophron percnopterus Gyps fulvus
		griffon vulture	VI 0
		golden eagle	Aquila chrysaetos
		black kite	Milvus migrans
	~	red kite	Milvus milvus
CY	Cyprus	black vulture	Aegypius monachus
		griffon vulture	Gyps fulvus
РТ	Portugal	black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
		golden eagle	Aquila chrysaetos
SK	Slovakia	golden eagle	Aquila chrysaetos
		imperial eagle	Aquila heliaca
		white-tailed eagle	Haliaeetus albicilla
		black kite	Milvus migrans
		red kite	Milvus milvus

 <sup>(</sup>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:

- (i) 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:
  - (i) 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

- 1. If the competent authority authorises the disposal of animal by-products on site in accordance with Article 19(1)(a), (b), (c) and (e) of 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;

- (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.

#### 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.

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#### 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.
- 2. 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**

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- 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.

- 3. 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:
  - temperature,
  - pressure,
  - time, and
  - microbiological criteria.

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:
    - (i) 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.
- 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

- 1. 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.
- 3. Reusable containers must be dedicated to the carriage of a particular animal by-product or derived product to the extent necessary to avoid cross-contamination.

However, reusable containers may be used, 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.
- 4. Packaging material must be disposed of, by incineration or by other means in accordance with Union legislation.

#### Section 2

#### **Temperature conditions**

 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.

- 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.

# 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.
- 2. 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';

- (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';
- (x) 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);
- (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);

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

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

- 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;

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(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 (<sup>1</sup>), (EC) No 853/2004 (<sup>2</sup>) or (EC) No 183/2005 of the European Parliament and of the Council (<sup>3</sup>), and the nature and the method of the treatment, as applicable;

<sup>(&</sup>lt;sup>1</sup>) 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).

<sup>(2)</sup> 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).

<sup>(&</sup>lt;sup>3</sup>) 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).

- (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 (<sup>1</sup>);
- (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 (<sup>2</sup>) of exit.

▼<u>B</u>

- (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.

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

<sup>(2)</sup> 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).

## **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

EURO	EUROPEAN UNION Commercial document													
	l.1.	-							ocument referer	nce No	I.2.a Local reference	e No		
		Name Address						I.3. Central competent authority						
									I.4. Local competent authority					
		Approval or registration number												
		Postcode												
	1.5.	Consignee						I.6. Registered trader						
		Name							Name					
ät	Address							Registration number						
<u> </u>					Address									
nsig		Postcode												
20		Approval or registration number						Pc	ostcode					
cheo		Tel.							ember State					
ispat														
Part I: Details of dispatched consignment	I.8.	Country of origin	ISO code	1.9. F	Region of origin	Code	I.10.		ountry of estination	ISO code	I.11. Region of destination	Code		
<u> </u>														
Part	l.12	2 Place of origin						I.13. Place of destination						
		Establishment						Es	stablishment					
		Name Approval or registration number							ame	Appr	oval or registration nu	mber		
		Address						Address						
		Postcode							ostcode					
	l.14.	<ol> <li>Place of loading</li> <li>Means of transport</li> </ol>						I.15. Date of departure						
	I.16.							I.17. Transporter						
		Aeroplane 🛛 Ship 🗖 Railway wagon 🗍						Na	ame	Appr	roval or Registration nu	umber		
		Road vehicle   Other						Ac	ddress					
		Identification:						Pc	ostcode	Mem	ber State			
	I.18. Description of commodity								I.19. Commod	lity code	(CN code)			
										1	.20. Total Quantity			

I.21. Temperature of	produ	cts								1.22	. Number of packages
Ambient		Chilled		Frozen		C	ontrolled ter	mperatu	re 🛛		
I.23. Seal number if	a seal	imposed by	comp	petent aut	hority a	and the	Container	BIC ID r	umber	1.24	. Type of packaging
I.25. Commodities ce	ertified	for:									
Animal feedingstuff Technical use			pe	etfood use	)			Orga	inic fertilis	ers/sc	il improvers
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.						1.	27. Transit	through	Member	States	
		_					Membe	-			ISO code
							Membe	er State			ISO code
							Membe	er State			ISO code
I.28. Export						١.	29.				
Third country	19	SO code									
Exit point		ode									
1.30.											
I.31. Identification of the commodities Approval number of establishments											
Species Natur	e of co	mmodity	Cat	egory	Trea	tment	type	Manufa	cturing pla	ant	Batch number

	COUNTRY				Animal by-products/derived products not intended for human consumption							
	II.	н	ealth informati	on	II.a.	Certificate reference No	II.b.					
	II.1		Declaration b	y the consignor								
			I, the undersi	gned, declare that:								
	II.1.1	1.	the information	on 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 paragents and cross-contamination between various categories.											
uo	5 Notes											
larati	Part	I:										
Part II: Declaration	_				cal person ordering the transport indicated in the document required by the Convention ernational de Marchandises par Route (CMR).							
Part	—	Box	reference 1.5:	The legal or physical person for	which	the consignment is destined.						
	-	Box	reference I.6[c	optional, if appropriate]: Register	ed tra	der name, address, registration	number.					
	—	Box	reference I.9 a	and I.11: if appropriate.								
	—	Box	reference I.12	, I.13: approval number or regist	ration	number.						
		In ca	ise of:									
	-	_	plant register	ed in accordance with Article 23	(1)(a		plant, incineration or co-incineration roved in accordance with Article 24 nation;					
		_					lation (EU) 2015/786 indicate the 005 or Regulation (EU) 2015/786.					
	—	Box	reference I.14	complete if different from I.1. ar	nd I.1	2.						
	_		reference I.17 only box I.17.	: registration or approval number	er of t	the actual transporter. If this is the	he same information as in Box I.6,					
	—	Box	reference I.23	in case of transport in container	r, the	the complete container identification number ("BIC code") is obligatory.						
	_			: technical use: any use other the cannot be used in feed,petfood			c fertilisers or soil improvers OF/SI.					
	-	Box	reference I.31	:								
	Anin	nal sp	ecies:	the following: Aves, Ruminar	nts, S	Suidae, other Mammalia, Peso	r use as feed material. Select from ca, Mollusca, Crustacea, Insecta species, Mixed species containing					
	Nature of commodity:		commodity:	"bloodmeal", "digestion reside innards", "gelatine", "greaves improvers", "pet food", "proces "raw pet food", "rendered fats" products" "centrifuge or s "tricalciumphosphate", "collage "pig bristles", "feathers", "anima "cadavers", "manure", "fat deriv oil", "treated hides and skins"	ues", ", "h sed a , "co separ n", "e n", "e l by-p rative , "gro mixe	"digestive tract content", "dc ides and skins", "hydrolysed nimal protein", "animal by-produ mpost", "processed manure", "fi ator sludge from milk pri gg products", "serum of equida oroducts for processing", "derivec s", "glycerine", "former food stuff owing media", "dead pet anima	proteins", "organic fertilisers/soil licts for the production of pet food", sh oil", "milk products", "colostrum					

COUNTRY	Animal by-products/derived products not intended for human consumption								
II. Health informatio	n	II.a. Certificate reference No	II.b.						
Category:	Specify Categories 1, 2 or 3	materials.							
	In case of Category 3 material intended for use as feedstuff, indicate the point of Article 10 of 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 on 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 on 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-salted for at least 14 days prior to dispatch;								
	"(c)" for salted for seven days in sea salt with the addition of 2 % sodium 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.								
	For derived products from Category 3 material destined for use in feed, indicate the relevant standard processing method (choose a method from 1 to 7 referred to in Chapter III of Annex IV to Regulation (EU) No 142/2011 in case of processed animal protein (PAP)), an alternative method referred to Chapter IV of Annex IV in case of ensilage, or describe the nature and the methods of treatment set out in Chapter II of Annex X to Regulation (EU) No 142/2011.								
	Fish oil or fishmeal for detoxification shall be labelled as "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"								
Batch number:	Enter batch number or ear ta	g number, if applicable.							
Manufacturing plant:	in the case of PAP and other	feed materials indicate the processir	ng plant						
Part II:									
— The signature mu	ust be in a different colour to tha	at of the printing.							
Signature									
Done at		on							
	(place)	(d	ate)						
	(signature of the re	esponsible person of place of origin)							
	(na	me, in 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:
  - (i) 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

- 1. 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;

- (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
  - (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;

▼<u>M1</u>

(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.

## ▼<u>M4</u>

#### 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:

- (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 hereto;

▼<u>B</u>

(j) sieving.

## **General requirements**

- 1. 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

- 1. The sorting of animal by-products shall be carried out in such a way as to avoid any risk of the propagation of animal diseases.
- 2. 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.
- 3. 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.
- 3. 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.
- 2. Samples of the final products taken during storage or at the time of withdrawal from storage, shall at least comply with the microbiological standards set out in 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.
- 2. Operators shall keep records in a form which is accessible to the competent authority.
- 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.

▼<u>M9</u>

## CHAPTER V

## CONTAINMENT METHODS

## Section 1

#### **General provisions**

- 1. 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.

# ▼<u>M9</u>

#### 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.

# ▼<u>M9</u>

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.

# ▼<u>M</u>9

- (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.

## ▼<u>M9</u>

#### 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

## ▼<u>M12</u>

- 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.
  - 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 (*Alphi-tobius 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
  - (i) 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.
- 2. 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

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

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

- 2. Products in conveyors, elevators and bins must be protected from casual contamination.
- 3. 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.

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.

# ▼<u>B</u>

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; or
- (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;

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

<sup>(\*\*)</sup> UHT = Ultra High Temperature treatment at 132 °C for at least one second.

<sup>(\*\*\*)</sup> 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:
    - (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 6,0 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.
- 2. 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.
- 3. 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.

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- 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-andmouth disease;

<sup>(\*)</sup> 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  $^{\circ}$ C for 60 minutes or of at least 80  $^{\circ}$ 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.

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#### 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.
- 3. 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
  - 1. 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.
- 2. 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

1. 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.

- 2. The use of preservatives, other than those permitted under Union legislation shall be prohibited.
- C. Other requirements

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

- (a) a room or a dedicated place must be provided for storing materials for wrapping and packaging;
- (b) wrapping and packaging must take place in a room or in a place intended for that purpose.

## 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.

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#### 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.

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## CHAPTER III

## **REQUIREMENTS FOR CERTAIN FISH FEED AND FISHING BAITS**

- 1. 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.
- 2. 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

- 1. 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:
    - (i) from an area which is not subject to restrictions by virtue of a serious transmissible disease; and
    - (ii) intended for application, under the supervision of the competent authorities, to land forming part of a single holding located on both sides of the border of two Member States.
  - (b) However, the competent authority 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:

EUR	OPEA	N UNION	Commercial	document	
	l.1.	Consignor	I.2. Document reference No I.2.a. Local reference	e No	
Part I: Details of dispatched consignment		Name	I.3. Central competent authority		
		Address Postcode	I.4. Local competent authority		
	1.5.	Consignee	1.6.		
lignr		Name			
cons		Address	1.7.		
Itched		Postcode Tel.			
of dispa	1.8.	Country of origin ISO code I.9. Region of origin Code	I.10. Country of ISO I.11. Region of destination code destination	Code	
Details	1.12.	Place of origin	I.13. Place of destination	1	
÷.		Establishment	Establishment D Other		
Pai		Name Approval number Address	Name Approval number Address		
		Postcode	Postcode		
	1.14.	Place of loading	I.15. Date of departure		
	I.16.	Means of transport	I.17. Transporter		
	Aeroplane E Ship E Railway wagon E Road vehicle D Other E Identification		Name Approval nur Address	nber	
			Postcode Member Stat	te	
	1 18	Description of commodity	I.19. Commodity code (HS code)		
			1.20. Quantity		
			I.22. Number of packages		
	1.21.	Temperature of products Ambient Chilled	Frozen		
	1.23.	Seal/Container No	I.24. Type of packaging		
	1.25.	Commodities certified for: Technical use			
	1.26.	Transit through third country	I.27. Transit through Member States		
		Third country ISO code Exit point Code	Member State ISO code		
		Exit point     Code       Entry point     BIP unit No	Member State ISO code Member State ISO code		
	1.28.	Export	1.29.		
		Third country ISO code Exit point Code			
		Exit point Code			
	1.30.				
	1.31.	Identification of the commodities			
			Approval number of establishments		
		Species Nature of commodity Category (scientific name)	Treatment type Manufacturing plant Batch r	number	

col	JNTRY		Animal	by-products/derived products not	intended for human consumption		
	11.	Health inform	nation	II.a. Certificate reference No	ll.b.		
	ш.	Health attesta	tion				
		I, the undersigned official veterinarian, declare that I understand that the competent authority of the place of destination has given its to the introduction of the unprocessed manure on its territory and that the unprocessed manure referred to in box reference I.18 with the following conditions:					
c		(a) in case of	unprocessed poultry manure (1):				
icatio		[ <b>T</b> he	manure originates from an area which is not sul	oject to restrictions by virtue of New	castle disease or avian influenza.]		
Part II: Certification			e case of unprocessed manure from poultry flocks n which has obtained Newcastle disease non-vacci				
Part		(b) in case of	unprocessed manure of species other than poultry	/ or equidae ( <sup>1</sup> ):			
		[The	manure originates from an area which is not subje	ct to restrictions by virtue of a serious	transmissible disease.]		
		and					
		either	[The manure is intended for processing in a pla outside the feed chain or manure intended for tran No 1069/2009 with a view to the manufacture of	nsformation into biogas or composting	in accordance with Regulation (EC)		
	-	or	[The manure is intended for applying to land on a	a holding.]			
	Notes						
	Part I:						
	— Во>	reference I.9	and I.11: if appropriate.				
	— Во>	reference I.12	, I.13 and I.17: approval number or registration nu	mber.			
	— Во>	reference I.14	complete if different from 'I.1. Consignor'.				
	— Вох	reference I.25	: technical use: any use other than for animal con-	sumption.			
	— Во>	reference I.31	:				
	Nat	ure of commod	lity: 'manure'.				
	Part II	:					
	( <sup>1</sup> ) Del	ete as appropr	iate.				
	Official	veterinarian/Of	fficial inspector				
	Nar	me (in capital l	etters):	Qualification and title:			
	Dat	te:		Signature:			
	Sta	mp:					

- 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.
- 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:

## ▼B

- (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:

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

or

*Enterococcaceae*: n = 5, c = 5, m = 0,  $M = 1\ 000$  in 1 g;

and

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

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

where:

- n = number of samples to be tested;
- m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria 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

## ▼<u>B</u>

- (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.
- 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.

## ▼<u>M9</u>

#### 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:

- 1. 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:
    - 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:
    - (i) 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:
    - 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.

## ▼<u>M9</u>

- 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;

## ▼B

- (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:
    - (i) be subjected to a heat treatment of at least 90 °C throughout the substance of the final product;

- (ii) be subjected to a heat treatment to at least 90 °C of the ingredients of animal origin; or
- (iii) be produced as regards feed 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,  $M = 5\ 000$  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.
- 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.

- 2. 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:

- 1. 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
  - 1. 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
  - 1. 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;

## ▼<u>M4</u>

- (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:
  - (i) 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.

## ▼<u>B</u>

- 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,
    - (i) 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
  - 1. 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.

## ▼<u>M2</u>

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:

## ▼<u>B</u>

- (a) been boiled, dyed or bleached; or
- (b) undergone some other form of treatment which is certain to kill pathogenic agents, provided that evidence to this effect is submitted in the form of a certificate from the veterinarian responsible for the place of origin. Factory washing may not be regarded as a form of treatment for the purposes of this provision.
- 3. The provisions of 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.

## ▼<u>M2</u>

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.

## ▼<u>B</u>

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:

- 1. not come from an area which is subject of a prohibition order associated with an occurrence of:
  - (a) American foulbrood (*Paenibacillus larvae larvae*), except where the competent authority has assessed the risk to be negligible, issued a specific authorisation for use only in that Member State, and taken all other necessary measures to ensure no spread of that disease;
  - (b) acariosis (*Acarapis woodi* (Rennie)), except where the area of destination has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC;
  - (c) small hive beetle (Aethina tumida); or

(d) Tropilaelaps 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  $^{\circ}\mathrm{C}$  2 bars (2 000 hPa) for eight minutes; or
  - (c) hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes.
- 2. 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.

## ▼<u>B</u>

### 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:
  - (i) 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.

## ▼<u>M1</u>

## 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  $^{\circ}$ C or more and which has subsequently been purified by distillation at a temperature of 200  $^{\circ}$ 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:
  - 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.

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).	<ul> <li>(a) The processed animal protein must have been produced in accordance with Section 1 of Chapter II of Annex X; and</li> <li>(b) the processed animal protein shall comply with the additional requirements set out in Section 2 of this Chapter.</li> </ul>	<ul> <li>(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.</li> <li>(b) In the case of fishmeal: Third countries listed in Annex II to Decision 2006/766/EC.</li> </ul>	<ul> <li>(a) In the case of processed animal protein other than those derived from farmed insects:</li> <li>Annex XV, Chapter 1.</li> <li>(b) In the case of processed animal protein derived from farmed insects:</li> <li>Annex XV, Chapter 1a.</li> </ul>
▼ <u>B</u>	2	Blood products for feed material	Category 3 materials referred to in Article 10 (a) and (b)(i).	▶ <u>M9</u> 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. ◀	<ul> <li>(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.</li> <li>(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.</li> </ul>	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	<ul> <li>(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).</li> <li>(b) In the case of fish oil: Category 3 materials referred to in Article 10(e), (f), (i) and (j).</li> </ul>	<ul> <li>(a) The rendered fat and the fish oil must have been produced in accordance with Section 3 of Chapter II of Annex X; and</li> <li>(b) The rendered fat shall comply with the additional requirements set out in Section 3 of this Chapter.</li> </ul>	fish oil: Third countries listed in Part 1 of Annex II to Regulation (EU)	<ul> <li>(a) In the case of rendered fats excluding fish oil: Annex XV, Chapter 10 (A).</li> <li>(b) In the case of fish oil: Annex XV, Chapter 9.</li> </ul>
4	Milk, milk-based products and milk-derived products, colostrum, colostrum products	<ul> <li>(a) Milk, milk-based products: Category 3 materials referred to in Article 10(e), (f) and (h).</li> <li>(b) Colostrum, colostrum products</li> <li>Category 3 materials from live animals that did not show any signs of disease transmissible through the colostrums to humans or animals.</li> </ul>	The milk, milk-based products, colostrum and colostrum products shall comply with the requirements set out in Section 4 of this Chapter.	<ul> <li>(a) In the case of milk and milk-based products:</li> <li>Authorised third countries listed in Annex I to Regulation (EU) No 605/2010.</li> <li>(b) In the case of colostrum and colostrum products:</li> <li>Third countries listed as authorised in column 'A' of Annex I to Regulation (EU) No 605/2010.</li> </ul>	<ul> <li>(a) In the case of milk, milk-based products and milk-derived products: Annex XV, Chapter 2(A).</li> <li>(b) In the case of colostrum and colostrums products: Annex XV, Chapter 2(B).</li> </ul>

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

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	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and third	Annex XV, Chapter 15.
			of Annex X.	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.	

#### Section 2

## ▼<u>M1</u>

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

## ▼<u>B</u>

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

1. Before consignments are released for free circulation within the Union, the competent authority must sample processed animal protein from imported consignments at the border inspection post to ensure compliance with the 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.

- 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.

# ▼<u>M12</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*),

- Yellow Mealworm (*Tenebrio molitor*) and Lesser Mealworm (*Alphi-tobius 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.

## ▼<u>B</u>

#### 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.

## ▼<u>M12</u>

### 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.

## ▼<u>M9</u>

#### 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.

## ▼<u>B</u>

#### 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;

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- (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
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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
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.	<ul> <li>Third countries listed in:</li> <li>(a) Part 1 of Annex II to Regulation (EU) No 206/2010;</li> <li>(b) Annex I to Decision 2004/211/EC; or</li> <li>(c) Part 1 of Annex I to Regulation (EC) No 798/2008.</li> </ul>	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.	<ul> <li>The following third countries:</li> <li>(a) in the case of untreated blood products of ungulates:</li> <li>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.</li> <li>(b) in the case of untreated blood products of poultry and other avian species:</li> <li>Third countries or parts of third countries listed in Part 1 of Annex I to Regulation (EC) No 798/2008. Japan.</li> <li>(c) in the case of untreated blood products of other animals:</li> </ul>	<ul> <li>(a) In the case of untreated blood products: Annex XV, Chapter 4 (C).</li> <li>(b) In the case of treated blood products: Annex XV, Chapter 4 (D).</li> </ul>

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
				<ul> <li>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.</li> <li>Japan.</li> <li>(d) in the case of treated blood products of any species:</li> <li>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.</li> <li>Japan.</li> </ul>	
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.	<ul> <li>The following third countries:</li> <li>(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:</li> <li>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.</li> <li>(b) in the case of blood products which have been treated in accordance with point 2(b)(ii) of Chapter IV of Annex XIII:</li> </ul>	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.	<ul> <li>(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.</li> <li>(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.</li> </ul>	<ul> <li>(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).</li> <li>(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).</li> </ul>

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
					<ul> <li>(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.</li> </ul>
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).	The game trophies and other preparations shall comply with the requirements set out in Section 5.	<ul> <li>(a) In the case of game trophies and other preparations referred to in Section 5, point 2: Any third country.</li> <li>(b) In the case of game trophies and other preparations referred to in Section 5, point 3: <ul> <li>(i) Game trophies from birds:</li> <li>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:</li> <li>(GL) Greenland</li> <li>(TN) Tunisia.</li> </ul> </li> <li>(ii) Game trophies from ungulates: <ul> <li>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.</li> </ul> </li> </ul>	<ul> <li>trophies referred to in Section 5, point 2: Annex XV, Chapter 6(A).</li> <li>(b) In the case of game trophies referred to in Section 5, point 3: Annex XV, Chapter 6(B).</li> </ul>

02011R0142 — EN — 14.12.2019 — 016.001 — 148

	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.	<ul> <li>(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.</li> <li>(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.</li> </ul>	<ul> <li>(a) If no case of African swine fever has occurred during the 12 previous months: Annex XV, Chapter 7(A).</li> <li>(b) In case one or more cases of African swine fever have occurred during the previous 12 months: Annex XV, Chapter 7(B).</li> </ul>
▼ <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).	<ul> <li>(1) The dry untreated wool and hair must be</li> <li>(a) securely enclosed in packaging; and</li> <li>(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.</li> </ul>	(1) Any third country.	(1) For imports of untreated wool and hair, no health certificate is required.

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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
				(2) The wool and hair are wool and hair as referred to in Article 25(2)(e).	<ul> <li>(2) Third country or region thereof</li> <li>(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</li> <li>(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.</li> </ul>	(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.

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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
10	Apiculture by-products	Category 3 materials referred to in Article 10 (e).	<ul> <li>(a) In the case of apiculture by-products intended for use in apiculture, other than beeswax in the form of honeycomb:</li> <li>(i) The apiculture by-products have been subjected to a temperature of - 12°C or lower temperature for at least 24 hours; or</li> <li>(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.</li> <li>(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 processing method 1 to 5 or processing methods 1 to 5 or processing methods 1 to 5 or purposes other than feeding to farmed animals, the beeswax has been refined or processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV before importation.</li> </ul>	<ul> <li>(a) In the case of apiculture by-products intended for use in apiculture:</li> <li>Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following country:</li> <li>(CM) Cameroon.</li> <li>(b) In the case of beeswax for purposes other than feeding to farmed animals: Any third country.</li> </ul>	<ul> <li>(a) In the case of apiculture by-products intended for use in apiculture: Annex XV, Chapter 13.</li> <li>(b) In the case of beeswax for purposes other than feeding to farmed animals: A commercial document attesting the refinement or processing.</li> </ul>

<u>B</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.	<ul> <li>The products shall be accompanied by:</li> <li>(a) a commercial document as et out in Section 7, point 2; and</li> <li>(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.</li> </ul>
' <u>M10</u>	12	Petfood, including dogchews	<ul> <li>(a) In the case of processed petfood and of dogchews: materials referred to in Article 35(a)(i) and (ii).</li> <li>(b) In the case of raw petfood: materials referred to in Article 35(a)(iii).</li> </ul>	been produced in accordance with Chapter	<ul> <li>(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.</li> <li>(b) In the case of dogchews and petfood other than raw petfood:</li> </ul>	<ul> <li>(a) In the case of canned petfood: Annex XV, Chapter 3(A).</li> <li>(b) In the case of processed petfood other than canned petfood: Annex XV, Chapter 3(B).</li> <li>(c) In the case of dogchews: Annex XV, Chapter 3(C).</li> <li>(d) In the case of raw petfood: Annex XV, Chapter 3(D).</li> </ul>

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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
-					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>M17</u>						
	13	Flavouring innards for the manufacture of petfood		The flavouring innards must have been produced in accordance with Chapter III of Annex XIII.		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 of poultry origin, 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.	
					In the case of flavouring innards from certain wild land mammals and leporidae, third countries listed in Part 1 of Annex I to Regulation (EC) No 119/2009 from which Member States authorise imports of fresh meat from the same species.	

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	<ul> <li>M4 (a) Category 3 materials referred to in Article 10(a) to (m). ◄</li> <li>(b) In the case of materials for the manufacture of petfood, Category 1 materials referred to in Article 8(c).</li> <li>(c) In the case of fur for the manufacture of derived products, Category 3 materials referred to in Article 10(n).</li> </ul>	The products shall comply with the requirements set out in Section 8.	<ul> <li>(a) In the case of animal by-products for the manufacture of petfood:</li> <li>(i) In the case of animal by-products from bovine, ovine, caprine, porcine and equine animals, including farmed and wild animals: <ul> <li>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.</li> <li>(ii) Raw material from poultry including ratites:</li> <li>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.</li> <li>(iii) Raw material from fish:</li> <li>Third countries listed in Annex II to Decision 2006/766/EC.</li> <li>(iv) Raw material from other wild land mammals and leporidae:</li> <li>Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EC) No 798/2008.</li> </ul> </li> </ul>	<ul> <li>(a) In the case of animal by-products for the manufacture of processed petfood: Annex XV, Chapter 3(F).</li> <li>(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.</li> </ul>

No	Product Raw materials (reference to provisions of Regulation (EC) No 1069/2009)		Import and transit conditions	Third countries' lists	Certificates/model documents
		<ul> <li>(b) In the case of animal by-products for the manufacture of pharmaceuticals:</li> <li>Third countries listed in Part 1 or 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:</li> </ul>			
				(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.	

No	Product	Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
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		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).

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Ν	Product	Product Raw materials (reference to provisions of Regulation (EC) No 1069/2009)	Import and transit conditions	Third countries' lists	Certificates/model documents
17					
17	Rendered fats for certain purposes outside the feed chain for farmed animals		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 X

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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
	<ul> <li>(d) In the case of materials destined to other purposes:</li> <li>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 (f)(i) and Category 3 materials referred to in Article 10, other than in points (c) and (p).</li> </ul>					
▼ <u>M4</u>						
	18	Fat derivatives	<ul> <li>(a) In the case of 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.</li> <li>(b) In the case of fat derivatives for use as feed: Category 3 materials referred to in Article 10.</li> <li>(b) In the case of fat derivatives for use as feed: Category 3 materials other than materials referred to in Article 10(n), (o) and (p);</li> </ul>	The fat derivatives shall comply with the requirements set out in Section 10.	Any third country.	<ul> <li>(a) In the case of fa derivatives for uses outsid the feed chain for farme animals: Annex XV, Chapter 14(A)</li> <li>(b) In the case of fa derivatives for use as feed Annex XV, Chapter 14(B)</li> </ul>

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.	1 1 8 15	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		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:

1. 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.

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- 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.

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- 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:

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- 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.

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2. 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;

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

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- 3. 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:
    - (i) 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.

- 3. Game trophies or other preparations from birds and ungulates consisting of entire anatomical parts, not having been treated in any way may be imported if:
  - (a) they come from animals originating in an area not subject to restrictions as a result of the presence of serious transmissible diseases to which animals of the species concerned are susceptible;
  - (b) they were packaged without being in contact with other products of animal origin likely to contaminate them, in individual, transparent and closed packages so as to avoid any subsequent contamination.

### 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;

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(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;

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(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.

- 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;
- 3. 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:

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 (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;

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(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;

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- (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

- 1. 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:
    - (i) 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.
- 3. 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

- 1. 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 Shizuoka 418-0073 Japan	The Netherlands	Rotterdam	FujifilmEurope, Oudenstaart 1, 5047 TK Tilburg, The Netherlands
	Nitta Gelatin Inc., 2-22 Futamata Yao-City, Osaka 581-0024 Japan	United Kingdom	Liverpool Felixstowe Heathrow	Kodak Ltd. Headstone Drive, Harrow, 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, MA, 01960 USA	United Kingdom	Liverpool Felixstowe Heathrow	Kodak Ltd. Headstone Drive, Harrow, Middlesex, HA4 4TY, United Kingdom
	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.
- 3. 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**

- 1. 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.
- 3. 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

- 1. 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.

- 3. 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:

- 1. 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'.
- 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

- 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	Processed manure and organic fertilizers, compost or digestion residues from biogas trans- formation containing no other animal by-products or derived products than processed manure	Processed manure and organic fertilizers, compost or digestion residues from biogas trans- formation 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 (f) When the certificate, including produced by the exporting third additional schedules referred to in e), country, based on the models set out comprises more than one page, each in this Annex, according to the layout page shall be numbered - (page of the model that corresponds to the number) of (total number of pages) animal by-products or derived at the bottom of the page and shall products concerned. Thev shall bear the code number of the certificate contain, in the numbered order that that has been designated by the appears in the model, the attestations competent authority at the top of the that are required for any third country page. and, as the case may be, those supplementary guarantees that are required (g) The original of the certificate must be for the exporting third country or part completed and signed by an official thereof. veterinarian. In doing so, the competent authorities of the exporting (b) Where the model certificate states that country shall ensure that the principles certain statements shall be kept as of certification equivalent to those laid appropriate, statements which are not down in Directive 96/93/EC are relevant may be crossed out and followed. initialled and stamped by the certifying

officer, or completely deleted from the

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 indi-

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 desti-

nation. However, these Member States

may allow other languages, accompanied, if necessary, by an official

(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.

(d) It shall be drawn up in at least one of

(c) The original of each certificate shall

certificate.

visible.

translation.

- (h) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark.
- (i) The original of the certificate must accompany the consignment at the EU border inspection post.
- (j) If health certificates are used for consignments in transit, box No I.5 ('Consignee') of the relevant health certificate shall be completed with the name and address of the border inspection post through which the consignment is intended to leave the European Union.

## CHAPTER 1

### Health certificate

For processed animal protein, 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

### COUNTRY:

### Veterinary certificate to EU

	l.1.	Consignor					1.2.	Certificate refere	nce No	1.2	2.a.	
		Name Address					1.3.	I.3. Central competent authority				
		Tel.						I.4. Local competent authority				
gnment	I.5.	Consignee Name Address					1.6.	Person responsi Name Address	ble for the loa	ad in E	U	
onsi		Postcode						Postcode				
o pei		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	l.10.	Region of destination	Code
t I : Detail	I.11.	Place of origi	n				I.12.	I.12. Place of destination				
Part		Name	A	oprova	l number				Custo	om war	ehouse	
		Address						Name	Appro	oval nu	mber	
		Name	A	oprova	l number			Address				
		Address										
		Name	Aj	oprova	ll number			Postcode				
		Address										
	I.13.	Place of load	ing				I.14.	Date of departure	e			
	l.15.	Means of tra	nsport				I.16.	Entry BIP in EU				
		Aeroplane 🗖	-		Railway wa	gon 🗖						
		Road vehicle Identification	Other				l.17.					
		Documentati	on references	3								

## ▼<u>M15</u>

▼<u>M15</u>

l.18.	Description of commodity				I.19. Commo	odity c	ode (HS code)
						1.20.	Quantity
I.21.	Temperature of product Ambient			Frozen	]	1.22.	Number of packages
I.23.	Seal/Container No					1.24.	Type of packaging
1.25.	Commodities certified for:						
	Animal feedingstuff 🗖	Technic	al use 🗖	Manufacture of	petfood 🗖		
I.26.	For transit through EU to thir	d country		I.27. For import	or admission in	to EU	
	Third country	ISO code					
I.28.	Identification of the commod		oval number	of establishments			
Sp	ecies (Scientific Nature name)	of commodity	Manufacti	uring plant	Net weight		Batch number

▼<u>M15</u>

	COUNT	RY					farmed insects,	not inten	other than those derived from ded for human consumption products other than petfood containing such protein		
	П.	Health	informatio	n		II.a.	Certificate reference No		II.b.		
	-	the Eu	ropean Parli lo 142/2011	ament	and of the (	Counc	are that I have read and under il ( <sup>1a</sup> ) and in particular Article tion 1 of Chapter II of Annex X,	10 thereof	, and Commission Regulation		
ation	II.1.				rotein or pro umption that:	oduct	described above contains ex	clusively p	processed animal protein not		
Part II: Certification		(a) has been prepared and stored in an establishment or plant approved and supervised by the authority in accordance with Article 24 of Regulation (EC) No 1069/2009, and									
art II:		(b)	has been pre	eparec	exclusively	with th	e following animal by-products:				
<b>–</b>	( <sup>2</sup> ) either [- carcases and parts of animals slaughtered or, in the case of game, bodies animals killed, and which are fit for human consumption in accordance legislation, but are not intended for human consumption for commercial reason								on in accordance with Union		
	( <sup>2</sup> ) and/or [- carcases and the following parts originating slaughtered in a slaughterhouse and were consumption following an ante-mortem inspec animals from game killed for human consumption							onsidered on or bodi	fit for slaughter for human ies and the following parts of		
					consu	mptior	r bodies and parts of animals n in accordance with Union le ease communicable to humans	egislation,	but which did not show any		
					(ii) heads	of po	ultry;				
						halang	kins, including trimmings and s ges and the carpus and meta				
					(iv) pig bri	istles;					
					(v) feathe	ers;]					
			(²) and/or	[-	to humans slaughterho	or a use at	which did not show any signs inimals, obtained from anima fter having been considered f mortem inspection in accordan	als that h it for slauç	ave been slaughtered in a ghter for human consumption		
			(²) and/or	[-		n, incl	cts arising from the product luding degreased bone, greav ing;]				
			(²) and/or	[-	longer inten	ded fo ng or	I origin, or foodstuffs containing or human consumption for con packaging defects or other c e;]	nmercial re	easons or due to problems of		
			(²) and/or	[-		t did r	vool, feathers, hair, horns, hoo not show signs of any disease s;]				
			(²) and/or	[-			and parts of such animals, exo ses communicable to humans of				
			(²) and/or	[-			ts from aquatic animals orig oducts for human consumption;]		om establishments or plants		

## ▼<u>M15</u>

### 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 П. Health information II.a. Certificate reference No ll b (<sup>2</sup>) and/or [the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals: shells from shellfish with soft tissue or flesh: (i) the following originating from terrestrial animals: (ii) hatchery by-products, eggs. egg by-products, including egg shells; (iii) day-old chicks killed for commercial reasons;] (<sup>2</sup>) and/or [aquatic and terrestrial invertebrates other than species pathogenic to humans or animals and other than insects:1 animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except (2) and/or [animals and parts thereof of the 200 given orders of November and Lagonno pha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;] and (C) has been subjected to the following processing standard: (2) either [heating to a core temperature of more than 133°C for at least 20 minutes without interruption at a pressure (absolute) of at least 3 bars produced by saturated steam, with a particle size prior to processing of not more than 50 millimetres;] (<sup>2</sup>) or [in the case of non-mammalian protein other than fishmeal, the processing method 1-2-3-4-5-7 (indicate the processing method) as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011;] (2) or [in the case of fishmeal the processing method 1-2-3-4-5-6-7 . (indicate the processing method) as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011;] (2) or [in the case of porcine blood, the processing method 1-2-3-4-5-7 ...... (indicate the processing method) as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011, where in case of method 7 a heat treatment of at least 80 °C has been applied throughout its substance;] 112 the competent authority examined a random sample immediately prior to dispatch and found it to comply with the following standards (3): Salmonella: Absence in 25 g: n = 5, c = 0, m = 0, M = 0 Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1g; II.3. the product has undergone all precautions to avoid recontamination with pathogenic agents after treatment; 11.4. the end product: (<sup>2</sup>) either [was packed in new or sterilised bags,]

							ded for human consumption products other than petfood containing such protein				
II.	Health in	formatio	n		II.a. Certificate re	eference No	II.b.				
	(²) or		ransported ir cted before u		n containers or other means of transport that were thoroughly cleaned and						
	which bea	ar labels i	ndicating 'NO	DT FOF	R HUMAN CONSUM	IPTION';					
II.5.	the end p	roduct wa	as stored in e	enclose	d storage;						
(²) [II.6.	the proce ruminant			or pro	oduct described ab	ove contains or is derived	d from animal-by products o				
	(²)	either		e with			osing a negligible BSE risk in nas been no indigenous BSE				
	(2)	( <sup>2</sup> ) or [originates from a country or region classified as posing a negligible BSE risk in acc with Decision 2007/453/EC in which there has been an indigenous BSE case, and the by-product or derived product were derived from animals born after the date from w ban on the feeding of ruminants with meat-and-bone meal and greaves deriv ruminants, as defined in the OIE Terrestrial Animal Health Code, has been effectively in that country or region, and]									
	(2)	either	[is derived	l from c	other ruminants than	minants than bovine, ovine or caprine animals.]					
	(2)	or	[is derived	l from b	oovine, ovine or capr	ine animals and does not c	ontain and is not derived from				
			(²) either	contir	nuously reared and		se derived from animals born r region classified as posing a /453/EC.]]				
			(²) or	[ (a)		erial as defined in point 1 d e European Parliament and	of Annex V to Regulation (EC I of the Council ( <sup>4</sup> );				
				(b)	caprine animals, reared and slaug negligible BSE	except from those animals ghtered in a country or r	n bones of bovine, ovine o that were born, continuously egion classified as posing a with Commission Decision indigenous BSE case,				
				(c)	caprine animals w central nervous ti introduced into th cranial cavity, exc and slaughtered in	rhich have been killed, after ssue by means of an elor ne cranial cavity, or by me ept for those animals that v	ained from bovine, ovine o r stunning, by laceration of the ngated rod-shaped instrumen eans of gas injected into the were born, continuously reared ied as posing a negligible BSE C.]]]				
II.7.	the proce	ssed anir	nal protein o	r produ	ct described above:						
	(²) either				milk products of ovi n fur animals.]	ne or caprine animal origin	or is not intended for feed fo				
	(²) or				ducts of ovine or c mals, and the milk o		s intended for feed for farmed				
					ine and caprine ani Ilowing conditions ar		t continuously since birth in a				
		(i	)	lassica	I scrapie is compuls	orily potificallo:					

### COUNTRY

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

	Health 1.1				containing su	ch protein
II.	Health inform			cate reference No	II.b.	
		(ii)	an awareness, surveill	ance and monitoring sys	stem is in place for classical s	scrapie;
		(iii)		ply to holdings of ovine e confirmation of classic	e or caprine animals in the al scrapie;	case of a
		(iv)	ovine and caprine anir	nals affected with classi	cal scrapie are killed and des	stroyed;
		(v)	defined in the Terrest Health (OIE), of rumi	rial Animal Health Code	f meat-and-bone meal or g e of the World Organisation panned and effectively enfor eding seven years;	for Animal
	(t	o) originate fr	om holdings where no of	ficial restrictions are imp	posed due to a suspicion of T	SE;
	(0				has been diagnosed during ation of a case of classical so	
		(²) either	slaughtered, except fe	or breeding rams of the ARR allele and no VRQ	ng have been killed and de e ARR/ARR genotype, bree allele and other ovine anima	ding ewes
		(²) or	and the holding has b of confirmation of the including testing with r laboratory methods se No 999/2001, of all o	een subjected for a per e last classical scrapic negative results for the p et out in point 3.2 of Ch	firmed have been killed and iod of at least two years sind a case to intensified TSE in presence of TSE in accordan apter C of Annex X to Regu which are over the age of 2 pe:	ce the date monitoring, ce with the lation (EC)
			— animals which hav	ve been slaughtered for	human consumption; and	
				ve died or been killed on a disease eradication ca	the holding but which were r mpaign.]]	not killed in
II.8.			n or product described ding to the statement of		erived from animal-by producto in Box I.1,	cts of non-
	(²) either [r	not intended for	the production of feed for	or farmed animals, other	than fur animals.]	
	C	onsignor has u esults of the ar	ndertaken to ensure that	at the Border Inspection	nimals, other than fur anima I Post of entry will be provide ods set out in Annex VI to C	ed with the
Notes						
Part I:						
it	is a certificate for	a commodity			this box is required to be fille may be filled in if the certific	
			ation: this box is to be fi ones, free warehouses a		ficate for transit commodity. I S.	Products in
	ox reference 1.15: formation is to be			or container and lorries)	, flight number (aircraft) or na	ame (ship);

соι	JNTRY	farmea	insects, not inten	, other than those derived from ded for human consumption products other than petfood containing such protein						
П.	Health information	II.a. Certificate reference	No	II.b.						
_	Box reference I.19: use the appropriate HS c	ode: 05.05; 05.06; 05.07; 05	.11; 23.01 or 23.09	Э.						
_	Box reference I.25: technical use: any use production or manufacturing of pet food.	e other than feeding of fai	med animals, oth	er than fur animals, and the						
—	Box reference I.26 and I.27: fill in according t	o whether it is a transit or ar	import certificate.							
_	Box reference I.28: Species: select from the Suidae, Pesca, Mollusca, Crustacea, inverter the scientific name of the fish.									
Part	11:									
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.									
( <sup>1b</sup> )	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		en 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 described in this health certificate is intended than fur animals, the consignment must be a (EC) No 152/2009, in order to verify the ab result of such analysis must be attached to inspection post.	I to be used for the production analysed, in accordance wit sence of unauthorised cons	on of feed for non-r h the methods set tituents of animal	uminant farmed animals, other out in Annex VI to Regulation origin. The information on the						
(7)	OJ L 54, 26.2.2009, p. 1.									
_	The signature and the stamp must be in a dif	ferent colour to that of the p	rinting.							
_	Note for the person responsible for the consi and must accompany the consignment until i			is only for veterinary purposes						
Offic	ial 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  $(^2)$  the European Union

#### COUNTRY:

#### Veterinary certificate to EU

	l.1.	Consignor					1.2.	Certificate refere	ence No	1.2	2.a.	
		Name					1.3.	Central compete	ent authority			
		Address					1.4.	Local competent	authority			
		Tel.										
	1.5.	Consignee					1.6.	Person responsi	ble for the loa	ıd in El	J	
lent		Name					Name					
gnm		Address						Address				
onsi												
о С		Postcode						Postcode				
tche		Tel.						Tel.				
ispa	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 di		orongin	1		ongin	1		destination			destination	
Part I : Details of dispatched consignment	111	Place of or	iain				112	Place of destinat	tion			
Det			1911									
Ë		Name		Appro	val number				Custo	om war	ehouse	
Ъа		Address						Name	Appro	oval nu	mber	
		Name		Appro	val number			Address				
		Address										
		Name		Appro	val number			Postcode				
		Address										
	I.13.	Place of loa	ading				I.14.	Date of departur	e			
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU				
				_		_						
		Aeroplane			Railway wa	agon 🗀	147					
		Road vehic		er 🗀			1.17.		_			
		Identificatio	ation reference									
	119		n of commodi						110 Comm	odity	code (HS code)	<u> </u>
	1.10.	Description		ity					1.19. Comm			)
										120	Quantity	
	1.04	Tomporation									-	ockogoo
	1.21.	Ambient	re of product 1	L	Chilled <b>D</b>	7		Frozen 🕻	7	1.22.	Number of p	ackayes
	1.00					4		Frozen L	_	1.24		
	1.23.	Seal/Conta								1.24.	Type of pack	aging

1.25.	Commodities certi	fied for:				
	Animal feedingstut	ff 🗆	Technical use 🗖		Manufacture of pe	etfood 🗖
I.26.	For transit through	EU to third country		I.27. For im	port or admission into EU	
	Third country	ISO cod	e			
1.28.	Identification of the	e commodities	Approval number	of establishme	ents	
Sr	oecies (Scientific name)	Nature of commo	dity Manufactu	uring plant	Net weight	Batch number

	COUNTR	T				not intended for human of	ein derived from farmed insect consumption including mixture petfood containing such protei						
	н.	Healt	h informatio	n		II.a. Certificate reference No	II.b.						
		the E	uropean Parl No 142/2011	iamer	it and of the Counc	are that I have read and understood il ( <sup>1a</sup> ) and in particular Article 10 the tion 1 of Chapter II of Annex X, and C	reof, and Commission Regulation						
ation	II.1.					m farmed insects or product desc iman consumption that:	ribed above contains exclusivel						
Part II: Certification		(a)				n establishment or plant approved a 4 of Regulation (EC) No 1069/2009, a							
art II:		(b)	has been pr	epare	d exclusively from fa	armed insects of the following species							
			(²) either	[-	Black Soldier Fly (	(Hermetia illucens);]							
			( <sup>2</sup> ) and/or	[-	Common Housefly	y (Musca domestica);]							
			(²) and/or	[-	Yellow Mealworm	(Tenebrio molitor);]							
			(²) and/or	[-	Lesser Mealworm	(Alphitobius diaperinus);]							
			(²) and/or	[-	House cricket (Ac	heta domesticus);]							
			(²) and/or	[-	Banded cricket (G	ryllodes sigillatus);]							
			(²) and/or	[-	Field Cricket (Gryl	llus assimilis).]							
		and	1										
		(c)	has been pi (EU) No 142			2]-[3]-[4]-[5]-[7] (²) as set out in Cha	pter III of Annex IV to Regulatio						
		and											
		(d)				med insects may only contain proc Category 3 material:	lucts of non-animal origin or the						
			— fishme	al;									
			— blood p	oroduo	cts from non-rumina	nts;							
			— di and	tricalc	ium phosphate of ar	nimal origin;							
			— hydroly	/sed p	roteins from non-ru	minants;							
			— hydroly	/sed p	roteins from hides a	and skins of ruminants;							
			— gelatin	e and	collagen from non-r	ruminants;							
			— eggs a	nd eg	g products;								
			— milk, m	nilk ba	sed-products, milk-c	derived products, and colostrum;							
			— honey;										
			— render	ed fat	S;	<ul> <li>rendered fats;</li> </ul>							

II.	Health informa	tion		II.a.	and products other than Certificate reference No	Jettood	II.b.					
	and											
	materials		gin than t		the insects or their larvae have rred to in point (d) and the s							
II.2.	the competent authority examined a random sample immediately prior to dispatch and found it to comply with the following standards ( <sup>3</sup> ):											
	Salmonella:		Absenc	e in 25 g: r	n = 5, c = 0, m = 0, M = 0							
	Enterobacteriac	eae:	n = 5, c	= 2, m = 1	0, M = 300 in 1g;							
II.3.	the product has	undergone all	precautio	ns to avoid	recontamination with pathoger	nic agenf	ts after treatment;					
II.4.	the end product:											
	( <sup>2</sup> ) <i>either</i> [was packed in new or sterilised bags,]											
	( <sup>2</sup> ) or [was transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected before use,]											
					ONSUMPTION/ PROCESSED EPT AQUACULTURE AND FU							
II.5.	the end product	was stored in e	enclosed	storage;								
(²) [II.6.	the processed animal protein or product described above contains or is derived from animal-by products of ruminant origin and:											
	(²) either	( <sup>2</sup> ) <i>either</i> [originates from a country or region, which is classified as posing a negligible BSE ri accordance with Decision 2007/453/EC, and in which there has been no indigenous case, and]]										
	( <sup>2</sup> ) or	[originates from a country or region classified as posing a negligible BSE risk in accord with Decision 2007/453/EC in which there has been an indigenous BSE case, and the ar by-product or derived product were derived from animals born after the date from whic ban on the feeding of ruminants with meat-and-bone meal and greaves derived ruminants, as defined in the OIE Terrestrial Animal Health Code, has been effectively enfor in that country or region, and]]										
	(²) either	[is derived	d from oth	er ruminar	nts than bovine, ovine or caprine	e animal	s.]]					
	(²) or	[is derived	d from boy	vine, ovine	or caprine animals and does no	ot contai	in and is not derived fron					
		(²) either	continue	ously reare	d caprine materials other than ad and slaughtered in a countr k in accordance with Decision 2	y or reg	ion classified as posing					
		(²) or			isk material as defined in point 01 of the European Parliament							
					Ily separated meat obtained imals. except from those anin							

II.	Health inf	ormation		II.a. Certificate reference No	II.b.
			cap cen intro crar and	nal by-product or derived product rine animals which have been killed, tral nervous tissue by means of an oduced into the cranial cavity, or by nial cavity, except for those animals the slaughtered in a country or region cla in accordance with Decision 2007/45	after stunning, by laceration of th elongated rod-shaped instrumer y means of gas injected into th hat were born, continuously reare assified as posing a negligible BS
II.7.	the proces	sed animal pr	otein or product des	cribed above:	
	(²) either		ntain milk or milk p als, other than fur a	roducts of ovine or caprine animal or nimals.]	rigin or is not intended for feed fo
	(²) or			of ovine or caprine animal origin ar and the milk or milk products:	nd is intended for feed for farme
				d caprine animals which have been g conditions are fulfilled:	kept continuously since birth in
		(i)	classical scra	pie is compulsorily notifiable;	
		(ii)	an awareness	s, surveillance and monitoring system	is in place for classical scrapie;
		(iii)		tions apply to holdings of ovine or SE or the confirmation of classical sc	
		(iv)	ovine and cap	rine animals affected with classical so	crapie are killed and destroyed;
		(v)	defined in the Health (OIE),	o ovine and caprine animals of me e Terrestrial Animal Health Code of t of ruminant origin has been banne for a period of at least the preceding	the World Organisation for Anim ed and effectively enforced in th
		(b) origina	te from holdings wh	ere no official restrictions are imposed	d due to a suspicion of TSE;
				ere no case of classical scrapie has an years or, following the confirmation	
		(²) eith	slaughtered,	d caprine animals on the holding hat except for breeding rams of the AR ast one ARR allele and no VRQ allele RR allele;]	R/ARR genotype, breeding ewe
		( <sup>2</sup> ) or	and the holdir of confirmatic including testi laboratory me No 999/2001,	which classical scrapie was confirme ng has been subjected for a period o on of the last classical scrapie cas ng with negative results for the prese thods set out in point 3.2 of Chapter of all of the following animals which animals of the ARR/ARR genotype:	f at least two years since the dat se to intensified TSE monitoring ince of TSE in accordance with th C of Annex X to Regulation (EC
			— animals w	hich have been slaughtered for huma	an consumption; and
				/hich have died or been killed on the l work of a disease eradication campai	

[the processed animal protein or product described above contains or is derived from animal-by products of nonruminant origin and is, according to the statement of the Consignor referred to in Box I.1,

				onsumption including mixture petfood containing such protein
II.	Health inf	ormation	II.a. Certificate reference No	II.b.
	(²) either	[not intended for the production of	of feed for farmed animals, other than t	fur animals.]
	( <sup>2</sup> ) ( <sup>6</sup> ) or	Consignor has undertaken to er	eed for non-ruminant farmed animals sure that the border inspection post of the analyses carried out in accord tion (EC) No 152/2009 ( <sup>7</sup> ).]	of entry into the European Union
Note	es			
Part	:1:			
_	it is a certificate		ignment in the European Union: this b rough the European Union; it may be t 1.	
_			s to be filled in only if it is a certificate rehouses and custom warehouses.	for a transit commodity. Product
_		15: Registration number (railway v be provided in the event of unload	wagons or container and lorries), flight ling and reloading.	number (aircraft) or name (ship)
_	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	er than feeding of farmed animals,	other than fur animals, and the
	Box reference I.	26 and I.27: fill in according to whe	ether it is a transit or an import certifica	te.
	Box reference I.	28: Species: insects, specify its sc	ientific name.	
Part	: 11:			
( <sup>1a</sup> )	OJ L 300, 14.11	.2009, p. 1.		
( <sup>1b</sup> )	OJ L 54, 26.2.20	011, p. 1.		
( <sup>2</sup> )	Delete as appro	priate.		
( <sup>3</sup> )	Where:			
.,	n = number of	samples to be tested;		
	m = threshold	•	; the result is considered satisfactory	y if the number of bacteria in a
		value for the number of bacteria; amples is M or more; and	the result is considered unsatisfactory	y if the number of bacteria in one
		f samples the bacterial count of e if the bacterial count of the other	which may be between m and M, th samples is m or less.	he sample still being considered
(4)	OJ L 147, 31.5.2	2001, p. 1.		
( <sup>5</sup> )	OJ L 172 30.6.2	007 n 84		

COI	JNTRY	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.							
(6)	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 different	t colou	r to that of the printing.								
_	Note for the person responsible for the consignme and must accompany the consignment until it reac			nly for veterinary purposes							
Offic	cial veterinarian/Official inspector										
	Name (in capital letters):		Qualification and t	itle:							
	Date:		Signature:								
	Stamp:										

### 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

#### COUNTRY:

Veterinary certificate to EU

	I.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.		
		Name					1.3.	Central compete	ent authority			
		Address					1.4.	Local competent	t authority			
		Tel.										
	1.5.	Consignee					1.6.	Person responsible for the load in EU				
nent		Name						Name				
ignn		Address						Address				
Part I : Details of dispatched consignment		Postcode						Postcode				
ed e		Tel.						Tel.				
atch	I.7.	Country	ISO code	1.8.	Region of	Code	1.9.	Country of	ISO	I.10. Region of	Code	
disp		of origin			origin	oouo	1.0.	destination	code	destination		
s of												
etail	l.11.	Place of or	igin				I.12.	Place of destination	tion			
<u> </u>												
Part		Name Approval number								Custom warehouse		
		Address						Name		Approval number		
		Name		Appro	val number			Address				
		Address										
		Name		Appro	val number			Postcode				
	1.10	Address					144	Data at data d				
	1.13.	Place of loa	ading				1.14.	Date of departur	e			
	l.15.	Means of tr	ransport				I.16.	Entry BIP in EU				
		Aeroplane	🛛 Ship		Railway wa	agon 🗖						
		Road vehic	cle 🛛 Othe	er 🗖			I.17.	Number(s) of Cl	TES			
		Identificatio										
			ation reference									
	l.18.	Description	n of commodi	ty					I.19. Comm	odity code (HS code)		
	1.6.1	<b>-</b>								I.20. Quantity		
	1.21.		re of product I			-		<b>E</b>	-	I.22. Number of pa	ackages	
	1.00					1		Frozen C	J		aging	
	1.23.	Seal/Conta	iner No							I.24. Type of pack	aging	

1.25.	Commodities certified for:			
	Animal feedingstuff ☐ Technical use ☐	Further process	Production of per	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

COUNT	ſRY		I	Wilk, milk-based pro		ived products no man consumptioı
Π.	Health info	rmation	II.a. Certificate	reference No	II.b.	
_	the Europea (EU) No 142 certify that t	an Parliament a 2/2011 ( <sup>1b</sup> ), and	reterinarian, declare that I h ind of the Council ( <sup>1a</sup> ), and in particular Section 4 of Ch milk-based products ( <sup>2</sup> ) and	in particular Article f apter II of Annex X, a	10 thereof, and Com and Chapter I of Anne	mission Regulation ex XIV thereto, and
II.1.			rived in			
	listed in Par mouth disea	t I of Annex II t ase (FMD) and	Commission Regulation (E rinderpest for a period of 1 est during that period;	U) No 605/2010 ( <sup>4</sup> ),	and which has been	free from foot-and
II.2.	any disease	e transmissible	aw milk derived from anima through milk to humans or on holdings that were not su	animals, and which	had been kept for a	a period of at leas
II.3.	they are mil	k or milk produc	ts that:			
	(²) either	[have under	gone one of the treatments o	or combinations there	eof described in point	ll.4;]
	( <sup>2</sup> ) or		rhey to be fed to animals of bllected from milk subjected			
		(²) either	[the whey was collected a	it least 16 hours afte	r clotting and has a p	H below 6;]
		( <sup>2</sup> ) ( <sup>5</sup> ) or	[the whey has been proc period no cases of FMD b			
		( <sup>2</sup> ) ( <sup>5</sup> ) or	[the whey has been prod voyage duration, being a border inspection post of	at least 21 days bef	ore the consignment	
II.4.	they have b	een subject to o	one of the following treatmen	ts:		
	(²) either		rature short time pasteuris on achieving a negative rea			
		(²) either	[a subsequent second hig 15 seconds or an equiva to a phosphatase test in t	lent pasteurisation w		
		( <sup>2</sup> ) or	[a subsequent drying p combined with additional			ded for feeding i
		( <sup>2</sup> ) or	[a subsequent process by level below 6;]	v which the pH is rec	luced and kept for at	least one hour at
		( <sup>2</sup> ) ( <sup>5</sup> ) or	[the condition that the mi the date of shipping and the exporting country;]			
		( <sup>2</sup> ) ( <sup>5</sup> ) or	[the milk/milk product has consideration of the fores that the consignment is Union;]	een voyage duratior	i, being at least 21 da	iys prior to the dat
		( <sup>2</sup> ) or	[sterilisation at a level of a			

	TRY		I			oducts and milk-derived products for human consumpt			
II.	Health info	rmation		II.a.	Certificate reference No	II.b.			
	( <sup>2</sup> ) or	[ultra high te	emperature t	reatr	nent at 132°C for at least one se	econd in combination with:			
		(²) either			nt drying process that in the n additional heating to 72°C or h	case of milk intended for feeding igher;]			
		(²) or	[a subse level belo			luced and kept for at least one hour a			
		( <sup>2</sup> ) ( <sup>5</sup> ) or		of sh	ipping and during that period no	been produced at least 21 days prio cases of FMD has been detected in			
		( <sup>2</sup> ) ( <sup>5</sup> ) or	consider	ation	of the foreseen voyage duration	/ (insert the date), this date h, being at least 21 days prior to the d order inspection post of the Europe			
II.5.	every prec processing;		en to avoid	l cor	ntamination of the milk/milk-ba	sed product/milk-derived product a			
II.6.	the milk/mil	k-based produc	t/milk-derive	d prc	oduct was packed:				
	(²) either	[in new cont	tainers;]						
	(²) or	[in vehicles competent a		ontair	ners disinfected prior to loadi	ng using a product approved by			
	and		d bear label			he milk/milk-based product/milk-deriv tegory 3 material and not intended			
II.7.	the milk, mi	the milk, milk-based products and milk-derived products described above:							
	(²) either		ontain milk o nals, other th			imal origin or is not intended for feed			
	(²) or				cts of ovine or caprine animal or als, and the milk or milk products	rigin and is intended for feed for farn ::			
		(a)			om ovine and caprine animals w htry where the following conditior	vhich have been kept continuously si ns are fulfilled:			
			(i)		classical scrapie is compulsorily	notifiable;			
			(ii)		an awareness, surveillance a classical scrapie;	nd monitoring system is in place			
			(iii)			lings of ovine or caprine animals in e confirmation of classical scrapie;			
			(iv)		ovine and caprine animals affec destroyed;	cted with classical scrapie are killed a			
			(17)		destroyed,				
			(v) (v)		the feeding to ovine and capri greaves, as defined in the Terre Organisation for Animal Healtl	ine animals of meat-and-bone meal estrial Animal Health Code of the We h (OIE), of ruminant origin has be d in the whole country for a period o ;			

	Health information		.a. Certificate reference No	II.b.
	(c)	during a p		e of classical scrapie has been diag seven years or, following the confirmat
		( <sup>2</sup> ) either	destroyed or slaughtered, genotype, breeding ewes d	mals on the holding have been kille except for breeding rams of the ARR arrying at least one ARR allele and no als carrying at least one ARR allele;]
		( <sup>2</sup> ) or	and destroyed, and the ho least two years since the scrapie case to intensifi negative results for the laboratory methods set oo Regulation (EC) No 999/2	ical scrapie was confirmed have been olding has been subjected for a period date of confirmation of the last cla date of confirmation, including testing presence of TSE in accordance wit it in point 3.2 of Chapter C of Annex Jo11 (°), of all of the following animals nths, except ovine animals of the ARF
			<ul> <li>animals which have and</li> </ul>	been slaughtered for human consum
				died or been killed on the holding but the framework of a disease eradi
Part I	:			
C		be transited t	nrough the European union;	nis box is required to be filled in only if it may be filled in if the certificate is
0	certificate for a commodity to commodity to be imported into the	be transited t le European L	nrough the European union; nion.	
- E i	certificate for a commodity to l commodity to be imported into th Box reference I.12: Place of des Box reference I.15: Registration	be transited t ne European L tination: this b number (railw	nrough the European union; nion. ox is to be filled in only if it is a ay wagons or container and le	it may be filled in if the certificate is
- E - E - E - E	certificate for a commodity to l commodity to be imported into th Box reference I.12: Place of des Box reference I.15: Registration s to be provided. In the case of European Union.	be transited t te European L tination: this b number (railw of unloading a popriate Harmo	nrough the European union; nion. bx is to be filled in only if it is a ay wagons or container and le nd reloading, the consignor m nised System (HS) code of th	it may be filled in if the certificate is certificate for transit commodity. prries), flight number (aircraft) or name
- E - E - E - E - C	certificate for a commodity to lo commodity to be imported into the Box reference I.12: Place of des Box reference I.15: Registration is to be provided. In the case of European Union. Box reference I.19: use the appro 04.03; 04.04; 23.09.10, 23.09.90	be transited t ne European L number (railw of unloading a copriate Harmo ), 35.01, 35.02	nrough the European union; nion. bx is to be filled in only if it is a ay wagons or container and le nd reloading, the consignor m nised System (HS) code of th or 35.04.	it may be filled in if the certificate is certificate for transit commodity. prries), flight number (aircraft) or name ust inform the border inspection post
	certificate for a commodity to l commodity to be imported into the Box reference I.12: Place of des Box reference I.15: Registration is to be provided. In the case of European Union. Box reference I.19: use the approved back of the the terms of the terms of the terms back of the terms of the terms of the terms of the terms back of the terms of the terms of the terms of the terms back of the terms of the terms of the terms of the terms back of the terms of the terms of the terms of the terms back of the terms of terms of the terms of	be transited t ne European L tination: this b number (railw of unloading a opriate Harmo ), 35.01, 35.02 ainers, the cor use: any use	nrough the European union; nion. bx is to be filled in only if it is a ay wagons or container and lu nd reloading, the consignor m unised System (HS) code of th or 35.04. tainer number and the seal nu	it may be filled in if the certificate is certificate for transit commodity. prries), flight number (aircraft) or name ust inform the border inspection post e World Customs Organisation: 04.01; (
0 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	certificate for a commodity to l commodity to be imported into the Box reference I.12: Place of des Box reference I.15: Registration is to be provided. In the case of European Union. Box reference I.19: use the approvement of the approvement of the approvement Box reference I.23: for bulk contained Box reference I.25: technical u	be transited t ne European L tination: this b number (railw of unloading a opriate Harmo 0, 35.01, 35.02 ainers, the cor use: any use et food.	nrough the European union; nion. bx is to be filled in only if it is a ay wagons or container and le nd reloading, the consignor m inised System (HS) code of th or 35.04. Itainer number and the seal nu other than feeding of farmed	it may be filled in if the certificate is certificate for transit commodity. orries), flight number (aircraft) or name ust inform the border inspection post e World Customs Organisation: 04.01; ( mber (if applicable) must be included. I animals, other than fur animals, ar
9 9 19 19 19 19 19 19 19 19 19 19 19 19	certificate for a commodity to le commodity to be imported into the Box reference I.12: Place of des Box reference I.15: Registration is to be provided. In the case of European Union. Box reference I.19: use the approved Box reference I.23: for bulk contra- Box reference I.23: for bulk contra- Box reference I.25: technical up production or manufacturing of p Box reference I.26 and I.27: fill in	be transited t ne European L number (railw of unloading a opriate Harmo , 35.01, 35.02 ainers, the cor use: any use let food. n according to	nrough the European union; nion. bx is to be filled in only if it is a ay wagons or container and le nd reloading, the consignor m inised System (HS) code of th or 35.04. Itainer number and the seal nu other than feeding of farmed whether it is a transit or an imp	it may be filled in if the certificate is certificate for transit commodity. orries), flight number (aircraft) or name ust inform the border inspection post e World Customs Organisation: 04.01; ( mber (if applicable) must be included. I animals, other than fur animals, ar
9 9 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	certificate for a commodity to le commodity to be imported into the Box reference I.12: Place of desi Box reference I.15: Registration is to be provided. In the case of European Union. Box reference I.19: use the approved ALO3; 04.04; 23.09.10, 23.09.90 Box reference I.23: for bulk contra- Box reference I.25: technical up production or manufacturing of p Box reference I.26 and I.27: fill in Box reference I.28: 'Manufacturin	be transited t ne European L number (railw of unloading a opriate Harmo , 35.01, 35.02 ainers, the cor use: any use let food. n according to	nrough the European union; nion. bx is to be filled in only if it is a ay wagons or container and le nd reloading, the consignor m inised System (HS) code of th or 35.04. Itainer number and the seal nu other than feeding of farmed whether it is a transit or an imp	it may be filled in if the certificate is certificate for transit commodity. orries), flight number (aircraft) or name ust inform the border inspection post e World Customs Organisation: 04.01; ( mber (if applicable) must be included. d animals, other than fur animals, ar port certificate.
( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( (	certificate for a commodity to le commodity to be imported into the Box reference I.12: Place of desi Box reference I.15: Registration is to be provided. In the case of European Union. Box reference I.19: use the approved ALO3; 04.04; 23.09.10, 23.09.90 Box reference I.23: for bulk contra- Box reference I.25: technical up production or manufacturing of p Box reference I.26 and I.27: fill in Box reference I.28: 'Manufacturin	be transited t ne European L number (railw of unloading a opriate Harmo , 35.01, 35.02 ainers, the cor use: any use let food. n according to	nrough the European union; nion. bx is to be filled in only if it is a ay wagons or container and le nd reloading, the consignor m inised System (HS) code of th or 35.04. Itainer number and the seal nu other than feeding of farmed whether it is a transit or an imp	it may be filled in if the certificate is certificate for transit commodity. orries), flight number (aircraft) or name ust inform the border inspection post e World Customs Organisation: 04.01; ( mber (if applicable) must be included. d animals, other than fur animals, ar port certificate.

COI	UNTRY		Milk, milk-based	products	and milk-derived products not for human consumption				
П.	Health information	II.a.	Certificate reference No		ll.b.				
(²)	Delete as appropriate.								
(3)	For completion if the authorisation to import into or transit through the European Union is restricted to certain regions of the third country concerned.								
(4)	OJ L 175, 10.7.2010, p. 1.								
(5)	this condition applies only to third countries	listed i	in column 'A' of Annex I to Re	egulation (	EU) No 605/2010.				
( <sup>6</sup> )	OJ L 147, 31.5.2001, p. 1.								
-	The signature and the stamp must be in a d	ifferen	t colour to that of the printing	l.					
_	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):		C	Qualificatio	on and title:				
	Date:		S	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

#### COUNTRY:

Veterinary certificate to EU

	I.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.	
		Name					1.3.	Central compete	ent authority	-	
		Address					1.4.	Local competent	t authority		
		Tel.									
	1.5.	Consignee					1.6.	Person responsi	ible for the loa	d in EU	
Jent		Name						Name			
ignn		Address						Address			
suo		Destauts						Destanda			
ed c		Postcode						Postcode			
atch	1.7.	Tel.	ISO code	1.8.	Region of	Code	1.9.	Tel. Country of	ISO	I.10. Region of	Code
disp	1.7.	Country of origin	130 code	1.0.	origin	Code	1.9.	destination	code	destination	Code
of											
Part I : Details of dispatched consignment	I.11.	Place of ori	gin				I.12.	Place of destination	tion		
ă											
art		Name		Appro	val number					Custom warehouse	
ш		Address						Name		Approval number	
		Name		Appro	val number			Address			
		Address									
		Name		Appro	val number			Postcode			
		Address									
	1.13.	Place of loa	ading				1.14.	Date of departur	е		
	I.15.	Means of tr	ansport				I.16.	Entry BIP in EU			
		Aeroplane	☐ Ship		Railway wa	agon 🗖					
		Road vehic		er 🗖			1.17.	Number(s) of Cl	TES		
		Identificatio									
			tion reference								
	l.18.	Description	of commodi	ty					I.19. Comm	odity code (HS code)	
								l		I.20. Quantity	
	1.24	Temperatur	e of product							-	ckagoo
	1.21.	Ambient			Chilled <b>C</b>	1		Frozen 🕻	7	I.22. Number of pa	unayes
	123	Seal/Contai	iner No			-		r iozeli L	-	I.24. Type of packa	aging
Į	1.20.	SeanConta									-911 IY

1.25.	Commodities certified for:			
	Animal feedingstuff ☐ Technical use ☐	Further process	Production of per	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

П.	Health inform	ation	II.a. Certificate reference No	II.b.
	Health Informa	ation	II.a. Centificate reference no	II.D.
	the European (EU) No 142/20	Parliament and of t 011 ( <sup>1b</sup> ), and in part	he Council ( <sup>1a</sup> ), and in particular Art icular Section 4 of Chapter II of Anne	nderstood Regulation (EC) No 1069/2009 o icle 10 thereof, and Commission Regulatio ex X and Chapter I of Annex XIV thereto, an box I.28 comply with the following conditions
II.1.				
	listed in Annex disease (FMD)	I to Commission F	Regulation (EU) No 605/2010 ( <sup>4</sup> ), ar or a period of 12 months immedia	(insert name of region) ( <sup>3</sup> ), which id which has been free from foot-and-mou itely prior to export and has not practise
II.2.	any disease tra	nsmissible through the date of produc	colostrum to humans or animals, an	time of milking did not show clinical signs d d which had been kept for a period of at lea at to official restrictions due to foot-and-mou
II.3.	pasteurisation	at 72°C for at leas		been subject to high temperature short tim eurisation achieving a negative reaction to
	( <sup>2</sup> ) ( <sup>5</sup> ) either	least 21 days l		ucts have been produced during a period ing this period no cases of FMD have bee
	( <sup>2</sup> ) ( <sup>5</sup> ) or	the date), this	date, in consideration of the forese	cts have been produced on// (inse en voyage duration, being at least 21 day pection post of the European Union,]
	and		ained from animals subject to regula ings on which all bovine herds are:	ar veterinary inspections to ensure that the
		( <sup>2</sup> ) ( <sup>5</sup> ) <i>either</i>	[recognised as officially tuberculo	sis and brucellosis free ( <sup>6</sup> ),]
		( <sup>2</sup> ) ( <sup>5</sup> ) or	[not restricted under the national eradication of tuberculosis and br	legislation of the third country of origin for th rucellosis,]
	and	( <sup>2</sup> ) ( <sup>5</sup> ) either	[recognised as official enzootic-b	ovine-leukosis-free ( <sup>6</sup> ),]
		( <sup>2</sup> ) ( <sup>5</sup> ) or		r the control of enzootic bovine leukosis ar result of clinical and laboratory testing of th riod of the preceding two years,]]
II.4.	every precautio	on has been taken t	o avoid contamination of the colostru	m/colostrum product after processing;
II.5.	the colostrum of	or colostrum produc	t was packed:	
	( <sup>2</sup> ) either	[in new contain	ers,]	
	( <sup>2</sup> ) or	[in vehicles or competent auth		o loading using a product approved by th
	and			ture of the colostrum/colostrum product ar ry 3 material and not intended for huma
II.6.	the colostrum o	or colostrum produc	t does not contain milk or milk produc	cts of ovine or caprine animal origin.
Notes				
Part I:				

So reference 1.0. Person responsible for the load in the European Union; this box is required to be fined in only in 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.

col	JNTRY		Colostrum and	l colostrun	n products from bovine animals not for human consumption
П.	Health information	II.a.	Certificate reference No		II.b.
_	Box reference I.12: Place of destination: thi	s box i	is to be filled in only if it is a	certificate f	or transit commodity.
—	Box reference I.15: Registration number (r is 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	contai	ner number and the seal nu	mber (if app	blicable) must be included.
_	Box reference 1.25: technical use: any u production or manufacturing of pet food	ise oth	ner than feeding of farmed	l 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 imp	ort certifica	te.
_	Box reference I.28: 'Manufacturing plant': p	rovide	the registration number of the	he treatmer	nt or processing establishment.
Par	t II:				
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.				
(2)	Delete as appropriate.				
( <sup>3</sup> )	For completion if the authorisation for intr country concerned.	oducti	on into the European Unior	n is restrict	ed to certain regions of the third
(4)	OJ L 175, 10.7.2010, p. 1.				
( <sup>5</sup> )	This condition applies only to third coun No 605/2010 (OJ L 175, 10.7.2010, p. 1).	itries a	authorised in column 'A' o	f 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 dif	ferent	colour from that of the printir	ng.	
_	Note for the importer: this certificate is only the border inspection post of the European			accompan	y the consignment until it reaches
Offic	cial veterinarian/Official inspector				
	Name (in capital letters):			Qualificatio	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:

Veterinary certificate to EU

	I.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.	
		Name					1.3.	Central compete	ent authority		
		Address					1.4.	Local competen	t authority		
		Tel.									
	1.5.	Consignee					1.6.	Person respons	ible for the loa	d in EU	
Jent		Name						Name			
ignn		Address						Address			
suo								Destaula			
ed c		Postcode						Postcode			
atch		Tel.				<u> </u>		Tel.	10.0		
lispä	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
ofo											
Part I : Details of dispatched consignment	I.11.	Place of or	igin				I.12.	Place of destina	ition		
å											
art		Name		Appro	val number					Custom warehouse	•
đ		Address						Name		Approval number	
		Name		Appro	val number			Address			
		Address									
		Name		Appro	val number			Postcode			
		Address									
	I.13.	Place of lo	ading				I.14.	Date of departur	re		
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU			
		Aeroplane	Ship		Railway wa	agon 🗖					
		Road vehic	cle 🛛 Othe	er 🗖			I.17.				
		Identificatio	on								
		Documenta	ation reference	ces							
	I.18.	Description	n of commodi	ty					I.19. Comm	odity code (HS code)	)
										23.09	
										I.20. Quantity	
	I.21.		re of product			_			_	I.22. Number of pa	ackages
		Ambient			Chilled C			Frozen			
	1.23.	Seal/Conta	ainer No							I.24. Type of pack	aging

1.25.	Commodities certified f	or:			
	Petfood 🗖			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.	Identification of the com	nmodities			
		/	Approval number	of establishments	
	Species (Scientific name)	Manufact	uring plant	Net weight	Batch number

П.		Health infor	matio	on	II.a. Certificate reference No	II.b.
_	-	l, the unders the Europea Regulation (	signeo an Pa EU) N	d official veterinari rliament and of th	an, declare that I have read and understood Reg ne Council ( <sup>1a</sup> ), and in particular Articles 8 and and in particular Chapter II of Annex XIII and Ch	ulation (EC) No 1069/2009 of 10 thereof, and Commission
		and certify t		e petiood describe		
11.	.1.				establishment or plant approved and supervised ation (EC) No 1069/2009;	by the competent authority in
11.	.2.	has been pre	epare	d exclusively with	he following animal by-products:	
11.		(²) either	[-	killed, and which	rts of animals slaughtered or, in the case of garr 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 the nd were considered fit for slaughter for human co on or bodies and the following parts of animals ccordance 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) ł	eads of poultry;	
				i	ides and skins, including trimmings and splitt ncluding the phalanges and the carpus and m netatarsus bones;	
				(iv) p	ig bristles;	
				(v) f	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 communicabl	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	[-		ts arising from the production of products inten sed bone, greaves and centrifuge or separator slug	
		(²) and/or	[-	intended for hum	al origin, or foodstuffs containing products of anin 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 ;e;]	ommercial 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 products for hum	ts from aquatic animals originating from plants or an consumption:1	establishments manufacturing

П.	Health info	rmation		II.a. Certificate reference No	II.b.			
	(²) and/or			al originating from animals which did not h that material to humans or animals:	show any signs of diseas			
		(i)	shells	from shellfish with soft tissue or flesh;				
		(ii)	the fo	llowing originating from terrestrial animals:				
			— I	natchery by-products,				
			— 6	eggs,				
			— 6	egg by-products, including egg shells;				
		(iii)	day-c	Id chicks killed for commercial reasons;]				
	(²) and/or		r-products_fi r animals;]	rom aquatic or terrestrial invertebrates othe	r than species pathogenic to			
	(²) and/or	Category	1 material a	hereof of the zoological orders of Roden s referred to in Article 8(a)(iii), (iv) and (v) of F ial as referred to in Article 9(a) to (g) of that R	Regulation (EC) No 1069/200			
	(²) and/or	- Council D	irective 96/	which have been treated with certain substa 22/EC ( <sup>2b</sup> ), the import of the material being julation (EC) No 1069/2009;]				
II.3.	has been su	bjected to heat treatment to a minimum Fc value of 3 in hermetically sealed containers;						
II.4.				at least five samples from each processed l ant of the whole consignment as foreseen und				
II.5.	has undergo	one all precaution	ns to avoid c	ontamination with pathogenic agents after tre	atment.			
(²) [II.6.	the petfood	described above						
	(²) either	[is derived fro	om other run	ninants than bovine, ovine or caprine animals.	]			
	(²) or	[is derived fro	om bovine, c	vine or caprine animals and does not contain	and is not derived from:			
		(²) either	contir	[bovine, ovine and caprine materials other than those derived from animals bor continuously reared and slaughtered in a country or region classified as posing negligible BSE risk in accordance with Decision 2007/453/EC.]]				
		(²) or	[(a)	specified risk material as defined in point 1 o No 999/2001 of the European Parliament ar				
			(b)	mechanically separated meat obtained fro caprine animals, except from those animals reared and slaughtered in a country or r negligible BSE risk in accordance 2007/453/EC ( <sup>4</sup> ), in which there has been no	that were born, continuousl egion classified as posing with Commission Decisio			
			(c)	animal by-product or derived product obt caprine animals which have been killed, a the central nervous tissue by means o	fter stunning, by laceration c			

col	JNTRY	1	Canned Petfood
11.	Health information	II.a. Certificate reference No	II.b.
Not	es		
Part	t I:		
—		e consignment in the European Union: this bo sited through the European Union; it may be Union.	
—	Box reference I.12: Place of destination: this transit may only be stored in free zones, free	box is to be filled in only if it is a certificate for warehouses and custom warehouses.	or transit commodity. Products in
—		lway wagons or container and lorries), flight unloading and reloading in the European Unio	
—	Box reference I.23: for bulk containers, the c	ontainer number and the seal number (if app	licable) must be given.
-	Box reference I.25: technical use: any us production or manufacturing of pet food	e other than feeding of farmed animals, c	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 certificat	e.
—	Box reference I.28: Species: select from th Suidae, Pesca, Mollusca, Crustacea, inverte	e following: Aves, Ruminantia, Suidae, Man brates other than Mollusca and Crustacea.	nmalia other than Ruminantia or
Par	: II:		
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.		
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.		
( <sup>2</sup> )	Delete as appropriate.		
( <sup>2a</sup> )	OJ L 139, 30.4.2004, p. 55.		
( <sup>2b</sup> )	OJ L 125, 23.5.1996, p. 3.		
( <sup>3</sup> )	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	fferent colour to that of the printing.	
—	Note for the person responsible for the cons and must accompany the consignment until	ignment in the European Union: This certifica it reaches the border inspection post.	te is only for veterinary purposes
Offic	cial veterinarian/Official inspector		
	Name (in capital letters):	Qualificatio	n and title:
	Date:	Signature:	
	Stamp:		

### (CHAPTER 3(B)

### Health certificate

For processed petfood other than canned petfood, intended for dispatch to or for transit through  $\binom{2}{1}$  the European Union

#### COUNTRY:

Veterinary certificate to EU

	l.1.	Consignor		1.2.	Certificate referer	nce No	l.2.a.	
		Name		1.3.	Central competer	nt authority		
		Address		1.4.	Local competent	authority		
		Tel.						
	1.5.	Consignee		1.6.	Person responsib	ole for the load	d in EU	
nent		Name			Name			
ignr		Address			Address			
Part I : Details of dispatched consignment		Postcode			Postcode			
per		Tel.			Tel.			
oatcl	I.7.	Country ISO code I.8. Region of	Code	1.9.	Country of	ISO	I.10. Region of	Code
disp		of origin origin			destination	code	destination	
ls of								
etai	I.11.	Place of origin		I.12.	Place of destinati	on		
<u> </u>								_
Part		Name Approval number					Custom warehouse	
		Address			Name		Approval number	
		Name Approval number			Address			
		Address						
		Name Approval number Address			Postcode			
	112	Place of loading		114	Date of departure	<u></u>		
	1.13.	Flace of loading		1.14.		;		
	l.15.	Means of transport		I.16.	Entry BIP in EU			
		Aeroplane Ship Railway w	ragon 🗖					
		Road vehicle D Other D		I.17.				
		Identification						
		Documentation references						
	I.18.	Description of commodity				I.19. Commo	odity code (HS code)	
							I.20. Quantity	
	1.24	Temperature of product					I.22. Number of page	ekagee
	1.21.	Ambient Chilled	-		Frozen 🗖	I		Snayes
	1.23	Seal/Container No	<b></b>				I.24. Type of packa	aina
	1.23.						п.24. туре ограска	igiriy

1.25.	Commodities certified for	or:			
	Petfood 🗖			Technical use 🗖	
1.26.	For transit through EU t	to third country		I.27. For import or admission into EU	
	Third country	ISO code			
I.28.	Identification of the com	nmodities			
		Ap	proval number	of establishments	
	Species (Scientific name)	Manufactu	ring plant	Net weight	Batch number

COUNT						•	food other than canned petfoo
II.	Health info	ormati	on		II.a.	Certificate reference No	II.b.
	the Europe Regulation	an Pa (EU)	arliamen No 142/	t and of the	Coun d in p	are that I have read and understood I cil ( <sup>1a</sup> ), and in particular Articles 8 a articular Chapter II of Annex XIII and :	and 10 thereof, and Commissio
II.1.				stored in a pla EC) No 1069/2		pproved and supervised by the compe	etent authority in accordance wit
II. <b>2</b> .	has been p	repare	ed exclus	sively with the	follo	wing animal by-products:	
	(²) either	[-	killed,	and which are	e fit fo	nimals slaughtered or, in the case of or human consumption in accordance umption for commercial reasons;]	
	(²) and/or	[-	slaugh morter	iterhouse and	were or bo	ng parts originating either from animale considered fit for slaughter for huma odies and the following parts of anin ce with Union legislation:	in consumption following an ante
			(i)	consumptior	n in a	dies and parts of animals which a accordance with Union legislation, but icable to humans or animals;	
			(ii)	heads of po	ultry;		
			(iii)			including trimmings and splitting ther le carpus and metacarpus bones, tarsu	
			(iv)	pig bristles;			
			(v)	feathers;]			
	(²) and/or	[-	Article	1(3)(d) of R	Regula	n poultry and lagomorphs slaughtere ation (EC) No 853/2004 of the Eu t show any signs of disease communic	uropean Parliament and of th
	(²) and/or	[-	humar having	ns or animals, g been consid	obtai dered	did not show any signs of disease ined from animals that have been slau l fit for slaughter for human consur with Union legislation;]	ightered in a slaughterhouse afte
	(²) and/or	[-				ng from the production of products in e, greaves and centrifuge or separator	
	(²) and/or	[-	intende	ed for human	consi	, or foodstuffs containing products of a umption for commercial reasons or du er defects from which no risk to public	e to problems of manufacturing o
	(²) and/or	[-	derive proble	d products, w	hich cturir	is of animal origin, or feedingstuffs of animal origin, or feeding function of the feeding function of the second se	or commercial reasons or due t
	(²) and/or	[-		id not show		athers, hair, horns, hoof cuts and raw s of any disease communicable thro	
	(²) and/or	[-				ts of such animals, except sea mamm le to humans or animals;]	als, which did not show any sign

II.	Health info	ormati	on		.a.	Certificate reference No		II.b.
	(²) and/or	[-		l by-products fro cts for human co		aquatic animals originating fro umption;]	om plants o	r establishments manufactur
	(²) and/or	[-				originating from animals wh at material to humans or anin		t show any signs of disea
			(i)	shells from she	ellfi	ish with soft tissue or flesh;		
			(ii)	the following o	origi	inating from terrestrial animal	S:	
				— hatchery	/ by	r-products,		
				— eggs,				
				— egg by-p	roc	ducts, including egg shells,		
			(iii)	day-old chicks	; kil	led for commercial reasons;]		
	(²) and/or	[-		l by-products frances	om	aquatic or terrestrial inverte	ebrates oth	er than species pathogenic
	(²) and/or	[-	Categ	ory 1 material as	s re	eof of the zoological order: ferred to in Article 8(a)(iii), (iv as referred to in Article 9(a) to	) and (v) of	Regulation (EC) No 1069/20
	(²) and/or	[-	Cound	il Directive 96/2	22/8	nich have been treated with c EC ( <sup>2b</sup> ), the import of the ma tion (EC) No 1069/2009;]		
1.3.								
	(²) either	[wa	s subjec	ted to a heat tre	atr	nent of at least 90 °C through	out its subs	stance;]
	(²) or	[wa	s produ	ced as regards i	ngr	edients of animal origin using	exclusively	r products which had been:
		(a)				products or derived products 90 °C throughout its substan		or meat products subjected to
		(b)	in the	case of milk and	i m	ilk based products,		
			(i)	Commission F	Reg	nird countries or parts of thirc gulation (EU) No 605/2010 ( <sup>3</sup> uce a negative phosphatase t	3) submitted	
			(ii)	column C of A	۸nn	ed to less than 6 from third co ex I to Regulation (EU) No 60 nt to produce a negative phos	05/2010, firs	st submitted to a pasteurisati
			(iii)	Regulation (E	U)	nird countries or parts of third No 605/2010, submitted to each treatment was sufficier	a sterilisat	tion process or a double he
			(iv)	Regulation (E disease in th	U) ne	nird countries or parts of third No 605/2010, where there preceding 12 months or w n carried out in the preceding?	has been a here vaccii	an outbreak of foot-and-mou nation against foot-and-mou
				either				
				— a sterilis	atic	on process whereby an Fc val	ue equal or	greater than 3 is achieved
				or				
						eat treatment with a heating on process of at least 72 °C		

Health informati	on	II.a.	Certificate reference No	II.b.
	either			
	initial to a	heat t bhosp	treatment, and which would be s	ct at least equal to that achieved by ufficient to produce a negative reac ase of dried milk, or dried milk-ba
	or	·		
	— an ac least			as been maintained at less than 6 fo
(C)	material is subjecters subsequent adjustr	ed to nent c	a treatment with acid or alkali	ensures that unprocessed Catego , followed by one or more rinses ecessary repeated, extraction by h ion;
(d)	measures to minim protein entirely or p dedicated only to below 10000 Dalto	ise co partly nydrol n and	ontamination of raw Category 3 i derived from ruminant hides an lysed protein production, using	oduction process involving appropr material, and, in the case of hydroly d skins produced in a processing p only material with a molecular we aration of raw Category 3 materia
	temperature	e of n		n 11 for more than three hours a ently by heat treatment at more t
			material to a pH of 1 to 2, followe 140 °C for 30 minutes at 3 bar;	ed by a pH of more than 11, followed
(e)	in Chapter III of A	nnex		ssing methods 1 to 5 or 7, as referre 2/2011; or treated in accordance 853/2004 ;
(f)	subjected to a treat	ment i n and	involving washing, pH adjustmer d extrusion, the use of preservation	hat unprocessed Category 3 materi tt using acid or alkali followed by on ves other than those permitted by Ur
(g)			ducts, produced using any of th of Annex IV to Regulation (EU) N	ne processing methods 1 to 5 or 7 Io 142/2011;
(h)	methods 1 to 5 or methods 1 to 5 or	7 an 7 pro	nd, in the case of porcine bloo	submitted to any of the proces d, submitted to any of the proces hod 7 a heat treatment throughou applied;
(i)				e exclusion of fishmeal submitted to apter III of Annex IV to Regulation (
(j)	Chapter III of Anne ensure that the pro	x IV to duct c	o Regulation (EU) No 142/2011	sing methods 1 to 7 as referred t or to a method and parameters w I standards for derived products set
(K)	5 or 7 (and method (EU) No 142/2011 Regulation (EC) No	6 in th or pr 853/	he case of fish oil) as referred to roduced in accordance with Ch /2004; rendered fats from rumin	to any of the processing methods in Chapter III of Annex IV to Regula apter II of Section XII of Annex I ant animals must be purified in suc le impurities does not excess 0,15

II.	Health info	ormation			II.a. Ce	ertificate re	ference N	10		II.b.			
		(I) in th	e case of	dicalci	um phos	phate proc	uced by a	a process	that				
		(i)	and tr	eated v	with dilute		oric acid (	at a minii				with hot wa ⁄₀ and a p⊦	
		(ii)				re referred ing in a pr						ed phospho 7; and	oric
		(iii)				recipitate erature be				n inlet te	mperatu	re of 65 °C	; to
		(m) in th	e case of	tricalci	um phosj	ohate proc	luced by a	a process	that ens	sures			
		(i)				one-mater less than		ly crushe	d and d	egrease	d in cou	nter-flow v	vith
		(ii)	contir	iuous c	ooking w	ith steam	at 145 °C	during 30	) minute	s at 4 ba	r;		
		(iii)		ation o fugatio		rotein bro	th from	the hydr	oxyapat	te (trica	lcium pl	nosphate)	by
		(iv)	granu	lation c	of the trica	alcium pho	sphate af	fter drying	g in a flui	d bed wi	th air at :	200 °C ;	
		whic										l paramete eferred to	
	(²) or	[was sub competer			ient such	n as dryir	ig or ferr	mentation	, which	has bee	en autho	orised by	the
	( <sup>2</sup> ) or	animals,	has been	subjec	t to a tre		nich has b	een auth	orised b	y the co	mpetent	o humans authority a	
11.4.		sed by a ra the processi								d batch	taken d	uring or a	fter
	Salmonella	.:	abser	nce in 2	5g: n = 5	, c = 0, m	= 0, M = 0	D,					
	Enterobact	eriaceae:	n = 5,	c = 2,	m = 10, I	∕I = 300 in	1 gramm	e;					
II.5.	has underg	jone all prec	autions to	avoid	contamin	ation with	pathogen	iic agents	after tre	atment;			
II.6.		d in new pac hat the con TION'';											
(²) [II.7.	the petfood	l described a	above										
	(²) either	[is derive	d from oth	ier rum	inants tha	an bovine,	ovine or o	caprine a	nimals.]				
	(²) or	[is derive	d from bo	vine, o\	vine or ca	iprine anin	nals and c	loes not c	contain a	nd is not	derived	from:	
		(²) either	contir	nuously	reared		phtered ir	n a coun	ntry or r	egion cl		animals bo as posing	
		(²) or	[(a)	speci	fied risk	material	as define	ed in poir	nt 1 of	Annex \	/ to Re	gulation (E	EC)

н.	Health information	II.a. Certificate reference No II.b.
	(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 ( <sup>8</sup> ), 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 central 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.]]]
Note	25	
Part	l:	
_		for the consignment in the European Union: this box is required to be filled in only if e transited through the European Union; it may be filled in if the certificate is for a opean Union.
_		n: this box is to be filled in only if it is a certificate for a transit commodity. Products nes, free warehouses and custom warehouses.
—		er (railway wagons or container and lorries), flight number (aircraft) or name (ship) g and reloading, the consignor must inform the border inspection post of entry into
_		e Harmonized System (HS) code under the following headings: 04.01; 04.02; 04.03; 5.11, 15.01, 15.02, 15.03, 15.04, 23.01, 23.09; 28.35.25; 28.35.26; 35.01; 35.02;
—	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: a production or manufacturing of pet foo	ny use other than feeding of farmed animals, other than fur animals, and the d.
—	Box reference I.26 and I.27: fill in acco	rding to whether it is a transit or an import certificate.
—		om the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or nvertebrates other than Mollusca and crustacea.
Part	II:	
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.	
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.	
(2)	Delete as appropriate.	
( <sup>2a</sup> )	OJ L 139, 30.4.2004, p. 55.	
	OJ L 125, 23.5.1996, p. 3.	
( <sup>2b</sup> )	,, p	

COL	JNTR	1		Process	ed petfoo	d other than canned petfood
II.		Health information	II.a.	Certificate reference No		II.b.
(4)	Whe	e:				
	n =	number of samples to be tested;				
	m =	threshold value for the number of bas samples does not exceed m;	acteria;	the result is considered satis	sfactory if	the number of bacteria in all
	M =	maximum value for the number of bac more samples is M or more; and	teria; tł	e result is considered unsatisf	actory if th	e number of bacteria in one or
	c =	number of samples the bacterial cou acceptable if the bacterial count of the			nd 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 s	signature and the stamp must be in a di	fferent	colour to that of the printing.		
_		for the person responsible for the cons nust accompany the consignment until				
Offic	cial ve	erinarian/Official inspector				
	Nam	e (in capital letters):		Qua	alification a	and title:
	Date			Sigr	nature:	
	Stam	p:				

### CHAPTER 3(C)

### Health certificate

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

#### COUNTRY:

Veterinary certificate to EU

	I.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.	
		Name					1.3.	Central compete	ent authority		
		Address					1.4.	Local competen	t authority		
		Tel.									
	1.5.	Consignee					1.6.	Person respons	ible for the loa	ad in EU	
lent		Name						Name			
ignn		Address						Address			
onsi		_									
o pe		Postcode						Postcode			
tche		Tel.						Tel.			
ispa	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		Ū			•						
Part I : Details of dispatched consignment	I.11.	Place of or	igin				I.12.	Place of destina	tion		
: De											
art I		Name		Appro	val number					Custom warehous	e 🛛
ä		Address						Name		Approval number	
		Name		Appro	val number			Address			
		Address									
		Name		Appro	val number			Postcode			
		Address									
	I.13.	Place of lo	ading				I.14.	Date of departur	re		
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU			
			•					,			
		Aeroplane	Ship		Railway wa	agon 🗖					
		Road vehic	cle 🗖 Othe	er 🗖			I.17.				
		Identificatio	on								
		Documenta	ation referend	ces							
	l.18.	Description	n of commodi	ty					I.19. Comm	nodity code (HS code	e)
										I.20. Quantity	
	1.21.	Temperatu	re of product							I.22. Number of p	backages
		Ambient	]		Chilled 🕻	]		Frozen <b>[</b>	]		
	1.23.	Seal/Conta	ainer No							I.24. Type of pac	kaging

1.25.	Commodities certified f	or:			
	Petfood 🗖			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.	Identification of the com	nmodities			
		/	Approval number	of establishments	
	Species (Scientific name)	Manufact	uring plant	Net weight	Batch number

COUNT	RY									Dogchew
н.	Health info	ormati	on	II.a.	(	Certificate reference No		II.b.		
	the Europe Regulation	ean Pa (EU)	rliament and of the	Cour nd in	ncil pai	e that I have read and underst ( <sup>ta</sup> ), and in particular Article 1 rticular Chapter II of Annex XII e:	0 of th	at Regula	tion, an	d Commissio
II.1.	have been	prepa	red exclusively with	he fo	llov	wing animal by-products:				
	(²) either	[-	killed, and which a	re fit	for	nals slaughtered or, in the cas human consumption in accorda nption for commercial reasons;]	ance w			
	(²) and/or	[-	slaughterhouse ar mortem inspectior	d wer or b	re o ood	parts originating either from ar considered fit for slaughter for l lies and the following parts of e with Union legislation:	human	consump	tion follo	owing an ante
			consumpti	on in	ac	es and parts of animals whi cordance with Union legislatior able to humans or animals;				
			(ii) heads of p	oultry	;					
						ncluding trimmings and splitting carpus and metacarpus bones,				
			(iv) pig bristles	;						
			(v) feathers;]							
	(²) and/or	[-	humans or animals having been cons	s, obta sidere	ain d 1	id not show any signs of disc ed from animals that have beer fit for slaughter for human co rith Union legislation;]	n slaug	htered in	a slaugł	nterhouse afte
	(²) and/or	[-	• •		-	g from the production of produ greaves and centrifuge or sepa				
	(²) and/or	[-				of such animals, expect sea m o humans or animals;]	namma	ls, which c	lid not s	how any sign
	(²) and/or	[-	animal by-products products			quatic animals originating from p nption;]	plants	or establis	hments	manufacturing
	(²) and/or	[-	Council Directive	96/22	/EC	ch have been treated with certa $C$ ( <sup>2a</sup> ), the import of the materion (EC) No 1069/2009;]				
II.2.	have been	subjec	cted							
	(²) either					from hides and skins of ungulat s (including salmonella); and the				ment sufficien
	(²) and/or					e from animal by-products othe at least 90°C throughout their s			skins c	of ungulates o
II.3.				,		east five samples from each p with the following standards ( <sup>3</sup> ):		sed batch	taken o	during or afte
	Salmonella	a:	absence	in 25	g: ı	n = 5, c = 0, m = 0, M = 0,				
	Enterobact	eriace	ae: n = 5, c =	= 2. m	1 =	10, M = 300 in 1 gramme;				

II.	Health info	ormation		II.a.	Certificate reference No	II.b.
11.4.	have under	roone all prec	autions to	o avoid co	ontamination with pathogenic agents	s after treatment
11.5.	•	ed in new pac	0 0			
(²) [II.6.	the dogche	ews described	labove			
	(²) either	[is derived	from oth	er ruminaı	nts than bovine, ovine or caprine an	imals.]]
	(²) or	[is derived	from bov	vine, ovine	e or caprine animals and does not co	ontain and is not derived from:
		(²) either	contin	uously re		n those derived from animals born rry or region classified as posing 07/453/EC.]]
		(²) or	[(a)		d risk material as defined in poin 2001 of the European Parliament ar	t 1 of Annex V to Regulation (EC nd of the Council ( <sup>4</sup> );
			(b)	animals, slaughte accordai	except from those animals that ared in a country or region classifie	m bones of bovine, ovine or caprin were born, continuously reared an ad as posing a negligible BSE risk i 7/453/EC ( <sup>5</sup> ), in which there has bee
			(C)	animals nervous the cran those ar	which have been killed, after st tissue by means of an elongated r ial cavity, or by means of gas injec imals that were born, continuously n classified as posing a negligible l	ained from bovine, ovine or caprin unning, by laceration of the centra rod-shaped instrument introduced int cted into the cranial cavity, except for reared and slaughtered in a count BSE risk in accordance with Decision
						this box is to be filled in only if it is dity to be imported into the Europea
Uni	on.					
					t is to be filled in only if it is a certific varehouses and custom warehouse	cate for a transit commodity. Product s.
					v wagons or container and lorries), f Inloading and reloading in the Europ	flight number (aircraft) or name (ship bean Union.
— Box	reference I.1	9: 05.11, 23.0	09, 41.01	or 42.05.		
— Вох	reference I.2	3: for bulk co	ntainers,	the conta	iner number and the seal number (i	f applicable) must be given.
		.25: technical nufacturing o			her than feeding of farmed anima	als, other than fur animals, and th
— Вох	reference I.2	26 and I.27: fil	l in accor	ding to wh	hether it is a transit or an import cer	tificate.
					lowing: Aves, Ruminantia, Suidae, es Other Than Mollusca And Crusta	Mammalia Other Than Ruminantia o acea.
Part II:						
<sup>1a</sup> ) OJ	L 300, 14.11.	2009. p. 1				

(<sup>1b</sup>) OJ L 54, 26.2.2011, p. 1.

୍ରା୦୦	JNTRY		Dogchews
п.	Health information	II.a. Certificate reference No	II.b.
(2)	Delete as appropriate.		
( <sup>2a</sup> )	OJ L 125, 23.5.1996, p. 3.		
(3)	Where:		
-	n = number of samples to be tested;		
_	m = threshold value for the number of the samples does not exceed m;	pacteria; the result is considered satisfactory	if the number of bacteria in all
-	M = maximum value for the number of ba more samples is M or more; and	cteria; the result is considered unsatisfactory i	f the number of bacteria in one or
-	c = number of samples the bacterial co acceptable if the bacterial count of th	bunt of which may be between m and M, the other samples is m or less.	ne 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 d	different colour to that of the printing.	
_		signment in the European Union: This certifica I it reaches the border inspection post of entry	
Offic	cial veterinarian/Official inspector		
	Name (in capital letters):	Qualificatio	on 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  $\binom{2}{1}$  the European Union

#### COUNTRY:

Veterinary certificate to EU

	l.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.	
		Name					1.3.	Central compete	ent authority		
		Address					1.4.	Local competen	t authority		
		Tel.									
	1.5.	Consignee					1.6.	Person respons	ible for the loa	ad in EU	
lent		Name						Name			
Part I : Details of dispatched consignment		Address						Address			
onsi											
∋d c		Postcode						Postcode			
tche		Tel.						Tel.			
ispa	I.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
of d			[								
tails	I.11.	Place of or	igin				I.12.	Place of destina	tion		
: Def			•								
Ţ		Name		Appro	val number					Custom warehouse	e 🗆
Å		Address						Name		Approval number	
		Name		Appro	oval number			Address			
		Address									
		Name		Appro	val number			Postcode			
		Address									
	I.13.	Place of loa	ading				I.14.	Date of departur	re		
	115	Means of tr	ransport				116	Entry BIP in EU			
	1.10.		ransport				1.10.				
		Aeroplane	Ship		Railway wa	agon 🗖					
		Road vehic		_			I.17.				
		Identificatio	on								
		Documenta	ation referen	ces							
	l.18.	Description	n of commod	ity					I.19. Comm	nodity code (HS code	)
										I.20. Quantity	
	I.21.	Temperatu	re of product	t						I.22. Number of p	ackages
		Ambient	]		Chilled C	]		Frozen <b>D</b>	]		
	1.23.	Seal/Conta	ainer No							I.24. Type of pac	kaging

1.25.	Commodities certif	ied for:				
	Petfood			Tech	nnical 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		oval number	of establishments		
(5	Species Scientific name)	Nature of commodity	Manufactu	uring plant	Net weight	Batch number

COUNTI	ζî		Raw petfood for direct sa	fed to fur animal							
н.	Health informatio	n	II.a. Certificate reference No	II.b.							
-	the European Par (EU) No 142/2011	iament and of the Coun	lare that I have read and understood R cil ( <sup>1a</sup> ) and in particular Article 10 there hapter II of Annex XIII and Chapter II o described above:	eof, and Commission Regulation							
II.1.	consist of animal b	y-products that satisfy the	e health requirements below;								
II.2.	consist of animal b	y-products:									
	(a) derived from	meat which satisfies the	relevant animal and public health requi	rements laid down in:							
	derived	d come from the third cou	No 206/2010 ( <sup>3</sup> ) and provided that the intries, territories or parts thereof								
<ul> <li>and/or Commission Regulation (EC) No 798/2008 (<sup>4</sup>), and provided that the anima meat is derived come from the third countries, territories or parts thereof</li></ul>											
	meat is case o has be vesicul	derived come from the t f a country, or codes in t en free from foot and mo ar disease, Newcastle d	(EC) No 119/2009 ( <sup>5</sup> ), and provided hird countries, territories or parts thereo he case of territories or parts thereof) a uth disease, rinderpest, classical swine isease and avian influenza for the pred ing that time (only where relevant for the	f(ISO code in the as listed in that Regulation which fever, African swine fever, swine ceding 12 months and where no							
	(b) derived from animals that, at the slaughterhouse, have passed the ante-mortem health inspection during period of 24 hours before the time of slaughter and have shown no evidence of the diseases referred in Regulations referred to in point (a) for which the animals are susceptible; and										
	killing in acc	derived from animals that have been handled in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Union legislation and have met requirements at least equivalent to those laid down in Chapters II and III of Council Regulation (EC) No 1099/2009 ( <sup>6</sup> ); or									
	public health	requirements laid down	are derived from aquatic animals which i in Commission Decision 2006/766/EC ISO code of the country) as listed in Ani	(7), and come from countries c							
II.3.1.	consist only of the	following animal by-prod	ucts:								
	were deeme		htered or, in the case of game, bodies ption in accordance with Union legislat asons;								
	signs of dis		are rejected as unfit for human consum humans or animals and derived from n legislation;								
II.3.2.	in the case of feed	for fur animals in addition	n to II.3.1. consist also of the following a	nimal by-products:							
	(²) either [-	Article 1(3)(d) of Regul	n poultry and lagomorphs slaughtered lation (EC) No 853/2004 of the Eu ot show any signs of disease communica	ropean Parliament and of the							
	( <sup>2</sup> ) and/or [-	humans or animals, obta	did not show any signs of disease ained from animals that have been slaug d fit for slaughter for human consum with Union legislation;]	ghtered in a slaughterhouse afte							
	( <sup>2</sup> ) and/or [-		ing from the production of products in e, greaves and centrifuge or separator s								

II.	Health info	ormat	ion		II.a. Certificate reference No	II.b.
	(²) and/or	[-	inten	ded for human consu	or foodstuffs containing products of anin mption for commercial reasons or due to r defects from which no risk to public or a	problems of manufacturing o
	(²) and/or	[-	deriv probl	ed products, which a	s of animal origin, or feedingstuffs con are no longer intended for feeding for o g or packaging defects or other defects	commercial reasons or due to
	(²) and/or	[-		did not show signs	thers, hair, horns, hoof cuts and raw mi of any disease communicable throug	
	(²) and/or	[-			s of such animals, except sea mammals e to humans or animals;]	, which did not show any sign
	(²) and/or	[-		al by-products from a ucts for human consu	iquatic animals originating from plants or mption;]	establishments manufacturin
	(²) and/or	[-			riginating from animals which did not at material to humans or animals:	show any signs of diseas
			(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	[-		al by-products from ans or animals;]	aquatic or terrestrial invertebrates othe	er than species pathogenic t
	(²) and/or	[-	Cate	gory 1 material as ref	of of the zoological orders of Roder erred to in Article 8(a)(iii), (iv) and (v) of s referred to in Article 9(a) to (g) of that F	Regulation (EC) No 1069/200
II.4.					ntact with other material which does not and it has been handled so as to avoid	
II.5.	CONSUMP CONSUMP preventing NOT FOR	PTION PTION any I HUM	l'or'/ l'and eakage AN CO	ANIMAL BY-PRODU then placed in leak and officially sealed NSUMPTION' or 'AN	ch bear labels indicating 'RAW PET F JCTS FOR FEED FOR FUR ANIM/ -proof and officially sealed boxes/con- d boxes/containers which bear labels in IMAL BY-PRODUCTS FOR FEED FOR d the address of the establishment of dea	ALS — NOT FOR HUMA tainers or in new packagin dicating 'RAW PET FOOD - t FUR ANIMALS — NOT FO
II.6.	in the case	of rav	w petfoo	od:		
	· · /			d and stored in a pla Regulation (EC) No 1	int approved and supervised by the com 069/2009 and	petent authority in accordanc
					f at langt five annual a farm of the batt	teles during starses (befor

(b) was examined by random sampling of at least five samples from each batch taken during storage (before dispatch) and complies with the following standards (<sup>8</sup>):

II.	Health informat	ion		II.a. Certificate reference No	II.b.
	Salmonella:	a	bsence in	25 g: n=5, c=0, m=0, M=0	
	Enterobacteriace			=10. M=5000 in 1 gram:	
(²) [II.7.	[the petfood or a products of rumin			e fed to fur animals described above c	ontains or is derived from animal-b
	(²) either	originates	from a co	ountry or region, which is classified a sion 2007/453/EC, and in which there	
	(²) or	Decision 20 product or the feeding	007/453/E derived pr of rumin he OIE Te	Intry or region classified as posing a ne C in which there has been an indiger oduct were derived from animals born ants with meat-and-bone meal and g rrestrial Animal Health Code, has been	lous BSE case, and the animal b after the date from which the ban o reaves derived from ruminants, a
	(²) either	[is derived t	rom other	ruminants than bovine, ovine or caprin	e animals.]]
	( <sup>2</sup> ) or	[is derived t	rom bovin	e, ovine or caprine animals and does n	ot contain and is not derived from:
		(²) either	contin	e, ovine and caprine materials other th uously reared and slaughtered in a cou ible BSE risk in accordance with Decisi	untry or region classified as posing
		(²) or	[(a)	specified risk material as defined in p No 999/2001 of the European Parliam	
			(b)	mechanically separated meat obtain caprine animals, except from animals and slaughtered in a country or regi BSE risk in accordance with Commi which there has been no indigenous f	that were born, continuously reare on classified as posing a negligib ssion Decision 2007/453/EC ( <sup>10</sup> ),
			(c)	animal by-product or derived producaprine animals which have been king the central nervous tissue by merinstrument introduced into the cranial into the cranial cavity, except for continuously reared and slaughtered posing a negligible BSE risk in according to the cranial cavity is the control of the continuously reared and slaughtered posing a negligible BSE risk in according to the control of	Iled, after stunning, by laceration ans of an elongated rod-shape cavity, or by means of gas injecter those animals that were bor in a country or region classified a
Votes					
Part I:					
it is		commodity to	be transit	consignment in the European Union: thi ed through the European Union; it may nion.	
				ox is to be filled in only if it is a certifica arehouses and custom warehouses.	te for transit commodity. Products
is t				ay wagons or container and lorries), fl loading, the consignor must inform the	
	x I.19: use the app 01 or 23.09.	ropriate Harm	ionized Sy	stem (HS) code under the following h	eading: 04.08; 05.06; 05.08; 05.1
— Во	x reference I.23: for	bulk containe	rs, the cor	tainer number and the seal number (if	applicable) must be given.
	x reference 1.25: te oduction or manufact			other than feeding of farmed animal	s, other than fur animals, and th

COL	JNTRY	Raw petfood for direct sale or animal by- products to be fed to fur animals						
11.	Health information	II.a. Certificate reference No	II.b.					
_	Box reference I.28:							
	Nature of commodity: select raw petfood or animal	by-product.						
	In the case of raw material for the manufacture of	raw pet food indicate the scientific name of t	he species.					
	In case of raw material for manufacture of feed Mammalia other than Ruminantia or Suidae, F Crustacea.							
Part	0:							
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.							
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.							
(2)	Delete as appropriate.							
( <sup>2a</sup> )	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.							
( <sup>5</sup> )	OJ L 39, 10.2.2009, p. 12.							
( <sup>6</sup> )	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 satisfactory if the	e number of bacteria in al					
	M = maximum value for the number of bacteria; or more samples is M or more; and	the result is considered unsatisfactory if the	e number of bacteria in one					
	c = number of samples the bacterial count of acceptable if the bacterial count of the other		mple still being considered					
( <sup>9</sup> )	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	t colour to that of the printing.						
_	Note for the person responsible for the consignme and must accompany the consignment until it reac							
Offic	cial veterinarian/Official inspector							
	Name (in capital letters):	Qualification and	l title:					
	Date:	Signature:						
	Stamp:							

## CHAPTER 3(E)

### Health certificate

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

#### COUNTRY:

Veterinary certificate to EU

	I.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.		
		Name					1.3.	Central compete	ent authority	Let an		
		Address					1.4.	Local competen	t authority			
		Tel.										
	1.5.	Consignee					1.6.	Person respons	ible for the loa	ad in EU		
lent		Name						Name				
ignn		Address						Address				
Part I : Details of dispatched consignment		Postcode						Postcode				
pər		Tel.						Tel.				
atch	1.7.	Country	ISO code	1.8.	Region of	Code	1.9.	Country of	ISO	I.10. Region of		Code
disp		of origin			origin	0000	1.0.	destination	code	destinatio		0000
s of												
etail	l.11.	Place of or	igin				I.12.	Place of destina	tion			
ă												
art		Name		Appro	val number					Custom wareho	ouse	
ш		Address						Name		Approval numb	er	
		Name		Appro	val number			Address				
		Address										
		Name		Appro	val number			Postcode				
		Address										
	I.13.	Place of loa	ading				I.14.	Date of departu	re			
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU				
		Aeroplane	□ Ship		Railway wa	agon 🗖						
		Road vehic	cle 🛛 Othe	er 🗖			I.17.					
		Identificatio	on					_				
		Documenta	ation reference	ces								
	l.18.	Descriptior	n of commodi	ity					I.19. Comm	nodity code (HS c	ode)	
										I.20. Quantity		
	I.21.		re of product	t	_	-		_	_	I.22. Number	of pac	kages
		Ambient			Chilled <b>C</b>	1		Frozen				
	1.23.	Seal/Conta	ainer No							I.24. Type of p	backag	ging

1.25.	Commodities certif	ied for:				
	Petfood			Tech	nnical 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		oval number	of establishments		
(5	Species Scientific name)	Nature of commodity	Manufactu	uring plant	Net weight	Batch number

Г									of petfoo
	II.	Health info	ormati	on		II.a.	Certificate reference No		II.b.
		the Europe Regulation	ean Pa (EU)	arliamei No 142	nt and of the ( /2011 ( <sup>1b</sup> ), and	Counci in par	e that I have read and understood il ( <sup>1</sup> a), and in particular Article 8 ticular Chapter III of Annex XIII ar described above:	and	10 thereof, and Commission
	II.1.	consist of a	nimal	by-proc	lucts that satisf	/ the a	nimal health requirements below;		
	II.2.	have been	prepa	red and	include the foll	owing	animal by-products which are exc	lusive	ly:
		(²) either	[-	killed,	and which are	fit for	nals slaughtered or, in the case of human consumption in accordanc aption for commercial reasons;]		
		(²) and/or	[-	slaugl morte	hterhouse and m inspection o	were c r bodi	parts originating either from anim considered fit for slaughter for hun es and the following parts of an with Union legislation:	nan co	onsumption following an ant
				(i)	consumption	in acc	es and parts of animals which cordance with Union legislation, b able to humans or animals;		
				(ii)	heads of pou	ltry;			
				(iii)			cluding trimmings and splitting the carpus and metacarpus bones, tar		
				(iv)	pig bristles;				
				(v)	feathers;]				
		(²) and/or	[-	huma havin	ns or animals, o g been conside	obtaine ered f	d not show any signs of diseas ed from animals that have been sl it for slaughter for human cons ith Union legislation;]	aughte	ered in a slaughterhouse aft
		(²) and/or	[-			-	from the production of products greaves and centrifuge or separate		•
		(²) and/or	[-	intenc	led for human c	onsun	r foodstuffs containing products o nption for commercial reasons or o defects from which no risk to publi	due to	problems of manufacturing
		(²) and/or	[-	derive proble	ed products, wh	nich ar	of animal origin, or feedingstuffs e no longer intended for feeding or packaging defects or other def	for c	commercial reasons or due
		(²) and/or	[-		did not show s		ners, hair, horns, hoof cuts and ra of any disease communicable th		
		(²) and/or	[-				of such animals, except sea mam to humans or animals;]	imals,	which did not show any sig
		(²) and/or	[-		al by-products fr cts for human c		uatic animals originating from plar nption;]	nts or	establishments manufacturir
		(²) and/or	[-				ginating from animals which did material to humans or animals:	l not	show any signs of diseas
				(i)					

II.	Health info	rmatior	า		II.a. Certificate reference No	II.b.
		(	(ii) the fo	ollowing	originating from terrestrial animals:	
			_	hatche	ery by-products,	
			_	eggs,		
			-	egg b	y-products, including egg shells;	
		(	(iii) day-o	old chick	s killed for commercial reasons;]	
	(²) and/or		animal by-pr humans or a		rom aquatic or terrestrial invertebrat	tes other than species pathogenic
	(²) and/or	- (	Category 1 n	naterial a	thereof of the zoological orders of as referred to in Article 8(a)(iii), (iv) and rial as referred to in Article 9(a) to (g)	d (v) of Regulation (EC) No 1069/200
	(²) and/or	- (	Council Dire	ctive 96/	s which have been treated with certai /22/EC ( <sup>2a</sup> ), the import of the materia gulation (EC) No 1069/2009;]	
II.3.	have been order to kill			sing in ac	ccordance with Chapter III of Annex X	III to Regulation (EU) No 142/2011,
II. <b>4</b> .					of at least five samples from each p plies with the following standards (³) :	rocessed batch taken during or aft
	Salmonella	:	ab	sence in	25g: n = 5, c = 0, m = 0, M = 0,	
	Enterobacte	eriaceae	e: n =	5, c = 2	, m = 10, M = 300 in 1 gramme;	
II.5.	the end pro	duct wa	S:			
	(²) either	[pack	ed in new or	sterilised	d bags,]	
	( <sup>2</sup> ) or	-	•		ontainers or other means of transpo ant approved by the competent author	
	and which b	bear lab	els indicating	) 'NOT F	OR HUMAN CONSUMPTION';	
II.6.	the end pro	duct wa	s stored in e	nclosed	storage;	
II.7.	the product	has und	dergone all p	recaution	ns to avoid contamination with pathog	enic agents after treatment;
(²) [II.8.	the flavouri	ng innar	ds products	describe	d above	
	(²) either	[is de	rived from ot	her rumiı	nants than bovine, ovine or caprine ar	nimals.]]
	(²) or	[is de	rived from bo	ovine, ov	ine or caprine animals and does not c	ontain and is not derived from:
		(²) eiti	conti	nuously	e and caprine materials other than reared and slaughtered in a coun E risk in accordance with Decision 20	try or region classified as posing
		(²) or	[(a)	specif No 99	fied risk material as defined in poir 99/2001 of the European Parliament a	nt 1 of Annex V to Regulation (En nd of the Council ( <sup>4</sup> );
			(b)	anima slaugi accore	anically separated meat obtained fro als, except from those animals that htered in a country or region classifi dance with Commission Decision 200 ligenous BSE case,	were born, continuously reared an ed as posing a negligible BSE risk
			(c)	anima nervo the cr those	I by-product or derived product obt als which have been killed, after si us tissue by means of an elongated anial cavity, or by means of gas inje animals that were born, continuously ion classified as posing a negligible	tunning, by laceration of the centr rod-shaped instrument introduced in cted into the cranial cavity, except f y reared and slaughtered in a count

П.	Health information	II.a. Certificate reference No	II.b.						
Not									
Par									
		the consignment in the European Union: thi ansited through the European Union; it ma an 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.							
		(railway wagons or container and lorries), fli of unloading and reloading in the European							
—	Box reference I.19: use the appropriate H	S code: 05.04; 05.06, 05.11 or 23.09 .							
—	Box reference I.23: for bulk containers, the	e container number and the seal number (if	applicable) should be given.						
—	Box reference I.25: technical use: any production or manufacturing of pet food.	use other than feeding of farmed animal	ls, other than fur animals, and the						
_	Box reference I.26 and I.27: fill in accordin	ng to whether it is a transit or an import certi	ficate.						
_	Box reference I.28:								
	<ul> <li>— species: select from the following: Mollusca, Crustacea, Invertebrates</li> </ul>	Aves, Ruminantia, Suidae, Mammalia other other other other other than Mollusca and crustacea	than Ruminantia or Suidae, Pesca						
	<ul> <li>define the innard product.</li> </ul>								
Par	t II:								
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.								
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.								
(²)	Delete as appropriate.								
( <sup>2a</sup> )	OJ L 125, 23.5.1996, p. 3.								
( <sup>3</sup> )	Where:								
	n = number of samples to be tested;								
	m = threshold value for the number of samples does not exceed m;	bacteria; the result is considered satisfac	tory if the number of bacteria in al						
	M = maximum value for the number of t or more samples is M or more; and	bacteria; the result is considered unsatisfac	tory if the number of bacteria in one						
	c = number of samples the bacterial of acceptable if the bacterial count of t	count of which may be between m and N he other samples is m or less.	I, the 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 colour to that of the printing.							
	Note for the person responsible for the co and must accompany the consignment un	nsignment in the European Union: This cert itil it reaches the border inspection post.	ificate is only for veterinary purposes						
Offi	cial veterinarian/Official inspector								
	Name (in capital letters):	Qualific	ation and title:						
	Date:	Signatu	ire:						
	Stamp:								

## CHAPTER 3(F)

### Health certificate

For animal by-products  $\binom{3}{}$  for the manufacture of petfood, intended for dispatch to or for transit through  $\binom{2}{}$  the European Union

Veterinary certificate to EU

	l.1.	Consignor	1.2.	Certificate reference N	٥V	l.2.a.	
		Name	1.3.	3. Central competent authority			
		Address	1.4.	Local competent author	ority		
		Tel.					
	1.5.	Consignee	1.6.	Person responsible for	r the load ir	n EU	
nent		Name		Name			
ignr		Address		Address			
Part I : Details of dispatched consignment		Postcode		Postcode			
ed e		Tel.		Tel.			
atch	1.7.	Country ISO code I.8. Region of Code	1.9.	Country of ISC	0 1'	10. Region of	Code
disp	1.7.	of origin origin	1.0.		de	destination	0000
s of							
etail	l.11.	Place of origin	I.12.	Place of destination			
ם 							
Part		Name Approval number			C	Custom warehouse	
_		Address		Name	A	Approval number	
		Name Approval number		Address			
		Address					
		Name Approval number		Postcode			
	112	Address Place of loading	114				
	1.13.	Flace of loading	1.14.	Date of departure			
	l.15.	Means of transport	I.16.	Entry BIP in EU			
		Aeroplane Ship Railway wagon					
			1.17.		_		
		Identification					
	140	Documentation references			0		
	1.18.	Description of commodity		1.19.	Commoa	ity code (HS code)	
					1	.20. Quantity	
	1.21.	Temperature of product				.22. Number of pac	kages
		Ambient  Chilled		Frozen 🗖		P	J.
	1.23.	Seal/Container No			1	.24. Type of packag	ging

1.25.	Commodities cer	tified for:				
	Manufacture of p	etfood 🗖	Further pro	ocess 🗖	Technical use 🗖	
I.26.	For transit throug	gh EU to third count	ry 🗖	I.27. For import or	admission into EU	
	Third country	ISO c	ode			
1.28.	Identification of th	he commodities				
			Approval number	of establishments		
(Sci	Species ientific name)	Nature of commodity	Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY					Ar	nimal by-products for the manufactur of petfoo					
II.	Health inf	forma	tion		II.a. Certificate reference No	II.b.					
	the Europ	ean l	Parliame	ent and of		erstood Regulation (EC) No 1069/2009 egulation (EU) No 142/2011 ( <sup>1b</sup> ), and products described above:					
II.1.1.	consist of	anima	al by-pro	oducts that	satisfy the animal health requirements	below;					
II.1.2.	have beer	n obta	ined in t	he territory	of: (1°) f	from animals:					
	(²) either	[(a)			ed in this territory since birth or for a p ter or production;]	period of at least three months precedir					
	(²) or	[(b)	killed ir	n the wild in	this territory ( <sup>1d</sup> );]						
	(²) or	[(c)	derived	d from roder	nts, lagomorphs, aquatic animals or ter	rrestrial or aquatic invertebrates;]					
II.1.3.	have beer	n obta	ined fro	m or produc	ced by animals:						
	(²) either	[(a)	coming	oming from holdings:							
no case/c pathogeni African su					utbreak of rinderpest, swine vesicula c avian influenza during the period of t vine fever during the period of the p	animals are susceptible, there has bee r disease, Newcastle disease or high the preceding 30 days, nor of classical preceding 40 days; nor in the holding rring the period of the preceding 30 day					
			(ii)	the preced		-and-mouth disease during the period ted in their vicinity within a 25 km radiu					
		(b)	which:								
			(i)	were not k	illed to eradicate any epizootic disease	e;					
			(ii)	of departu		eriod of at least 40 days before the da lirectly to the slaughterhouse without ar with the same health conditions;					
			(iii)	of 24 hour		ortem health inspection during the perio have shown no evidence of the disease eptible; and					
			(iv)	accordanc	e with the relevant provisions of Unio quivalent to those laid down in Chapte	e and at the time of slaughter or killing n legislation and have met requiremen ers II and III of Council Regulation (E0					
	(²) or	[(a)	capture	ed and kille	d in the wild in an area:						
			(i)	diseases Newcastle preceding	for which the animals are susceptib disease or highly pathogenic avia	no case/outbreak of any of the followir le: foot-and-mouth disease, rinderpes an influenza during the period of th n swine fever during the period of th					
			(ii)	country no		any country or part of the territory of ean Union of poultry material during th the preceding 40 days; and					
		(b)	either f	to a collect		12 hours following the killing for chillir Is to a game handling establishment,					

н.	Health inform	ation		II.a. Certificate reference No	II.b.			
II.1.4.	have been obtained in an establishment around which, within a radius of 10 km, there has been no case/outbiof the diseases referred to in point II.1.3 for which the animals are susceptible during the period of the prece 30 days or, in the event of a case of disease, the preparation of raw material for exportation to the Europ Union has been authorised only after the removal of all meat, and the total cleaning and disinfection of establishment under the control of an official veterinarian;							
II.1.5.		have been obtained and prepared without contact with any other material that does not comply with the conditions required above, and it has been handled so as to avoid contamination with pathogenic agents;						
II.1.6.	indicating 'RAV	N MATER	IAL ONLY I	g preventing any leakage and in officia FOR THE MANUFACTURE OF PET FO European Union;				
II.1.7.	consist only of	the follow	ing animal l	oy-products:				
	( <sup>2</sup> ) either [-	( <sup>2</sup> ) 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;]						
	( <sup>2</sup> ) and/or [-	slaught mortem	erhouse and inspection	ollowing parts originating either from ar d were considered fit for slaughter for h or bodies and the following parts of ordance with Union legislation:	human consumption following an ante			
		(i)	consumptio	or bodies and parts of animals whi n in accordance with Union legislation mmunicable to humans or animals;				
		(ii)	heads of po	pultry;				
		(iii)		skins, including trimmings and splitting and the carpus and metacarpus bones,				
		(iv)	pig bristles;					
		(v)	feathers;]					
	( <sup>2</sup> ) and/or [-			arising from the production of produ d bone, greaves and centrifuge or sepa				
	( <sup>2</sup> ) and/or [-	intende	d for human	origin, or foodstuffs containing product consumption for commercial reasons or other defects from which no risk to p	or due to problems of manufacturing o			
	( <sup>2</sup> ) and/or [-			id parts of such animals, except sea m nicable to humans or animals;]	ammals, which did not show any sigr			
	( <sup>2</sup> ) and/or [-			from aquatic animals originating from p consumption;]	plants or establishments manufacturin			
	( <sup>2</sup> ) and/or [-			erial originating from animals which ugh that material to humans or animals				
		(i)	shells from	shellfish with soft tissue or flesh;				
		(ii)	the followin	g originating from terrestrial animals:				
			— hato	chery by-products,				
			— egg	S,				
			— eaa	by-products, including egg shells;				

				of petfoo
II.	Health information	II.a.	Certificate reference No	II.b.
	(iii)	day-old chicks kille	ed for commercial reasons;]	
		al by-products from ans or animals;]	aquatic or terrestrial invertebrat	es, other than species pathogenic t
	Cate	gory 1 material as ref		Rodentia and Lagomorpha, excep d (v) of Regulation (EC) No 1069/200 of that Regulation;]
	Cour	ncil Directive 96/22/E		in substances which are prohibited b al being permitted in accordance wit
II.1.8.	legislation in such a	way that they will not		in accordance with European Unio ivery to the plant of destination in th
II.1.9.		r the manufacture of		with certain substances prohibited b ted in accordance with Article 35(a)(i
	liquefied charco transported in p of destination in	al or activated carbor allets which are not d the European Union a way that the mark	n on each outer side of each froz ivided into separate consignmen or during the transit through the	r of the European Union by a cross of zen block, or, when the raw material i ts during transport to the petfood plar e European Union, on each outer sid liagonal length of the frozen block an
	entry into the te	rritory of the Europea		en marked in the third country befor efied charcoal or by applying charcoa al; and
				been treated as referred to above an ked as referred to in point (a) and (t
( <sup>2</sup> ) ( <sup>5</sup> ) [II.2.	Specific requirements			
( <sup>2</sup> ) ( <sup>6</sup> ) [II.2.1.		nation programmes a	against foot-and-mouth disease	ept in the territory referred to in poir are being regularly carried out an
( <sup>2</sup> ) ( <sup>7</sup> ) [II.2.2.	ruminants, which hav	re maturated at an a	mbient temperature of more that	erived from trimmed offal of domesti n + 2 °C for a period of at least thre meat of domestic animals, for a perio
( <sup>2</sup> ) [II.3.	the animal by-produc origin and:	ts for the manufacture	e of petfood contains or is derive	d from animal-by products of ruminar
			ion, which is classified as posin d in which there has been no indi	g a negligible BSE risk in accordanc genous BSE case, and]]
	Decision 2 or derived ruminants	2007/453/EC in which product were derived with meat-and-bone	there has been an indigenous from animals born after the date	gligible BSE risk in accordance wit BSE case, and the animal by-produc e from which the ban on the feeding o m ruminants, as defined in the OI that country or region, and]]

col	JNTRY				Anin	nal by-products for the manufacture of petfood
II.	Health in	nformation		II.a.	Certificate reference No	II.b.
	( <sup>2</sup> ) or	[is derived	from bovine,	ovine	or caprine animals and does not c	ontain and is not derived from:
		(²) either	continuous	y rea		n those derived from animals born, try or region classified as posing a 07/453/EC.]]]
		(²) or			risk material as defined in poir 001 of the European Parliament a	nt 1 of Annex V to Regulation (EC) nd of the Council $(^8)$ ;
			anii slau acc	nals, ughtere ordane	except from those animals that ed in a country or region classifi	om bones of bovine, ovine or caprine were born, continuously reared and ed as posing a negligible BSE risk in 07/453/EC( <sup>9</sup> ), in which there has been
			anii ner the those or r	nals v vous ti crania se anii egion	which have been killed, after s issue by means of an elongated al cavity, or by means of gas inje mals that were born, continuously	tained from bovine, ovine or caprine tunning, by laceration of the central rod-shaped instrument introduced into cted into the cranial cavity, except for y reared and slaughtered in a country BSE risk in accordance with Decision
Not						
Parl	Box reference I.6					this box is to be filled in only if it is a dity to be imported into the European
_					s to be filled in only if it is a certifi arehouses and custom warehouse	cate for a transit commodity. Products s.
_					wagons or container and lorries), ing and reloading in the Europear	flight number (aircraft) or name (ship); i Union.
_	Box reference I.1	9: use the ap	oropriate HS	code: (	05.04; 05.06; 05.07; 05.11.91 or 0	5.11.99; 23.01; 41.01.
_	Box reference I.2	3: for bulk cor	ntainers, the o	ontair	ner number and the seal number (	if applicable) should be included.
_	Box reference I. production or ma			e oth	er than feeding of farmed anim	als, other than fur animals, and the
_	Box reference I.2	6 and I.27: fill	in according	to whe	ether it is a transit or an import cer	tificate.
_	Box reference I.2	8:				
					uminantia, Suidae, Mammalia oth In Mollusca and Crustacea;	er than Ruminantia or Suidae, Pesca,
	— Manufactur	ing plant: pro	vide the veter	inary o	control number of the approved es	stablishment.
Part	t II:					
( <sup>1a</sup> )	OJ L 300, 14.11.2	2009, p. 1.				
. ,	,	••				

(<sup>1b</sup>) OJ L 54, 26.2.2011, p. 1.

CO	JNTRY		Ani	mal by-products for the manufacture of petfood				
П.	Health information	II.a.	Certificate reference No	II.b.				
( <sup>1c</sup> )	The name and ISO code number of the expo	orting o	country as laid down in:					
	— Part 1 of Annex II to Regulation (EU) No 206/2010;							
	— Part 1 of Annex I to Regulation (EC) N	lo 798/	/2008, and					
	— Part 1 of Annex I to Regulation (EC) N	lo 119/	/2009.					
	In addition the ISO code of regionalisation in the abovementioned Annexes (where applicable for the susceptible species concerned) must be included.							
( <sup>1d</sup> )	Only for countries from which game meat ir importation into the European Union.	ntende	d for human consumption of the	same animal species is authorised for				
( <sup>2</sup> )	Delete as appropriate.							
(3)	Excluding raw blood, raw milk, hides and certificates in that Annex for the import of the			es and feathers (see relevant specific				
(4)	OJ L 303, 18.11.2009, p. 1.							
( <sup>4a</sup> )	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	African	i countries.					
( <sup>8</sup> )	OJ L 147, 31.5.2001, p. 1.							
( <sup>9</sup> )	OJ L 172, 30.6.2007, p. 84.							
_	The signature and the stamp must be in a di	fferent	t colour to that of the printing.					
-	Note for the person responsible for the cons and must accompany the consignment until							
Offi	cial veterinarian/Official inspector							
	Name (in capital letters):		Qual	ification and title:				
	Date:		Sign	ature:				
	Stamp:							

## CHAPTER 4(A)

#### Health certificate

For the import of blood and blood products from equidae to be used outside the feed chain, for dispatch to or for transit through  $\binom{2}{}$  the European Union

cou	NTR	1	Veterinary certificate to EU				
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.				
		Address	I.3. Central competent authority				
		Tel.	I.4. Local competent authority				
ment	1.5.	Consignee Name	I.6. Person responsible for the load in EU Name				
nsign		Address	Address				
Part I: Details of dispatched consignment		Postcode Tel.	Postcode Tel.				
f dispat	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination				
ails o	l.11.	Place of origin	I.12. Place of destination				
t I: Det		Name Approval number Address	Name Custom warehouse Address Approval number				
Par		Name Approval number Address	Postcode				
		Name Approval number Address					
	l.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					
		Identification	l.17.				
		Documentation references					
	l.18.	Description of commodity	I.19. Commodity code (HS code)				
			I.20. Quantity				
	l.21.	Temperature of product Ambient  Chilled	I.22. Number of packages				
	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	I.27. For import or admission into EU				
	1.28.	Identification of the commodities					
		Species (Scientific name)	Approval number of establishments Manufacturing plant				

JNTRY			feed chain						
П.	Health infor	rmation	II.a. Certificate reference No	II.b.					
	and of the C	ouncil (1a) and in particular Article 8(c) and	ave read and understood Regulation (EC) No d (d) and Article 10 thereof, and Commission rtify that the blood or blood products of equic	Regulation (EU) No 142/2011 ( <sup>1b</sup> ), an					
II.1.	consist of bl	ood or blood products from equidae that	satisfy the health requirements below;						
II.2.	consist exclusively of blood or blood products of equidae not intended for human or animal consumption;								
11.3.	column "thirc following dise	been obtained from animals that originate from the EU Member States or from a third country, territory or part thereof listed in the mn "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 wing diseases are compulsorily notifiable: African horse sickness, dourine, glanders ( <i>Burkholderia mallel</i> ), equine encephalomyelitis (all s including Venezuelan equine encephalomyelitis), equine infectious anaemia, vesicular stomatitis, rables, anthrax;							
11.4.	accordance supervised b of the countr	with Regulation (EC) No 853/2004 of the by the competent authority of the country	as collected under the supervision of a veteri e European Parliament and of the Council of collection and in facilities approved and ng blood from equidae for the production of b	( <sup>3</sup> ), in slaughterhouses approved an supervised by the competent authorit					
II.5.	have been d	lerived from blood which was collected from	om 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 ( <sup>4</sup> ), 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;								
II.5.2.		bject to a prohibition order pursuant to A		and during blood collection on holdings under veterinary supervision which 5) or restrictions for African horse sickness in accordance with Article 5 of					
II.5.3.	which had no contact with equidae from a holding which was subject to a prohibition order for animal health reasons pursuant to Article 4(5) of Directive 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 susceptil period of prohibition must be at least:	ble to the disease located on the holding have	e been slaughtered , in which case th					
		<ul> <li>— six months in the case of glanders disease are slaughtered,</li> </ul>	(Burkholderia mallei), beginning on the date of	on which the equidae infected with th					
			e encephalomyelitis of any type, including N e equidae infected with the disease are slaug						
			emia, until the date on which, the infected ani egative reaction to two Coggins tests carried						
		— six months from the date of the las	st recorded case of vesicular stomatitis,						
		— one month from the date of the las	st recorded case of rabies,						
		<ul> <li>— 15 days from the date of the last re</li> </ul>	ecorded case of anthrax;]						
	( <sup>2</sup> ) or	disinfected, in which case the period of	to the disease located on the holding have be of prohibition must be 30 days, beginning or red, except in the case of anthrax, where the	n the date on which the animals wer					
II.6.		cts come from an establishment or plant ditions set out in Article 23 or 24 of Regu	approved or registered by the competent aut Ilation (EC) No 1069/2009;	hority of the third country meeting th					
11.7.	blood produc	cts have been produced from blood which	h fulfils the conditions referred in II.4 and II.5	and					
	( <sup>2</sup> ) either		ch have been kept for a period of at least th collection on holdings under veterinary superv lood collection has been free of:						
		(a) African horse sickness for two yea							

				feed chain						
II.	Health info	ormation		II.a. Certificate reference No	II.b.					
	(b) Venezuelan equine encephalomyelitis for a period of at least two years;									
		(c) glanders								
		(²) either	[for a period of three years;]							
		( <sup>2</sup> ) or	slaughterhouse referred to in I	.4, including a careful examination of	t-mortem inspection for glanders in the mucous membranes from the trachea ting the head in the median plane and					
		(d) in the case	e of blood products other than se	erum and plasma, vesicular stomatitis	for six months;]]					
	( <sup>2</sup> ) or	possible cause	ative pathogens for African horse		ctiveness check, for the inactivation o all types including Venezuelan equine <i>kholderia mallei</i> ):					
		( <sup>2</sup> ) either	[heat treatment at a temperatu	re of 65°C for at least three hours;]						
		(²) and/or	[irradiation at 25 kGy by gamr	na rays;]						
		(²) and/or	[change in pH to pH 5 for two	hours;]						
		(²) and/or	[heat treatment of at least 80°	C throughout their substance;]]						
II.8.	all precauti and packa		en to avoid contamination of the l	plood and blood products with pathoge	enic agents during production, handling					
11.9.		blood products PTION" and bearir		rmeable containers clearly labelled	"NOT FOR HUMAN OR ANIMAI					
	(a) in the c	case of blood, the	approval number of the establis	hment of collection;						
	(b) in the c	case of blood pro	ducts, the approval number of the	e establishment of production;						
II.10.	the produc	ts were stored in	enclosed storage.							
Notes										
Part I:										
			sible for the consignment in the E ne certificate is for import commo		ed in only if it is a certificate for transi					
	reference I. nority.	11 and I.12: Appr	oval number: the registration num	ber of the establishment or plant, whi	ich has been issued by the competer					
			nation: this box is to be filled in o ehouses and custom warehouses	nly if it is a certificate for transit comm	nodity. The products in transit can onl					
			umber (railway wagons or contai the consignor must inform the Bl	ner and lorries), flight number (aircraf IP of entry into the EU.	t) or name (ship) is to be provided. I					
— Box	I.19: use th	e appropriate Ha	monized System (HS) code unde	er the following heading: 30.02.						
— Box	reference I.	23: for bulk conta	iners, the container number and	the seal number (if applicable) must	be included.					
— Box	reference I.	25: technical use:	any use other than for animal c	onsumption.						
— Box	reference I.	26 and I.27: fill in	according to whether it is a tran	sit or an import certificate.						
— Box	reference I.	28:								
(a)	Manufacturir	ng plant:								
	(i) in the ca	se of blood, prov	ide the approval number of the re	egistered establishment of collection;						
	(ii) in the ca	use of blood produ	ucts, provide the approval numbe	r of the establishment of production;						
(1-)	Species: sel	ect amonast the f	ollowing: Equus cabalus, Equus	asinus. Equus cabalus*asinus						

cou	NTRY	feed chain					
II.	Health information	II.a. Certificate reference No	II.b.				
Part	П:						
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.						
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1						
( <sup>2</sup> )	Delete as appropriate.						
(3)	OJ L 139, 30.4.2004, p. 55.						
(4)	OJ L 192, 23.7.2010, p. 1.						
— 1	he signature and the stamp must be in a different colo	our to that of the printing.					
	Note for the person responsible for the consignment in the consignment until it reaches the border inspection p		veterinary purposes and must accompar				
Offic	ial veterinarian/Official inspector						
١	lame (in capital letters):	Q	ualification and title:				
[	Date:	Si	gnature:				
5	Stamp:						

Blood and blood products from equidae for purposes outside the

## CHAPTER 4(B)

#### Health certificate

For blood products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through  $(^2)$  the European Union

### COUNTRY:

Veterinary certificate to EU

	l.1.	Consignor	1.2.	Certificate reference	ce No	I.2.a.
		Name	1.3.	Central competent	authority	
		Address	1.4.	Local competent a	uthority	
		Tel.				
	1.5.	Consignee	1.6.	Person responsible	e for the load	in EU
nent		Name		Name		
ignn		Address		Address		
suos		Postcode		Postcode		
led o		Tel.		Tel.		
atch	1.7.	Country ISO code I.8. Region of Code	1.9.	Country of	ISO	I.10. Region of Code
disp	1.7.	of origin origin	1.0.	destination	code	destination
s of						
Part I : Details of dispatched consignment	I.11.	Place of origin	I.12.	Place of destinatio	'n	
<u> </u>						_
Part		Name Approval number				Custom warehouse
		Address		Name		Approval number
		Name Approval number		Address		
		Address				
		Name Approval number		Postcode		
	140	Address	144	Data of donorturo		
	1.13.	Place of loading	1.14.	Date of departure		
	I.15.	Means of transport	I.16.	Entry BIP in EU		
		Aeroplane  Ship  Railway wagon				
		Road vehicle 🔲 Other 🗖	1.17.			
		Identification				-
	140	Documentation references			10 0	
	1.18.	Description of commodity		1.	.19. Commo	dity code (HS code)
						I.20. Quantity
	121	Temperature of product				I.22. Number of packages
		Ambient Chilled		Frozen 🗖		
	1.23.	Seal/Container No				I.24. Type of packaging
l						51 1 5.05

1.25.	Commodities certified for:					
	Animal feedingstuff 🗖		Monufacti	ire of petfood 🗖	Technical	
			Manuacu		recrimca	
1.26.	For transit through EU to third	d country		I.27. For import or admissic	n into EU	
	Third country	ISO code				
1.28.	Identification of the commodi	ties				
		Appro	val number	of establishments		
	Species (Scientific name)	Nature of comn	nodity	Manufacturing plant		Batch number

				could be used as feed materia						
II.	Health infor	mation	II.a. Certificate reference No	II.b.						
	the Europea		Council (1a) and Commission Regul	derstood Regulation (EC) No 1069/2009 o ation (EU) No 142/2011 ( <sup>1b</sup> ) and certify tha						
II.1.	consist of blo	ood products that satisfy	the health requirements below;							
II.2.	consist exclu	exclusively of blood products not intended for human consumption;								
II.3.		repared and stored in a Regulation (EC) No 106		the competent authority in accordance with						
II.4.	have been prepared exclusively with the following animal by-products:									
	(²) either	( <sup>2</sup> ) <i>either</i> [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	accordance with Uni humans or animals slaughterhouse and	ion legislation, but which did not sho , which has been derived from ca	cted as unfit for human consumption in ow any signs of diseases communicable to arcases that have been slaughtered in a an consumption following an ante-morten						
II.5.	in order to in	in order to inactivate pathogenic agents, have been submitted								
	( <sup>2</sup> ) <i>either</i> [to processing in accordance with processing method									
	( <sup>2</sup> ) or	[to a method and parameters which ensure that the product complies with the microbiological 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 origin intended for the feeding of porcine animals, to a heat treatment at a temperature of at least 80°C throughout the substance and the dry blood and blood plasma does not contain more than 8% w/w moisture with a water activity (Aw) of less than 0,60.]								
II.6.	the end prod	uct was:								
	( <sup>2</sup> ) either	[packed in new or sterilised bags;]								
	( <sup>2</sup> ) or	[transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]								
	and which be	ear labels indicating 'NC	T FOR HUMAN CONSUMPTION';							
II.7.	the end prod	uct was stored in enclos	sed storage;							
II.8.	the product h	nas undergone all preca	utions to avoid contamination with pa	athogenic agents after treatment;						
	( <sup>2</sup> ) and	intended for the fee		blood and blood plasma of porcine origi stored in dry warehouse conditions unde						
II.9.			atch under the responsibility of the orage which was found to comply wi	competent authority by taking a randon th the following standards ( <sup>4</sup> ):						
	Salmonella:	absence i	in 25g: n = 5, c = 0, m = 0, M = 0,							
	Enterobacter		= 2, m = 10, M = 300 in 1 gram;							

COUNTR						could be used as feed materi			
II.	Health info	rmation		II.a.	Certificate reference No	II.b.			
(²) [II.10.	). the blood products described above								
	(²) either	[is derived	d from othe	r ruminant	s than bovine, ovine or caprine ar	nimals.]]			
	(²) or	[is derived	d from bovir	ne, ovine c	r caprine animals and does not c	ontain and is not derived from:			
		(²) either	continuou	isly reared		those derived from animals born y or region classified as posing 7/453/EC.]]			
		(²) or	[(a)		l risk material as defined in poil 2001 of the European Parliament	nt 1 of Annex V to Regulation (EC and of the Council $(5)$ ;			
			(b)	animals, slaughte accorda	except from those animals that red in a country or region classifi	om bones of bovine, ovine or caprir were born, continuously reared ar ed as posing a negligible BSE risk 2007/453/EC ( <sup>6</sup> ), in which there ha			
			(c)	animals nervous into the except fo in a cour	which have been killed, after si tissue by means of an elongate cranial cavity, or by means of or those animals that were born,	tained from bovine, ovine or caprir tunning, by laceration of the centr d rod-shaped instrument introduce gas injected into the cranial cavit continuously reared and slaughtere a negligible BSE risk in accordance			
II.11.	the blood pr	oducts descri	bed above:						
	(²) either		ontain milk o himals, othe			origin or is not intended for feed for			
	(²) or		nilk or milk other than fi			and is intended for feed for farme			
		(a)			vine and caprine animals which here the following conditions are f	have been kept continuously sinc ulfilled:			
			(i)	classica	scrapie is compulsorily notifiable	;			
			(ii)	an awar scrapie;	eness, surveillance and monitor	ring system is in place for classic			
			(iii)		estrictions apply to holdings of ov ion of TSE or the confirmation of	ine or caprine animals in the case classical scrapie;			
			(iv)	ovine a destroye		th classical scrapie are killed ar			
			(v)	as define Animal	ed in the Terrestrial Animal Healt Health (OIE), of ruminant origir I in the whole country for a	of meat-and-bone meal or greave h Code of the World Organisation for has been banned and effective period of at least the precedir			
		(b)	originate TSE;	from holdi	ngs where no official restrictions	are imposed due to a suspicion			

COUN	ITRY			Blood products not in		for human consumption that ould be used as feed material
Н.	Health info	rmation	II.a.	Certificate reference No		II.b.
		(²) either	or slaug ewes ca	e and caprine animals on the h htered, except for breeding ram arrying at least one ARR allele carrying at least one ARR allele	is of the	ARR/ARR genotype, breeding
		(²) or	destroye two yea intensifi presence point 3.2 the follo	mals in which classical scrapie ed, and the holding has beer rrs since the date of confirmatic ed TSE monitoring, including ce of TSE in accordance with 2 of Chapter C of Annex X to F owing animals which are over a of the ARR/ARR genotype:	n subject on of the testing n the la Regulation	cted for a period of at least b last classical scrapie case to with negative results for the boratory methods set out in on (EC) No 999/2001, of all of
			— ar	nimals which have been slaughte	ered for	human consumption; and
				nimals which have died or beer ot killed in the framework of a dis		
II.12.		oducts described above the statement of the Co		r are derived from animal-by pro eferred to in Box I.1,	oducts o	f non-ruminant origin, and are,
	(²) either	[not intended for the p	production	n of feed for farmed animals, oth	ner than	fur animals.]
	(²) ( <sup>7</sup> ) or	Consignor has under	taken to e ses carri	feed for non-ruminant farmed a ensure that the border inspectior ied out in accordance with th No 152/2009 ( <sup>8</sup> ).]	n post of	fentry will be provided with the
Notes	5					
Part I	:					
i	t is a certificate fo		be trans	gnment in the European Union: t ited through the European Unio bean Union.		
				to be filled in only if it is a certifi ehouses and custom warehouse		a transit commodity. Products
				agons or container and lorries), g and reloading in the European		mber (aircraft) or name (ship);
— E	Box reference I.19	: use the appropriate HS	code: 05	5.11.91, 05.11.99, 35.02 or 35.04	4.	
— E	Box reference I.23	: for bulk containers, the	containe	r number and the seal number (	if applica	able) should be included.
		5: technical use: any ι ufacturing of pet food.	use other	r than feeding of farmed anim	als, oth	er than fur animals, and the
— E	Box reference I.26	and I.27: fill in according	g to whet	her it is a transit or an import cer	rtificate.	
	Box reference   28	B: Species: select from t	the follow	ving: Avon Ruminantia Suidan		

col	JNTRY	Blood products not int	ended for human consumption that could be used as feed material
II.	Health information	II.a. Certificate reference No	II.b.
Par	t II:		
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.		
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.		
(2)	Delete as appropriate.		
(3)	Insert method 1 to 5 or method 7 as applicab	le.	
(4)	Where:		
	n = number of samples to be tested;		
	m = threshold value for the number of ba samples does not exceed m;	cteria; the result is considered satisfa	ctory if the number of bacteria in all
	M = maximum value for the number of bac or more samples is M or more; and	teria; the result is considered unsatisfa	ctory if the number of bacteria in one
	c = number of samples the bacterial cou acceptable if the bacterial count of the		M, the sample still 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 certificate are intended to be used for the pro- consignment must be analysed, in accordan order to verify the absence of unauthorised must be attached to this health certificate wh Union.	oduction of feed for non-ruminant farme ce with the methods set out in Annex \ constituents of animal origin. The infor	d animals, other than fur animals, the /I to Regulation (EC) No 152/2009, in mation on the result of such analysis
(8)	OJ L 54, 26.2.2009, p. 1.		
_	The signature and the stamp must be in a dif	ferent colour to that of the printing.	
_	Note for the person responsible for the consi and must accompany the consignment until Union.		
Offic	cial veterinarian/Official inspector		
	Name (in capital letters):	Qualifi	cation and title:
	Date:	Signat	ure:
	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  $\binom{2}{1}$  the European Union

COL	JNTRY	<b>'</b> :								Veterinary certi	ficate to EU
	l.1.	Consignor					1.2.	Certificate referer	nce No	I.2.a.	
		Name					1.3.	Central competer	it authority	Letter-	
		Address					1.4.	Local competent	authority		
		Tel.									
	I.5.	Consignee					1.6.	Person responsib	le for the loa	ad in EU	
nent		Name						Name			
ignr		Address						Address			
Part I : Details of dispatched consignment		Postcode						Postcode			
) pər		Tel.						Tel.			
batcl	1.7.		ISO code	1.8.	Region of	Code	1.9.	Country of	ISO	I.10. Region of	Code
disp		of origin		1	origin	-		destination	code	destination	_
ls of											
Detai	I.11.	Place of origi	in				I.12.	Place of destination	on		
											_
Рал		Name		Appro	val number					Custom warehou	
		Address						Name		Approval numbe	ſ
		Name Address		Аррго	val number			Address			
		Name		Annro	val number			Postcode			
		Address		Applo	varnamber			FUSICOUE			
	I.13.	Place of load	ling				I.14.	Date of departure			
			-					•			
	I.15.	Means of trai	nsport				I.16.	Entry BIP in EU			
		Aeroplane 🗖	] Ship	-	Railway wa						
		Road vehicle			Rallway wa	agun 🗖	1.17.				
		Identification					1.17.				-
		Documentati		ces							
	I.18.	Description of							I.19. Comm	nodity code (HS cod	de)
				-							
										I.20. Quantity	
	I.21.	Temperature	of product	:						I.22. Number of	packages
		Ambient 🗖			Chilled 🗖	]		Frozen 🗖			
	1.23.	Seal/Contain	ner No							I.24. Type of pa	ckaging

1.25.	Commodities certified for:	
	Technical use	
I.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 numb	er of establishments
	Species (Scientific name) Manufa	cturing plant Batch number

	COUNTR	۲Y					ived pro	uding those of equidae, fo ducts for purposes outsic ed chain for farmed anima	
	П.	Health infor	mation	1	II.a.	Certificate reference No		II.b.	
		the Europea	n Parlia	ament and of the Cour	ncil ( <sup>1a</sup>	that I have read and understo), and in particular Article 8(c) 1 ( $^{1b}$ ), and in particular Chapte	and Articl	e 8(d) and Article 10 thereo	
	II.1.	the blood pro	oducts of	described above cons	ist of I	plood products that satisfy the l	nealth rec	uirements below;	
	II.2.	they consist	exclusi	vely of blood products	not ir	ntended for human or animal co	onsumptic	on;	
	II.3.			epared and stored in by with the following a		nt supervised by the competer by-products:	nt authori	ty or in the establishment	
		(²) either				als, which is fit for human co ed for human consumption for c			
		(²) and/or	( <sup>2</sup> ) and/or [- blood of slaughtered animals, which is rejected as unfit for human consumption in with Union legislation, but which did not show any signs of diseases communicable trainimals, derived from carcases that have been slaughtered in a slaughterhous considered fit for human consumption following an ante-mortem inspection in account union legislation;]						
	humans or animals					als, which did not show any d from animals that have been for human consumption foll lation;]	slaughte	red in a slaughterhouse after	
		(²) and/or	-	blood and blood pro consumption;]	d products derived from the production of products intended for huma products originating from live animals that did not show signs of any diseas rough that product to humans or animals;] cts derived from animals which have been submitted to illegal treatment a t 1(2)(d) of Council Directive 96/22/EC ( <sup>2a</sup> ) or Article 2(b) of Council Directive				
		(²) and/or							
		(²) and/or	- c						
		(²) and/or	li	isted in Group B(3) of	Anne	ing residues of other substan x I to Directive 96/23/EC, if suc n or, in the absence thereof, in	ch residue	es exceed the permitted lev	
	II.4.	with Union le	ne blood, that such products were manufactured from, was collected in slaughterhouses approved in accorda vith Union legislation, in slaughterhouses approved and supervised by the competent authority of the countr ollection or from live animals in facilities approved and supervised by the competent authority of the countr ollection;						
	(²) [II.5.	Proboscidea where no ca least the pre	, includ ise of ri eceding	ling crossbreds betwe inderpest, peste des p	en sp etits /hich	n animals belonging to the ta pecies of those taxa, the blood ruminants and Rift Valley fever vaccination has not been carr ;	l was col r has bee	lected in a country or region n recorded for a period of	
		( <sup>2</sup> ) either [in third countries, territories or parts thereof (insert ISO country code in the case of country, or codes ( <sup>3</sup> ) in the case of territories or parts thereof) where no case of foot-and-mou disease has been recorded for a period of at least the preceding 12 months and in which vaccinatic has not been carried out against this disease for a period of at least the preceding 12 months, and]							
( <sup>2</sup> ) or [in third countries, territories or parts thereof						foot-and-mouth disease has and in which vaccination arried out and controlled			

COUNTR	T					derived pr	cluding those of equidae, for roducts for purposes outside eed chain for farmed animals			
П.	Health infor	rmation		II.a.	Certificate reference No		II.b.			
(²) [II.5.1.	in the case of animals other than Suidae and Tayassuidae, in third countries or regions in which :									
	(²) either	has been	recorded for a	period		months ar	sence of seropositive animals) nd in which vaccination has not eceding 12 months;]			
	(²) or	[vesicular	stomatitis and I	bluetor	ngue (²) seropositive animals	s are prese	ent ( <sup>4</sup> );]]			
(²) [II.5.2.	classical swi and vaccina	ine fever and	African swine	fever	has been recorded for a pe	riod of at l	se of swine vesicular disease, least the preceding 12 months ast the preceding 12 months in			
	(²) either	for a perio	[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;]]							
	( <sup>2</sup> ) or [vesicular stomatitis seropositive animals are present ( <sup>4</sup> );]]]									
(²) [II.6.	in the case of blood products derived from poultry or other avian species the animals and the products come from the territory of the country or region with code									
	which has been free from Newcastle disease and highly pathogenic avian influenza as defined in the Terrestria Animal Health Code of the OIE,									
	which for a period of at least the preceding 12 months has not carried out vaccination against avian influenza,									
							gainst Newcastle disease with ogenicity than lentogenic virus			
II.7.	the products	were:								
	(²) either	er [packed in new or sterilised bags or bottles,]								
	(²) or				ers or other means of tran pproved by the competent a		were thoroughly cleaned and fore use,]			
	the outer pa	ckaging or co	ntainers bear la	abels i	ndicating 'NOT FOR HUMAN		AL CONSUMPTION';			
II.8.	the products	were stored	in enclosed sto	rage;						
II.9.	all precautio	ns were take	n to avoid conta	minati	ion of the products with path	ogenic age	ents during transport;			
( <sup>2</sup> ) [II.10.	the untreated	d blood produ	icts described a	above						
	(²) either	[is derived	I from other rum	ninants	s than bovine, ovine or caprir	ne animals	s.]]			
	(²) or	[is derived	l from bovine, o	vine o	r caprine animals and does i	not contair	and is not derived from:			
		(²) either	continuously	reared		untry or r	e derived from animals born, region classified as posing a EC.]]			
		(²) or			sk material as defined in p 1 of the European Parliamen		Annex V to Regulation (EC) e Council ( <sup>6</sup> );			
			anima slaugh accord	ls, exe ntered dance	cept from those animals th in a country or region class	at were b sified as p	es of bovine, ovine or caprine porn, continuously reared and osing a negligible BSE risk in EC ( <sup>7</sup> ), in which there has been			

col	JNTRY	Untreated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals
П.	Health information	II.a. Certificate reference No II.b.
	anima nervou the cra those or reg	I by-product or derived product obtained from bovine, ovine or caprine Is which have been killed, after stunning, by laceration of the central us tissue by means of an elongated rod-shaped instrument introduced into anial cavity, or by means of gas injected into the cranial cavity, except for animals that were born, continuously reared and slaughtered in a country ion classified as posing a negligible BSE risk in accordance with Decision 453/EC.]]]
Note	25	
Part	1:	
_		consignment in the European Union: this box is required to be filled in only if transited through the European Union; it may be filled in if the certificate is European Union.
—	Box reference I.11 and I.12: Approval number issued by the competent authority.	er: the registration number of the establishment or plant, which has been
—	Box reference I.12: Place of destination: this b in transit may only be stored in free zones, free	ox is to be filled in only if it is a certificate for a transit commodity. Products a warehouses and custom warehouses.
_		ray wagons or container and lorries), flight number (aircraft) or name (ship) nd reloading in the European Union, the consignor must inform the border ropean Union.
—	Box I.19: use the appropriate Harmonized Syst	tem (HS) code under the following headings: 05.11; 30.02 or 35.02.
—	Box reference I.23: for bulk containers, the con	tainer number and the seal number (if applicable) must be included.
—	Box reference I.25: technical use: any use production or manufacturing of pet food.	other than feeding of farmed 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 Species: select from the f Suidae, Pesca, Reptilian.	following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or
Part	н:	
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.	
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.	
(²)	Delete as appropriate.	
( <sup>2a</sup> )	OJ L 125, 23.5.1996, p. 3.	
( <sup>2b</sup> )	OJ L 125, 23.5.1996, p. 10.	
(3)	Code of the territory as it appears in Part 1 of A	Annex II to Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010, p. 1).
(4)		provided for in Directive $97/78/EC$ (OJ L 24, 30.1.1998, p. 9), and in rticle 8(4) of that Directive, the products must be transported directly to the

COUNTRY		Untreated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals			
н.	Health information	II.a.	Certificate reference N	10	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.				
Official veterinarian/Official inspector					
	Name (in capital letters):			Qualification	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  $\binom{2}{1}$  the European Union

COL	JNTRY	<b>/:</b>						Veterinary certifica	te to EU	
	I.1.	Consignor			I.2.	Certificate referen	ice No	l.2.a.		
		Name			I.3. Central competent authority					
		Address			I.4.	Local competent a	authority			
		Tel.								
	I.5.	Consignee			I.6.	Person responsib	le for the loa	ad in EU		
nent		Name				Name				
ignn		Address				Address				
cons		Postcode				Postcode				
hed		Tel.				Tel.				
Part I : Details of dispatched consignment	I.7.	Country ISO code I.8. Region of Code of origin origin			I.9.	Country of destination	ISO code	I.10. Region of destination	Code	
of										
etails	I.11.	Place of origin			I.12.	Place of destination	on			
å:										
art I		Name Approval number Address						Custom warehouse		
а.						Name	Approval number			
		Name	Approval number			Address				
		Address								
		Name	Approval number			Postcode				
		Address								
	I.13.	Place of loading			I.14.	Date of departure				
	I.15.	Means of transport			I.16.	. Entry BIP in EU				
		Aeroplane 🛛 Ship		gon 🗖						
		Road vehicle D Other	r 🗖		l.17.					
		Identification								
		Documentation reference								
	l.18.	Description of commodit	У				I.19. Comm	nodity code (HS code)		
								I.20. Quantity		
	1.04	Temperature of product						-	ckages	
	1.21.	Ambient	Chilled 🗖			Frozen 🗖		I.22. Number of pa	unages	
	1.23	Seal/Container No							aina	
	1.23.	Seal/Container IND						I.24. Type of packa	agirig	

1.25.	Commodities certified for:	
	Technical use	
I.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 numb	er of establishments
	Species (Scientific name) Manufa	cturing plant Batch number

COUNTR	Y		Treated blood products, excluding those of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals							
П.	Health infor	mation	II.a. Certificate reference No II.b.							
	the Europear	Parliament and of the Co	buncil ( <sup>1a</sup> ), and in particular Article 8(c) and Article 8(d) and Article 10 thereof,							
II.1.	the blood pro	ducts described above con	sist of blood products that s	satisfy the require	ments below;					
11.2.	they consist exclusively of blood products not intended for human or animal consumption;									
II.3.	they have been prepared and stored in a plant supervised by the competent authority, exclusively with the follo animal by-products:									
	(²) either					ı				
	(²) and/or	with Union legislation animals, derived fro	, but which did not show ar m carcases that have be	ny signs of diseas en slaughtered i	es communicable to humans or n a slaughterhouse and were	-				
	(²) and/or	humans or animals, on having been consided	obtained from animals that have been slaughtered in a slaughterhouse after dered fit for human consumption following an ante-mortem inspection in							
	(²) and/or									
	(²) and/or	[- blood and blood p consumption;]	which have been derived from animals which have been submitted to illegal d in Article 1(2)(d) of Council Directive 96/22/EC ( $^{2a}$ ) or Article 2(b) of Council							
	(²) and/or	treatment as defined								
	(²) and/or	listed in Group B(3)	of Annex I to Directive 9	3/23/EC, if such	residues exceed the permitted					
11.4.	accordance v	with Union legislation, in sl bllection or from live anima	aughterhouses approved a	nd supervised by	the competent authority of the	•				
(²) [II.5.	crossbreeds, guaranteeing	other than Suidae and Ta the absence of pathogens (	yassuidae, the products h of foot-and-mouth disease	ave undergone o	one of the following treatments,	,				
	(²) either	[heat treatment at a check;]	temperature of 65 $^{\circ}\mathrm{C}$ for at least three hours, followed by an effectiveness							
	(²) and/or	[irradiation at 25 kGy	by gamma rays, followed b	y an effectivenes	s check;]					
	(²) and/or	[change in pH to pH s	5 for two hours, followed by	an effectiveness	check;]					
	(²) and/or	[heat treatment of a check.]]	at least 80 °C throughout their substance, followed by an effectiveness							
	<b>II.</b> II.1. II.2. II.3.	II.       Health information of the Europear and Commission that:         II. 1.       Ihe blood production of the pr	II.       Health information         I. the undersigned official veterinarian, of the European Parliament and of the Couland Commission Regulation (EU) No 1 that:         II.1.       the blood products described above conditate:         II.2.       they consist exclusively of blood products         II.3.       they have been prepared and stored in animal by-products:         (2) either       [- blood of slaughtered legislation, but is not entimated by animals, derived from considered fit for hum Union legislation;]         (2) and/or       [- blood of slaughtered humans or animals, derived from considered fit for hum Union legislation;]         (2) and/or       [- blood of slaughtered humans or animals, derived from considered fit for hum Union legislation;]         (2) and/or       [- blood and blood products with Union legislation;]         (2) and/or       [- blood and blood products with reatment as defined Directive 96/23/EC (2) and/or         (2) and/or       [- animal by-products with reatment as defined Directive 96/23/EC (2) (2) and/or         (1.4.       the blood that these products were maccordance with Union legislation, in skic country of collection or from live anima country of collection.         (2) [II.5.       In the case of blood products derive crossbreeds, other than Suidae and Taguarateeing the absence of pathogens ruminants, Rift Valley fever and bluetong (2) either         (2) and/or       [reat treatment at a check:]         (2) and/or       [reat guaranteeing the absence of	II.         Health information         II.a.         Certificate reference           I. the undersigned official veterinarian, declare that I have read are the European Parliament and of the Council (*), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation (EU) No 142/2011 (*b), and in particular 4 and Commission Regulation, but which did for human on animals, which is rejected with Union legislation, but which did not show are animals, derived from carcases that have be considered fit for human consumption following Union legislation;]           (*) and/or         [- blood of slaughtered animals, which is rejected with Union legislation;]           (*) and/or         [- blood of slaughtered animals, which did not humans or animals, obtained from animals that having been considered fit for human consum accordance with Union legislation;]           (*) and/or         [- blood and blood products derived from the consumption.]           (*) and/or         [- blood and blood products derived from the consumption.]           (*) and/or         [- animal by-products which have been derived from treatment as defined in Article 1(2)(d) of Council Directive 96/23/EC (*b);	Ite manufacture of derived products           II.         Health information         II.a. Certificate reference No           II. the undersigned official veterinarian, declare that I have read and understood Re the European Pariament and of the Council (*), and in particular Article 8(c) and Ar and Commission Regulation (EU) No 142/2011 (*), and in particular Chapter II of that.           II.1.         the blood products described above consist of blood products that satisfy the require           II.2.         they consist exclusively of blood products not intended for human or animal consumption for comme animal by-products.           (*) either         [- blood of slaughtered animals, which is fit for human consumption for comme legislation, but is not intended for human consumption for comme with Union legislation.           (*) either         [- blood of slaughtered animals, which is rejected as unfit for human consumption following an ante-morter Union legislation.           (*) and/or         [- blood of slaughtered animals, which did not show any signs furmans or animals, obtained from animals that have been slaughtered.           (*) and/or         [- blood and blood products originating from live animals that did isease communicable through these products to humans or animals obtained from the products or on animals which did not show any signs furmans or animals, obtained from the products on thumans or animal aconsumption following accordance with Union legislation.]           (*) and/or         [- blood and blood products derived from the products on animals which in a certain as defined in Article 1(2)(d) of Council Directive 96/23/EC (*).]	Ite manufacture of derived products for purpose outside the feed chain for farmed animals           II.         Health information         I.a. Certificate reference No         II.b.           II.         the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1482/2008 of and Commission Regulation (EU) No 142/2011 ( <sup>1</sup> b), and in particular Chaepter II of Annex XIV thereto, and certify that:           II.1.         the blood products described above consist of blood products that satisfy the requirements below;           II.2.         they consist exclusively of blood products not intended for human or animal consumption;           II.3.         they have been prepared and stored in a plant supervised by the competent authority, exclusively with the following animal by-products;           ( <sup>2</sup> ) either         [-         blood of slaughtered animals, which is fit of human consumption in accordance with Union legislation, but is not intended for human consumption for communicable to humans or animals, derived form carcases that have been slaughtered animals with bit angletad the tawa been slaughtered and slaughtero animals, which is fit of human consumption in accordance with Union legislation.]           ( <sup>2</sup> ) and/or         [-         blood of slaughtered animals, which id not show any signs of diseases communicable to humans or animals, obtained from animals that have been slaughterio a slaughterhouse and wree considered fit for human consumption following an ante-mortem inspection in accordance with Union legislation.]           ( <sup>2</sup> ) and/or         [-         blood of slaughtered animals, which id not show any signs of diseas				

II.	Health inform	nation		II.a. Certificate reference No	II.b.						
(²) [II.6.	undergone on and-mouth di	e of the following sease, vesicular	treatmen stomatitis	Nuidae, Tayassuidae, poultry and oth s guaranteeing the absence of pathog , swine vesicular disease, classical avian influenza, as appropriate to the	gens of the following diseases: foo swine fever, African swine feve						
	(²) either	[heat treatme check;]	ent at a temperature of 65 °C for at least three hours, followed by an effectiveness								
	(²) and/or	[irradiation at	[irradiation at 25 kGy by gamma rays, followed by an effectiveness check;]								
	(²) and/or			east 80 °C for Suidae/Tayassuidae ( $^2$ ) throughout the substance of the pro							
(²) [II.7.				om species other than those listed in ase specify):]	point II.5 or II.6, the products hav						
II.8.	The products	were:									
	(²) either	er [packed in new or sterilised bags or bottles,]									
	(²) or	<sup>(2)</sup> 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 pack	aging or container	rs bear la	els indicating 'NOT FOR HUMAN OR	ANIMAL CONSUMPTION';						
II.9.	the products v	vere stored in encl	losed stor	age;							
II.10.	all precautions	s were taken to ave	oid the co	ntamination of the products with patho	genic agents after treatment;						
(²) [II.11.	The treated blood products described above										
	(²) either	[is derived fro	[is derived from other ruminants than bovine, ovine or caprine animals.]]								
	(²) or	[is derived fro	om bovine	, ovine or caprine animals and does no	ot contain and is not derived from:						
		(²) either	continu	, ovine and caprine materials other tha ously reared and slaughtered in a cou le BSE risk in accordance with Decisio	ntry or region classified as posing						
		( <sup>2</sup> ) or	[(a)	specified risk material as defined in po No 999/2001 of the European Parliand							
			(b)	mechanically separated meat obtaine caprine animals, except from those ar reared and slaughtered in a country negligible BSE risk in accordar 2007/453/EC ( <sup>4</sup> ), in which there has be	nimals that were born, continuous / or region classified as posing nce with Commission Decisic						
			(C)	animal by-product or derived produc caprine animals which have been kill the central nervous tissue by mea instrument introduced into the cranial into the cranial cavity, except for continuously reared and slaughtered	led, after stunning, by laceration ans of an elongated rod-shape cavity, or by means of gas injecte those animals that were bor						

COI	JNTRY	ccluding those of equidae, for lerived products for purposes feed chain for farmed animals									
П.	Health information	II.a. Certificate reference No	II.b.								
Not	es										
Par	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.	per: the registration number of the establish	ment or plant, which has been								
—	Box reference I.12: Place of destination: this in transit may only be stored in free zones, free		r a transit commodity. Products								
—	Box reference I.15: Registration number (rail is to be provided. In the case of unloading a entry into the European Union.										
—	Box I.19: use the appropriate Harmonized Sy	stem (HS) code under the following headings	: 05.11, 30.02, 35.02 or 35.04.								
—	Box reference I.23: for bulk containers, the co	ntainer number and the seal number (if appli	cable) must be included.								
—	Box reference I.25: technical use: any use production or manufacturing of pet food.	other than feeding of farmed animals, ot	her 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 in case of Species: se Ruminantia or Suidae, Pesca, Reptilian.	lect from the following: Aves, Ruminantia,	Suidae, Mammalia other than								
Part	t II:										
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.										
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.										
(²)	Delete as appropriate.										
( <sup>2a</sup> )	OJ L 125, 23.5.1996, p. 3.										
( <sup>2b</sup> )	OJ L 125, 23.5.1996, p. 10.										
( <sup>3</sup> )	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 colour to that of the printing.									
—	Note for the person responsible for the consig and must accompany the consignment until it										
Offic	cial veterinarian/Official inspector										
	Name (in capital letters):	Qualification	and title:								
	Date:	Signature:									
	Stamp:										

### CHAPTER 5(A)

#### Health certificate

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

14						
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				
	-	Name				
		Address				
	Postcode	Postcode				
	Tel.	Tel.				
I.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination				
l.11.	Place of origin	I.12. Place of destination				
	Name Approval number Address	Name Custom warehouse Address Approval number				
	Name Approval number Address	Postcode				
	Name Approval number Address					
l.13.	Place of loading	I.14. Date of departure				
l.15.	Means of transport	I.16. Entry BIP in EU				
	Aeroplane Ship Railway wagon					
		I.17. Number(s) of CITES				
l.18.		I.19. Commodity code (HS code)				
		I.20. Quantity				
1.21.		I.22. Number of packages				
1.23.	Seal/Container No	I.24. Type of packaging				
I.25.	Commodities certified for:					
	Animal feedingstuff Technical use					
I.26.	For transit through EU to third country	I.27. For import or admission into EU				
I.28.	Identification of the commodities					
		er of establishments Net weight cturing plant				
	I.7. I.11. I.13. I.15. I.21. I.23. I.25. I.26.	Tel.         1.5. Consignee Name Address         Postcode Tel.         1.7. Country of origin       ISO code         1.8. Region of origin         Code         1.11. Place of origin         Name Address         Neas of transport         Aeroplane       Other Documentation references         1.18. Description of commodity         1.23. Seal/Container No         1.25.				

COUNTRY				Fresh or chill	led hides and skins of ungulates							
	II.	Health inf	ormation	II.a. Certificate reference No	II.b.							
		Parliament	ersigned official veterinarian, declare that I have r and of the Council ( <sup>1a</sup> ) and in particular Article 10 the , Chapter II thereof, and certify that the hides and si	ereof, and Commission Regulation (EU)								
	II.1.	have been obtained from animals that:										
ation		( <sup>2</sup> ) either [- were slaughtered and their carcases are fit for human consumption in accordance with Union legislation;]										
Part II: Certification		( <sup>2</sup> ) or [- were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were considered fit, as a such inspection, for slaughter for human consumption in accordance with Union legislation;]										
Part II	II.2.	originate from a country or, in the case of regionalisation in accordance with Union legislation, from a part of a country from which im of all categories of fresh meat of the corresponding species are authorised and which:										
		(a)	for at least 12 months before dispatch, has been fr	ree from the following diseases (3):								
			[- classical swine fever, and African swine fever;]									
			[- rinderpest;]									
		and										
		(b)	has been free for at least 12 months before dispatch no vaccination has been carried out against foot-ar		ere, for 12 months before dispatch,							
	II.3.	have been	obtained from:									
			at have remained in the territory of the country of orig imals less that three months old;]	gin for at least three months before bei	ng slaughtered or since birth in the							
			e of hides and skins from bi-ungulates, animals that or the previous 30 days, and around which within a ra									
		disease in	e of hides and skins from swine, animals that come the previous 30 days, or of classical or African swine been no case of these diseases for 30 days;]									
				ase], [rinderpest], [classical swine fever], [African swine fever] or [swine he slaughterhouse during the 24 hours before slaughter;]								
	II.4.	have unde	rgone all precautions to avoid contamination with pa	thogenic agents.								
	Notes											
	Part I:	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 tracommodity; 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 compet authority.										
			12: Place of destination: this box is to be filled in only e zones, free warehouses and custom warehouses.	/ if it is a certificate for transit commodi	ty. The products in transit can only							
			<ol> <li>Registration number (railway wagons or containe event of unloading and reloading.</li> </ol>	er and lorries), flight number (aircraft) c	r name (ship); information is to be							
	— Вох	reference I	.19: use the appropriate HS code: 41.01; 41.02 or 4	1.03.								

COUNT	TRY	Fresh or chilled hides and skins of ungulates								
Ш.	Health information	II.a. Certificate reference No	II.b.							
— Во	- 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.									
— Во	- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.									
Part I	Part II:									
( <sup>1a</sup> ) O	J L 300, 14.11.2009, p. 1.									
( <sup>1b</sup> ) O	J L 54, 26.2.2011, p. 1.									
(²) D	elete as appropriate.									
( <sup>3</sup> ) 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.								
	te for the person responsible for the consignment in the Eu company the consignment until it reaches the border inspection		only for veterinary purposes and has to							
Officia	l veterinarian/Official inspector									
Nar	ne (in capital letters):	Qualification a	nd title:							
Dat	e:	Signature:								
Sta	Stamp:									

### CHAPTER 5(B)

#### Health certificate

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

cou	NTR	(	Veterinary certificate to EU					
	l.1.	Consignor Name	I.2. Certificate reference No     I.2.a.       I.3. Central competent authority					
		Address	1.4. Local competent authority					
		Tel.						
Į	1.5.	Consignee	I.6. Person responsible for the load in EU					
l u		Name	Name					
nsig		Address	Address					
dispatched consignment		Postcode Tel.	Postcode Tel.					
of dispat	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO I.10. Region of Code destination code destination					
etails	1.11.	Place of origin	I.12. Place of destination					
Part I: Details		Name Approval number Address	Name Custom warehouse Address Approval number					
1		Name Approval number 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 Identification Documentation references	I.17. Number(s) of CITES					
	l.18.	Description of commodity	I.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						
	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	·					
			er of establishments Net weight sturing plant					

_	JNTRY				Irea	ated hides and skins of ungulates
	II. H	lealth ir	formation	П.	a. Certificate reference No	II.b.
			Parliamen	ersigned official veterinarian, declare that I have t and of the Council ( <sup>1a</sup> ) and in particular Article Annex XIV, Chapter II thereof, and certify that	10 thereof, and Commission Regu	lation (EU) No 142/2011 ( <sup>1b</sup> ), and in
		II.1.	have beer	n obtained from animals that:		
Caulou			( <sup>2</sup> ) either	[- were slaughtered and their carcases are fi	t for human consumption in accor	dance with Union legislation;]
			( <sup>2</sup> ) or	[- were slaughtered in a slaughterhouse, after result of such inspection, for slaughter for		
			(²) or	[- did not show any clinical signs of any disea were not killed to eradicate any epizootic of		nimals through the hide or skin, and
	( <sup>2</sup> ) either	[11.2.	part of a f	n animals originate from a third country or, in t third country listed in Part 1 of Annex II to Con ne corresponding species are authorised and h	mission Regulation (EU) No 206/	
			( <sup>2</sup> ) 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 transporter, the hides and skins will be transp have undergone a minimum of 14 days of sa	ported by ship and the duration of	transport will be such that they will
			( <sup>2</sup> ) or	[salted for seven days in sea salt with the ac	Idition of 2 % of sodium carbonate	ə;]
			( <sup>2</sup> ) or	[salted in sea salt with the addition of 2 % of and according to the declaration of the transp of transport will be such that they will have un border inspection post.]]	orter, the hides and skins will be t	transported by ship and the duratior
	( <sup>2</sup> ) or	[11.2.	part of a	n animals originate from a third country or, in t third country listed in Part 1 of Annex II to Re ding species are NOT authorised and have be	egulation (EU) No 206/2010 from	
			( <sup>2</sup> ) either	[salted for seven days in sea salt with the ac	Idition of 2 % of sodium carbonate	ə;]
			( <sup>2</sup> ) or	[salted in sea salt with the addition of 2 % of and according to the declaration of the transp of transport will be such that they will have un border inspection post;]	orter, the hides and skins will be t	transported by ship and the duratior
			(²) or	[dried for 42 days at a temperature of at leas	st 20 °C;]]	
		II.3.		nment has not been in contact with other anima ble disease.	al products or with live animals pre	senting a risk of spreading a serious
	Notes					
	Part I:					
				responsible for the consignment in the Europ ad in if the certificate is for import commodity.	ean Union: this box is to be filled	in only if it is a certificate for transi

COUNTRY	Treated hides and skins of ungulates								
II. Health information	II.a. Certificate reference No	II.b.							
<ul> <li>Box reference I.11 and I.12: Approval number: the registration number authority.</li> </ul>	— 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) and information is to be provided in the event of unloading and reloading.									
- Box reference I.19: use the appropriate HS code: 41.01; 41.02 or 41.03.									
- Box reference I.23: for bulk containers, the container number and the	- 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 cons	sumption.								
- Box reference I.26 and I.27: fill in according to whether it is a transit	or an import certificate.								
Part II:									
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.									
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.									
( <sup>2</sup> ) Delete as appropriate.									
( <sup>3</sup> ) OJ L 73, 20.3.2010, p. 1.									
( <sup>4</sup> ) OJ L 147, 31.5.2001, p. 1.									
- The signature and the stamp must be in a different colour to that of	the printing.								
<ul> <li>Note for the person responsible for the consignment in the Europe accompany the consignment until it reaches the border inspection per</li> </ul>		or veterinary purposes and has to							
Official veterinarian/Official inspector									
Name (in capital letters):	Qualification and	d title:							
Date:	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  $\binom{1}{1}$  the European Union and have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation

cou	NTR	Y										Veterinary certifi	cate to EU
	I.1.	Consignor					1.2.	Certificat	e reference	No	1.2	2.a.	
		Name					1.3.	Central c	ompetent a	uthority			
		Address					1.0.	Oentrai C	ompetent a	utionty			
		<b>T</b> .1					1.4.	Local co	mpetent aut	hority			
		Tel.						_					
ent	1.5.	•					1.6.		esponsible	for the loa	ad in E	0	
		Name						Name					
nsig		Address						Address					
Ī		Postcode						Postcode	9				
dispatched consignment		Tel.						Tel.					
Datc	1.7.	Country of origin	ISO code	18	Region of origin	Code	1.9.	Country	of	ISO	1 10	Region of	Code
dist	1.7.	obuility of origin	100 0006	1.0.	region of origin	COUB	1.0.	destinati	on	code	1.10.	destination	0006
ď													
Part I: Details	1.11.	Place of origin					l.12.	Place of	destination				
		Name		Appro	val number			Name				stom warehouse 🗌	]
art		Address						Address			Арр	proval number	
1		Name		Appro	oval number								
		Address Name		A	oval number			Postcode	Э				
		Address		Appro	var number								
	I.13.	Place of loading					I.14.	Date of	departure				
	I.15.	Means of transport	t				l.16.	Entry BI	⊃ in EU				
		Aeroplane 🗌 Ship 🗌 Railway wagon 🗌											
		Road vehicle	Other		, , ,		I.17. Number(s) of CITES						
		Identification											
		Documentation refe	erences										
	l.18.	Description of com	modity						1.19. Com	modity co	de (HS	6 code)	
										1.20.	Quant	ity	
	1.21.	Temperature of pro	oduct							1.22.	Numb	er of packages	
		Ambient 🔲		Chi	lled 🗌		Frozer	n 🗖					
	1.23.	Seal/Container No								1.24.	Туре	of packaging	
	1.25.	Commodities certif	ied for:										
		Animal feedingstuff	f 🗖		Technical us	e 🗌							
	1.26.	For transit through	EU to third	count	ry 🗆		1.27.	For impo	ort or admis	sion into I	EU	Ľ	]
		Third country		ISO (	code								
	1.28.	Identification of the	commoditie	es									
		Species (Scientific name)			Ар	proval num Manut		establish ng plant	ments			Net we	eight

П.	Healt	th informatio	on	uninterrupted days before impo	II.b.
			rsigned declare that the hides and		
	II.1.		obtained from animals that:		
	11.1.				
		( <sup>1</sup> ) either		arcases are fit for human consumption	-
		( <sup>1</sup> ) or		rhouse, after undergoing ante-mortem in laughter for human consumption in acco	
		( <sup>1</sup> ) or	- did not show any clinical signs and were not killed to eradica	of any disease communicable to human te any epizootic disease;]	ns or animals through the hide or sk
	II.2.	have been:	:		
		( <sup>1</sup> ) either	[- dried;]		
		( <sup>1</sup> ) or	[- dry-salted or wet-salted for at	least 14 days prior to dispatch;]	
		( <sup>1</sup> ) or	[- salted for seven days in sea s	alt with the addition of 2 % of sodium c	arbonate;]
	II.3.		been in contact with other anim ole disease;	al products or with live animals prese	enting a risk or spreading a seric
( <sup>2</sup> ) either	[11.4.	have been under poin		e dispatch for 21 days under official sup	pervision after the treatment describ
( <sup>2</sup> ) or	[11.4.	following th	ne declaration of the transporter, t	ne duration of the transport period is for	eseen to be at least 21 days.]
Notes					
Part I:					
— Box refe			sponsible for the consignment in t n if the certificate is for import co	he European Union: this box is to be fille mmodity.	ed in only if it is a certificate for tran
— Box refe commod	lity; it m rence l.	ay be filled i	n if the certificate is for import co		
<ul> <li>Box refection</li> <li>Box refection</li> <li>Box refection</li> <li>Box refection</li> </ul>	lity; it m rence l. rence l.	ay be filled i 11 and I.12: . 12: Place of a	n if the certificate is for import co Approval number: the registration	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comm	ich has been issued by the compet
<ul> <li>Box refection common</li> <li>Box refetiation authority</li> <li>Box refetible store</li> <li>Box refetible store</li> </ul>	lity; it m rence l. r. d in free erence l.	ay be filled i 11 and l.12: 12: Place of 2 zones, free 15: Registrat	n if the certificate is for import co Approval number: the registration destination: this box is to be filled warehouses and custom wareho	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comm	nodity. The products in transit can o
<ul> <li>Box references</li> </ul>	lity; it m rence I. r. d in free rence I. I in the	ay be filled i 11 and l.12: 12: Place of 2 zones, free 5: Registrat event of unic	n if the certificate is for import co Approval number: the registration destination: this box is to be filled warehouses and custom wareho tion number (railway wagons or co	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comn uses. Intainer and lorries), flight number (aircra	nodity. The products in transit can o
<ul> <li>Box references</li> </ul>	lity; it m arence I. d in free arence I. I in the arence I.	ay be filled i 11 and l.12: 12: Place of a zones, free 15: Registrat event of unic 19: use the a	n if the certificate is for import co Approval number: the registration destination: this box is to be filled warehouses and custom wareho tion number (railway wagons or co pading and reloading. appropriate HS code: 41.01; 41.02	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comn uses. Intainer and lorries), flight number (aircra	ich has been issued by the compet nodity. The products in transit can o ft) or name (ship); information is to
<ul> <li>Box refectormode</li> <li>Box refetormode</li> </ul>	lity; it m arence I. d in free arence I. I in the arence I. arence I.	ay be filled i 11 and l.12: 12: Place of ( a zones, free 15: Registrat event of unlo 19: use the a 23: for bulk (	n if the certificate is for import co Approval number: the registration destination: this box is to be filled warehouses and custom wareho tion number (railway wagons or co pading and reloading. appropriate HS code: 41.01; 41.02	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comm uses. Intainer and lorries), flight number (aircra 2 or 41.03. and the seal number (if applicable) shou	ich has been issued by the compet nodity. The products in transit can o ft) or name (ship); information is to
<ul> <li>Box refe commod</li> <li>Box refe authority</li> <li>Box refe be store</li> <li>Box refe provided</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> </ul>	lity; it m rence I. d in free prence I. I in the prence I. prence I. prence I.	ay be filled i 11 and I.12: 12: Place of ( 2 zones, free 15: Registrat event of unic 19: use the ( 23: for bulk ( 25: technical	n if the certificate is for import co Approval number: the registration destination: this box is to be filled warehouses and custom wareho tion number (railway wagons or co bading and reloading. appropriate HS code: 41.01; 41.0; containers, the container number	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comm uses. Intainer and lorries), flight number (aircra 2 or 41.03. and the seal number (if applicable) shou al consumption.	ich has been issued by the compet nodity. The products in transit can o ft) or name (ship); information is to
<ul> <li>Box refe commod</li> <li>Box refe authority</li> <li>Box refe be store</li> <li>Box refe provided</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> </ul>	lity; it m rence I. d in free prence I. I in the prence I. prence I. prence I.	ay be filled i 11 and I.12: 12: Place of ( 2 zones, free 15: Registrat event of unic 19: use the ( 23: for bulk ( 25: technical	n if the certificate is for import co Approval number: the registration destination: this box is to be filled a warehouses and custom wareho tion number (railway wagons or co bading and reloading. appropriate HS code: 41.01; 41.0; containers, the container number I use: any use other than for anim	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comm uses. Intainer and lorries), flight number (aircra 2 or 41.03. and the seal number (if applicable) shou al consumption.	ich has been issued by the compet nodity. The products in transit can o ft) or name (ship); information is to
<ul> <li>Box refe commod</li> <li>Box refe authority</li> <li>Box refe be store</li> <li>Box refe provided</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> </ul>	lity; it m arence I. d in free arence I. I in the arence I. arence I. arence I.	ay be filled i 11 and l.12: 12: Place of 2 zones, free 15: Registrat event of unic 19: use the 23: for bulk 25: technical 26 and l.27:	n if the certificate is for import co Approval number: the registration destination: this box is to be filled a warehouses and custom wareho tion number (railway wagons or co bading and reloading. appropriate HS code: 41.01; 41.0; containers, the container number I use: any use other than for anim	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comm uses. Intainer and lorries), flight number (aircra 2 or 41.03. and the seal number (if applicable) shou al consumption.	ich has been issued by the compet nodity. The products in transit can o ft) or name (ship); information is to
<ul> <li>Box refe commod</li> <li>Box refe be store</li> <li>Box refe provided</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> <li>Box refe</li> <li>Part II:         <ol> <li>Delete a</li> </ol> </li> </ul>	lity; it m prence I. d in free prence I. I in the prence I. prence I. prence I. prence I. prence I.	ay be filled i 11 and I.12: 12: Place of 2 zones, free 15: Registrat event of unic 19: use the 23: for bulk 25: technical 26 and I.27: priate.	n if the certificate is for import co Approval number: the registration destination: this box is to be filled a warehouses and custom wareho tion number (railway wagons or co bading and reloading. appropriate HS code: 41.01; 41.0; containers, the container number I use: any use other than for anim	mmodity. number of the establishment or plant, wh in only if it is a certificate for transit comm uses. Intainer and lorries), flight number (aircra 2 or 41.03. and the seal number (if applicable) shou al consumption. transit or an import certificate.	ich has been issued by the competent nodity. The products in transit can o ft) or name (ship); information is to

COUNTRY	kept separate for 21 days or	Treated hides and skins of ruminants and of equidae that have been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation		
II. Health information	II.a. Certificate reference No	II.b.		
Official veterinarian/Official inspector				
Name (in capital letters):	Qualification and	d title:		
Date:	Signature:			
Stamp:				

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

cou	INTR	(	Veterinary certificate to EL
	l.1.	Consignor Name	I.2. Certificate reference No     I.2.a.
		Address	I.3. Central competent authority
		Tel.	I.4. Local competent authority
of dispatched consignment	I.5.	Consignee Name Address	<ul> <li>I.6. Person responsible for the load in EU Name Address</li> </ul>
ched con		Postcode Tel.	Postcode Tel.
of dispate	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination
ails	1.11.	Place of origin	I.12. Place of destination
Part I: Details		Name Approval number Address	Name Custom warehouse Address Approval number
Part		Name Approval number Address	Postcode
		Name Approval number Address	
	l.13.	Place of loading	I.14. Date of departure
	l.15.	Means of transport	I.16. Entry BIP in EU
		Aeroplane Aeroplane Aeroplane Carlos Ship Aeroplane Railway wagon Carlos Aeroplane Aer	
		Road vehicle Other I Identification Documentation references	I.17. Number(s) of CITES
	l.18.	Description of commodity	I.19. Commodity code (HS code)
			I.20. Quantity
	l.21.		I.22. Number of packages
	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	I.27. For import or admission into EU
	1.29	Identification of the commodities	
	1.20.		of commodity Number of packages

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▼<u>M4</u>

INTRY					ner preparations of birds and ung orns, hooves, claws, antlers, tee			
II. He	ealth info	ormation		II.a. Certificate reference No	II.b.			
		European I		are that I have read and understood R and Commission Regulation (EU) No 1 ame trophies described above:				
	II.1.			tment, without being in contact with oth and closed packages so as to avoid any				
(²) either	[II.2.1	in the case	e of game trophies or other prepara	ations consisting only of hides or skin:				
		(²) either	[have been dried;]					
		(²) and/or	[have been dry-salted or wet-salt	ted for a minimum of 14 days before dis	patch;]			
		(²) and/or	porter, will be transported by ship	n (date) and, acc o and the duration of the transport will be re they reach the EU border inspection p	such that they will have undergone			
(²) and/or	[11.2.2	in the case	e of game trophies or other prepara	ations consisting only of bone, horns, ho	oves, claws, antlers or teeth:			
			peen immersed in boiling water for s, claws, antlers or teeth is remove	r an appropriate time so as to ensure tha ad, and	at any matter other than bone, horr			
	(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:								
			n if the certificate is for import con	ne European Union: this box is to be fille nmodity.	a in only if it is a certificate for tran			
— Box ref authorit		11 and I.12:	Approval number: the registration r	number of the establishment or plant, whi	ch has been issued by the compete			
			destination: this box is to be filled i warehouses and custom warehou	only if it is a certificate for transit commodity. The products in transit can or es.				
			tion number (railway wagons or co ding, the consignor must inform the	ntainer and lorries), flight number (aircrafi e BIP of entry into the EU.	t) or name (ship) is to be provided.			
— Box I.1	9: use th	e appropriate	e Harmonized System (HS) code u	under the following headings: 05.05, 05.0	6, 05.07 or 97.05.			
— Box ref	erence I.:	23: for bulk (	containers, the container number a	and the seal number (if applicable) should	d be included.			
— Box ref	erence I.:	25: technical	l use: any use other than for anima	al consumption.				
— Box ref	erence I.:	26 and I.27:	fill in according to whether it is a	transit or an import certificate.				
— Box ref	erence I.:	28:						
(a) for	nature of	commodity,	, select one or more of the follow	ing: [bones], [horns], [hooves], [claws], [a	antlers], [teeth], [hides] and/or [skin			
			ect from the following: Aves, Equid dae, Moschidae Suidae, Tayassuid	lae, Tapiridae, Rhinoceritidae, Antilocapa dae, Tragulidae and Elephantidae.	ridae, Bovidae, Camelidae, Cervida			
Gira								
Gira Part II:								

II.       Health information       II.a. Certificate reference No       II.b.         (1b) OJ L 54, 26.2.2011, p. 1       .       .         (c) 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       Qualification and title:       .         Date:       .       .         Stamp:       .       .	COUN	TRY		r preparations of birds and ungu- ms, hooves, claws, antlers, teeth					
<ul> <li>(<sup>2</sup>) Delete as appropriate.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters):</li> <li>Date:</li> <li>Signature:</li> </ul>	П.	Health information	II.a. Certificate reference No	II.b.					
<ul> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters):</li> <li>Date:</li> </ul>	( <sup>1b</sup> ) C	J L 54, 26.2.2011, p. 1							
<ul> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters):</li> <li>Date:</li> <li>Signature:</li> </ul>	( <sup>2</sup> ) D	elete as appropriate.							
the consignment until it reaches the border inspection post.         Official veterinarian/Official inspector         Name (in capital letters):       Qualification and title:         Date:       Signature:	— Th	e signature and the stamp must be in a different colour to that of	the printing.						
Name (in capital letters):     Qualification and title:       Date:     Signature:		— 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.							
Date: Signature:	Officia	I veterinarian/Official inspector							
	Na	ime (in capital letters):	Qualific	ation and title:					
Stamp:	Da	te:	Signatu	re:					
	Sta	amp:							

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### 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  $(^2)$  the European Union

### COUNTRY:

Veterinary certificate to EU

	l.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.	
		Name					1.3.	Central compete	ent authority		
		Address					1.4.	Local competen	t authority		
		Tel.					1.6.				
	1.5.	I.5. Consignee						Person respons	ible for the loa	ad in EU	
Jent		Name						Name			
ignn		Address						Address			
Part I : Details of dispatched consignment		Postcode						Postcode			
edo		Tel.						Tel.			
atch	I.7.	Country	ISO code	I.8.	Region of	Code	1.9.	Country of	ISO	I.10. Region of	Code
disp	1.7.	of origin	130 code	1.0.	origin	Code	1.9.	destination	code	destination	Code
° of											
etails	l.11.	1. Place of origin					I.12.	Place of destina	ition		
å											
artl		Name Approval number								Custom warehouse	
ш		Address						Name		Approval number	
		Name		Appro	oval number			Address			
		Address									
		Name		Appro	oval number			Postcode			
		Address									
	I.13.	Place of loa	ading				1.14.	Date of departur	re		
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU			
		Aeroplane	🛛 Ship		Railway wa	agon 🗖					
		Road vehicle Other					1.17.	Number(s) of Cl	TES		
		Identificatio	on								
		Documenta	ation referen	ces							
	I.18.	Description	n of commod	ity					I.19. Comm	nodity code (HS code)	
										I.20. Quantity	
	I.21.									I.22. Number of pa	ackages
	1.00	0									· . •
	1.23.	Seal/Conta	aner No							I.24. Type of pack	aging

1.25.	Commodities certified for:					
	Technical use 🗖					
I.26.	For transit through EU to thin	d country	1.27. F	For import or adm	ssion into EU	
	Third country	ISO code				
1.28.	Identification of the commodi	ties				
	Species (Scientific name)			Number of p	backages	

he European F particular Chapt II.1. with (a) (b)	Parliament and of the ter II of Annex XIV ther a period of the pre- diseases has taker the game trophies (i) were obtain authorised there have game anima (ii) originated fi of another t trophies of of the same trophies arespect to game trophies classical swine few porcine enteroviral out against any of the game trophies	A declare that I have read and understand a Council ( <sup>1a</sup> ), and Commission Regur- reto, and certify that the game trophies of hies or other preparations of cloven-hood 	Ilation (EU) No 142/2011 ( <sup>1b</sup> ), and in described above: ifed animals, excluding swine: -and-mouth disease and rinderpest fo od, no vaccination against any of those in the territory of that region, which i in the territory of that region, which is the period of the preceding 60 days to outbreaks of diseases to which the note of at least 20 km from the border of authorised to export untreated game is to the European Union;] e preceding 12 months, was free from r disease, foot-and-mouth disease and and no vaccinations have been carried priod; and
(a) (b) II.1. with (a)	a period of the pred diseases has taker the game trophies (i) were obtain authorised the susceptible there have game anima (ii) originated fi of another the trophies of of the respect to game troph classical swine few porcine enteroviral out against any of the the game trophies	(region) has been free from foot ceding 12 months, and during that period in place; and or other preparations described above: need from animals which were killed in for the exportation to the European Un domestic species and where, during been no animal health restrictions due als are susceptible; and rom animals that were killed at a distar third country or part of a third country no cloven-hoofed animals other than swine hies or other preparations of wild swine: 	-and-mouth disease and rinderpest for od, no vaccination against any of those in the territory of that region, which it ion of fresh meat of the corresponding the period of the preceding 60 days to outbreaks of diseases to which the noce of at least 20 km from the border of authorised to export untreated game to the European Union;]
(b) II.1. with (a)	a period of the prediseases has taker the game trophies (i) were obtain authorised i susceptible there have game anima (ii) originated fi of another t trophies of of respect to game trophies classical swine few porcine enteroviral out against any of the game trophies	ceding 12 months, and during that period n place; and or other preparations described above: hed from animals which were killed in for the exportation to the European Un domestic species and where, during been no animal health restrictions due als are susceptible; and rom animals that were killed at a distar hird country or part of a third country no cloven-hoofed animals other than swine hies or other preparations of wild swine: 	od, no vaccination against any of those in the territory of that region, which i ion of fresh meat of the corresponding the period of the preceding 60 days to outbreaks of diseases to which the nce of at least 20 km from the border of authorised to export untreated game to the European Union;]
II.1. with (a)	<ul> <li>(i) were obtain authorised t susceptible there have game animation</li> <li>(ii) originated fi of another t trophies of of erespect to game trophies</li> <li>classical swine few porcine enteroviral out against any of the game trophies</li> </ul>	hed from animals which were killed in for the exportation to the European Un domestic species and where, during been no animal health restrictions due als are susceptible; and rom animals that were killed at a distar third country or part of a third country no cloven-hoofed animals other than swine hies or other preparations of wild swine: 	In the territory of that region, which is ion of fresh meat of the corresponding the period of the preceding 60 days to outbreaks of diseases to which the note of at least 20 km from the border of authorised to export untreated game to the European Union;] e preceding 12 months, was free from r disease, foot-and-mouth disease and and no vaccinations have been carried priod; and
(a)	authorised f susceptible there have game anima (ii) originated fi of another t trophies of d respect to game troph classical swine few porcine enteroviral out against any of the game trophies	for the exportation to the European Un domestic species and where, during been no animal health restrictions due als are susceptible; and rom animals that were killed at a distar third country or part of a third country no cloven-hoofed animals other than swine hies or other preparations of wild swine: 	ion of fresh meat of the correspondin the period of the preceding 60 days to outbreaks of diseases to which the nce of at least 20 km from the border of authorised to export untreated gam to the European Union;] e preceding 12 months, was free from r disease, foot-and-mouth disease an and no vaccinations have been carrie priod; and
(a)	of another t trophies of o respect to game troph classical swine few porcine enteroviral out against any of the game trophies	third country or part of a third country no cloven-hoofed animals other than swine nies or other preparations of wild swine: 	ot authorised to export untreated game e to the European Union;] e preceding 12 months, was free fror r disease, foot-and-mouth disease an- and no vaccinations have been carrie priod; and
(a)	classical swine fev porcine enteroviral out against any of the game trophies	(region) during the period of the ver, African swine fever, swine vesicula l encephalmiyelitis (Teschen disease) a those diseases during that 12 month pe	e preceding 12 months, was free fror r disease, foot-and-mouth disease an and no vaccinations have been carrie priod; and
	classical swine fev porcine enteroviral out against any of the game trophies	ver, African swine fever, swine vesicula I encephalmiyelitis (Teschen disease) a those diseases during that 12 month pe	r disease, foot-and-mouth disease an and no vaccinations have been carrie rriod; and
(b)		or other preparations described above:	
	exportation domestic s	ned from animals which were killed in th to the European Union of fresh mu- pecies and where, during the period himal health restrictions due to outbrea s; and	eat of the corresponding susceptibl of the preceding 60 days, there hav
	of another t	from animals that were killed at a dista third country or part of a third country n wild swine to the European Union;]	
desc	cribed above were ob	otained from wild solipeds that were	
II.1. with	respect to game troph	nies or other preparations of game birds	X.
(a)	disease; and	(region) is free from highly path	ogenic avian influenza and Newcastl
(b)	that were killed in	that region and where during the perio	d of the preceding 30 days there hav
II.	des cou 1. with (a) (b) e game troph	described above were of country referred to above; 1. with respect to game troph (a) disease; and (b) the game trophies that were killed in been no animal h susceptible;] e game trophies or other preparatio	<ul> <li>described above were obtained from wild solipeds that were country referred to above;]</li> <li>1. with respect to game trophies or other preparations of game birds <ul> <li>(a)</li></ul></li></ul>

COUNTRY Game trophies or other preparations of ungulates consisting of entire parts which hav						
П.	Health information			II.a.	Certificate reference No	ll.b.
(²) [II.3.	The game	trophies or o	ther preparation	s desc	cribed above	
	(²) either	[are derived	from other rumi	nants	than bovine, ovine or caprine anim	als.]]
	(²) or	[are derived	l from bovine, ov	ine or	caprine animals and does not con	tain and is not derived from:
		(²) either	continuously	reare	•	those derived from animals born, or region classified as posing a /453/EC.]]
		(²) or			isk material as defined in point 01 of the European Parliament and	1 of Annex V to Regulation (EC) of the Council $(^3)$ ;
			anim slaug accol	als, e htereo dance	xcept from those animals that w d in a country or region classified	bones of bovine, ovine or caprine ere born, continuously reared and as posing a negligible BSE risk in 453/EC ( <sup>4</sup> ), in which there has been
			anima nervo the c those or reg	als wi ous tis ranial anim	hich have been killed, after stur sue by means of an elongated roc cavity, or by means of gas injecte als that were born, continuously r lassified as posing a negligible BS	ned from bovine, ovine or caprine ning, by laceration of the central I-shaped instrument introduced into d into the cranial cavity, except for eared and slaughtered in a country E risk in accordance with Decision
it is	a certificate	for a commo		ted th	rough the European Union; it may	box is required to be filled in only if be filled in if the certificate is for a
		.11 and I.12: ompetent auth		er: th	e registration number of the estat	blishment or plant, which has been
					to be filled in only if it is a certificat ouses and custom warehouses.	e for transit commodity. Products in
					agons or container and lorries), flig nd reloading in the European Unior	ht number (aircraft) or name (ship);
— Вох	k reference I.	19: use the a	ppropriate HS co	de: 0	5.05; 05.06, 05.07, 05.11; 96.01 or	97.05.
— Во>	k reference I.	23: for bulk co	ontainers, the co	ntaine	er number and the seal number (if a	pplicable) must be included.
— Вох	k reference I.	25: technical	use: any use oth	er tha	n for animal consumption.	
— Вох	k reference I.	26 and I.27: fi	ill in according to	whet	her it is a transit or an import certifi	cate.
Bov						e, Rhinoceritidae, Antilocaparidae, ie, Tayassuidae, Tragulidae and

CO	JNTRY				er preparations of birds and e parts which have not been treated
П.	Health information	II.a.	Certificate reference No		II.b.
Par	t II:				
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> )	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	ferent	colour to that of the printi	ng.	
_	Note for the person responsible for the cons and must accompany the consignment until Union.				
Offi	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

cou	NTR	(	Veterinary certificate to El				
	1.1.	Consignor	I.2. Certificate reference No I.2.a.				
		Name	I.3. Central competent authority				
		Address					
		Tel.	I.4. Local competent authority				
ent	1.5.	Consignee	I.6. Person responsible for the load in EU				
gnm		Name	Name				
onsi		Address	Address				
g		Postcode	Postcode				
dispatched consignment		Tel.	Tel.				
dispa	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO I.10. Region of Code destination				
õ							
Part I: Details of	1.11.	Place of origin	I.12. Place of destination				
ă∷		Name Approval number	Name Custom warehouse				
Part		Address Name Approval number	Address Approval number				
		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	l.17.				
		Identification Documentation references					
	l.18.	Description of commodity	I.19. Commodity code (HS code) 05.02				
			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					
	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 Nu Manufacturing plant	mber of packages Net weight				

col	UNTRY		Pig bristles from third countries or regions thereof that are free from African swine fever							
	Ш.	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 ( <sup>1a</sup> ) and in particular Article 10(b)(iv) thereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), 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 slaug	hterhouse, in the country of origin;						
ation	II.2.	at the time of slaughtering, signs of ;								
II.2.       The pigs, norm which the pig briates have been obtained, on hot show during inspection, carried out at the time of stadghtening, so diseases communicable to humans or animals and were not killed to eradicate any epizotic 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 swir for at least 12 months;         II.4.       the pig bristles are dry and securely enclosed in packaging.										
art II:	II.4.	the pig bristles are dry and securely enclosed in packaging.								
ш	Notes									
	Part I:									
		reference I.6: Person responsible for the consignment in the Euromodity; it may be filled in if the certificate is for import commodi		n only if it is a certificate for transit						
		reference I.11 and I.12: Approval number: the registration number ority.	er of the establishment or plant, which	has been issued by the competent						
		reference I.12: Place of destination: this box is to be filled in only stored in free zones, free warehouses and custom warehouses.	r if it is a certificate for transit commod	ity. The products in transit can only						
		reference I.15: Registration number (railway wagons or containe vided in case of unloading and reloading.	r and lorries), flight number (aircraft) c	or name (ship); information is to be						
	— Вох	reference I.23: for bulk containers, the container number and the	e seal number (if applicable) should b	e included.						
	— Вох	reference I.25: technical use: any use other than for animal con	sumption.							
	— Вох	reference I.26 and I.27: fill in according to whether it is a transit	t or an import certificate.							
	— Вох	reference I.28: Manufacturing plant: provide the veterinary control	ol number of the registered establishm	ient.						
	Part II:									
	( <sup>1a</sup> ) O.	J L 300, 14.11.2009, p. 1.								
	( <sup>1b</sup> ) O.	J L 54, 26.2.2011, p. 1.								
	(²) De	elete as appropriate.								
	— The	signature and the stamp must be in a different colour to that of	the printing.							
		e for the person responsible for the consignment in the European L consignment until it reaches the border inspection post.	Jnion: this certificate is only for veterina	ry purposes and has to accompany						
	Official	veterinarian/Official inspector								
	Na	ame (in capital letters):	Qualification and	d title:						
	Da	ate:	Signature:							
	Sta	amp:								

### 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  $\binom{2}{1}$  the European Union

cou	NTR	Y	Veterinary certificate to EU
	l.1.	Consignor	I.2. Certificate reference No I.2.a.
		Name Address	I.3. Central competent authority
		Tel.	I.4. Local competent authority
ŧ	1.5.	Consignee	I.6. Person responsible for the load in EU
Ĩ		Name	Name
Isigi		Address	Address
S		Postcode	Postcode
dispatched consignment		Tel.	Tel.
atcl	17	Country of origin ISO code I.8. Region of origin Co	de I.9. Country of ISO I.10. Region of Code
disp	1.7.	Country of origin ISO code I.8. Region of origin Co	de I.9. Country of ISO I.10. Region of Code destination code destination
٥			
Details	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 Name Approval number	Postcode
		Name Approval number Address	
	l.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	l.17.
		Identification Documentation references	
	1 1 0	. Description of commodity	I.19. Commodity code (HS code)
	1.10.		05.02
			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	
	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 Manufacturing plant	Number of packages Net weight

co	JNTRY			Pig bristles from third countries or from African swine fever	regions thereof that are not free
	Π.	Health inf	ormation	II.a. Certificate reference No	II.b.
		and of the	ersigned official veterinarian, declare that I have read a Council ( <sup>1a</sup> ) and in particular Article 10(b)(iv) thereof, a ter II thereof, and certify that:		
	II.1.	the pig bri	stles described above have been obtained from pigs	originating, and slaughtered in a slaug	hterhouse, in the country of origin;
Part II: Certification	II.2.		om which the pig bristles have been obtained did not communicable to humans or animals and were not kill		
: Certi	II.3.	the pig bri	stles mentioned above have been:		
Part II		( <sup>2</sup> ) either	[boiled;]		
		( <sup>2</sup> ) or	[dyed;]		
		(²) or	[bleached;]		
	II.4.	the pig bri	stles are dry and securely enclosed in packaging.		
	Notes				
	Part I:				
			.6: Person responsible for the consignment in the Eur nay be filled in if the certificate is for import commodi		n only if it is a certificate for transit
	— Box auth		.11 and I.12: Approval number: the registration numbe	er of the establishment or plant, which	has been issued by the competent
			.12: Place of destination: this box is to be filled in only e zones, free warehouses and custom warehouses.	r if it is a certificate for transit commodi	ty. The products in transit can only
			.15: Registration number (railway wagons or containe e of unloading and reloading.	r and lorries), flight number (aircraft) o	r name (ship); information is to be
	— Box	reference I	.23: for bulk containers, the container number and the	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	or an import certificate.	
	— Box	reference I	.28: Manufacturing plant: provide the veterinary contro	ol number of the registered establishm	ent.
	Part II:				
	( <sup>1a</sup> ) OJ	L 300, 14.	11.2009, p. 1.		
	( <sup>1b</sup> ) OJ	L 54, 26.2.	.2011, p. 1.		
	(²) Del	ete as appr	ropriate.		
	— The	signature a	and the stamp must be in a different colour to that of	the printing.	
			son responsible for the consignment in the European L t until it reaches the border inspection post.	Jnion: this certificate is only for veterina	ry purposes and has to accompany

COUNTRY	Pig bristles from third countries from African swine fever	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):	Qualification a	nd title:				
Date:	Signature:					
Stamp:						

### CHAPTER 8

#### Health certificate

For animal by-products to be used for purposes outside the feed chain or for trade samples  $\binom{2}{}$ , intended for dispatch to or for transit through  $\binom{2}{}$  the European Union

#### COUNTRY:

Veterinary certificate to EU

	l.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.	
		Name					1.3.	Central compete	ent authority		
		Address					1.4.	Local competent	t authority		
		Tel.									
	1.5.	Consignee					1.6.	Person responsi	ble for the loa	d in EU	
lent		Name						Name			
ignn		Address						Address			
Part I : Details of dispatched consignment		Postcode						Postcode			
eqo											
atch	17	Tel.	100	1.0	Deview of	Quala	10	Tel.	100	140 Design of	Quida
disp	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
of											
tails	l.11.	Place of or	igin	1			I.12.	Place of destination	tion		
å											
art I		Name		Appro	val number					Custom warehouse	
ď		Address						Name		Approval number	
		Name		Appro	oval number			Address			
		Address									
		Name		Appro	oval number			Postcode			
		Address									
	I.13.	Place of lo	ading				I.14.	Date of departur	e		
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU			
		Aeroplane	D Ship		Railway wa	agon 🗖					
		Road vehic	cle 🗖 Othe	er 🗖			I.17.				
		Identificatio	on								
		Documenta	ation reference	ces							
	l.18.	Descriptior	n of commod	ity					I.19. Comm	odity code (HS code)	
										1	
										I.20. Quantity	
	I.21.		re of product	t						I.22. Number of pa	ckages
		Ambient	]		Chilled <b>C</b>			Frozen 🕻			
	1.23.	Seal/Conta	ainer No							I.24. Type of packa	aging

1.25.	Commodities cert	ified for:				
	Technical use 🗖					
1.26.	For transit through	n EU to third countr	ry 🗖	I.27. For import or a	idmission into EU	
	Third country	ISO co	ode			
1.28.	Identification of th	e commodities	Approval number	of establishments		
(Sci	Species ientific 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 ( <sup>2</sup> )					
II.	Health inform	mation		II.a.	Certificate reference No		II.b.		
	of the Europe	an Parliame	nt and of the	Counci	e that I have read and unders il ( <sup>1a</sup> ), and Commission Regu I certify that the animal by-pro	lation (E	U) No 142/2011 (1b), and		
	refe	erred to in the	e definition of	f trade :	animal by-products intended samples in point 39 of Anne» NOT FOR HUMAN CONSU	k I to Re	gulation (EU) No 142/20		
	(²) or [sat	isfy the anim	al health req	uiremer	nts set out in point II.1.];				
II.1.	The animal by	y products de	escribed abov	/e					
II.1.1.	have been								
	(²) either [(	a) obtained thereof:		iterials	imported from a thi ( <sup>3</sup> ) authorised to export f		intry, territory or p at to the European Union		
	(²) and/or [(	b) obtained i animals th		ng third	I country, territory or part the	reof:	( <sup>3</sup> ) fr		
		either:							
		(i)	meat to the	e Europ	that third country, territory or bean Union since birth or for re the date of slaughter; and,	r a perio			
		(ii)	were killed	in the v	wild in that third country, territ	tory or pa	art thereof ( <sup>4</sup> );]		
	(²) and/or [(			nilk, roc	lents, lagomorphs, or aqual	tic anima	als or terrestrial or aqua		
( <sup>2</sup> ) [II.1.2.	invertebrates;] in the case of materials other than materials derived from eggs, milk, rodents, lagomorphs, wo aquatic animals, terrestrial or aquatic invertebrates and unprocessed furs, have been obtained from								
	(²) either [(	a) coming fr	om holdings:						
		(i)	not been a disease or 30 days, n 40 days; n	any cas highly or of cla or in th	owing diseases for which the se/outbreak of rinderpest, s pathogenic avian influenza assical or African swine feve e holdings situated in their v receding 30 days; and	wine ve during t r during	sicular disease, Newcas he period of the preced the period of the preced		
		(ii)	period of th	ne prec	ot been any case/outbreak o eding 60 days, nor in the hol ıring the period of the preced	ldings sit	tuated in their vicinity wit		
	(t	o) which:							
		(i)	were not ki	lled to e	eradicate any epizootic disea	se;			
		(ii)	of departu	re and	holdings of origin for a period which were transported dire animals which did not compl	ectly to t	the slaughterhouse with		
		(iii)	of 24 hours	s before	use, passed the ante-morten a the time of slaughter and s for which the animals are sus	howed n	no evidence of the diseas		

П.	Health inf	orma	tion		II.a.	Certificate reference No		II.b.
	(²) or	[(a)	captured ar	nd killed in th	ne wild	in an area:		
				following dis rinderpest, period of the	seases Newca e prec	5 km radius there has been s for which the animals are sus astle disease or highly pathog reding 30 days nor of classical eding 40 days; and	ceptibl genic	le: foot-and-mouth diseas avian influenza during th
				another terr	itory o	t a distance that exceeds 20 of a third country or part thereof rtation of such material to the E	, whicl	h is not authorised at the
		(b)		l immediate		ported within a period of 12 hou terwards to a game establis		
(²) [II.1.3.	obtained in diseases r 30 days o exportation	n an referr r, in n to t	establishme ed to in poir the event of he Europear	aterials other than materials derived from fish or invertebrates caught in the wild, have been stablishment around which, within a radius of 10 km, there has been no case/outbreak of d to in point II.1.2 for which the animals are susceptible during a period of the preceding e event of a case/outbreak of one of those diseases, the preparation of raw material for e European Union was authorised only after the removal of all meat, and the total cleaning of the establishment under the control of an official veterinarian;]				
II.1.4.			tained and prepared without contact with other material which does not comply with the ired above, and it has been handled so as to avoid contamination with pathogenic agents;					
II.1.5.	disinfected sealed un PRODUCT	l befo ider TS Ol	ked in new packaging which prevents any leakage or in packaging which has been cleaned and fore use and, in the case of consignments shipped other than via parcel post, in containers the responsibility of the competent authority, bearing the label indicating 'ANIMAL BY- NLY FOR THE MANUFACTURE OF DERIVED PRODUCTS FOR USES OUTSIDE THE FEED e name and address of the establishment of destination in the European Union;					
II.1.6.	consist on	ly of t	he following	animal by-p	roduct	ts:		
	(²) either	[-	killed which	were deem	ed fit t	s slaughtered or, in the case of for human consumption in acco al by-products for commercial re	rdance	e with Union legislation un
	(²) and/or	[-	slaughterho ante-morter	ouse and wo	ere co n or b	parts originating either from an onsidered fit for slaughter for l bodies and the following parts dance with Union legislation:	numan	consumption following a
				consumptio	n in a	es and parts of animals which ccordance with Union legislati communicable to humans or ani	on, bu	
			(ii)	heads of po	ultry;			
						ncluding trimmings and splitting nd the carpus and metacarpu		
			(iv)	pig bristles;				
			(v)	feathers;]				
	(²) and/or	[-	Article 1(3)	(d) of Reg	ulatior	ultry and lagomorphs slaughter n (EC) No 853/2004 of the E ow any signs of disease commu	Europe	an Parliament and of the
	(²) and/or	[-	humans or	animals, ob	otaineo	not show any signs of disease d from animals that have been ed fit for slaughter for human	slaug	htered in a slaughterhous

II.	Health inf	orm	ation	II.a. Certificate reference No	II.b.
	(²) and/or	[-		sing from the production of products i one, greaves and centrifuge or separat	
	(²) and/or	[-	longer intended for h	igin, or foodstuffs containing products uman consumption for commercial (aging defects or other defects from v	reasons or due to problems or
	(²) and/or	[-	derived products, which	uffs of animal origin, or feedingstuffs ch are no longer intended for feeding f uring or packaging defects or other de ;]	or commercial reasons or due to
	(²) and/or	[-		, feathers, hair, horns, hoof cuts an low signs of any disease communicabl	
	(²) and/or	[-		parts of such animals, except sea ma municable to humans or animals;]	ammals, which did not show any
	(²) and/or	[-		from aquatic animals originating f s for human consumption;]	from establishments or plants
	(²) and/or	[-		originating from animals which did that material to humans or animals:	not show any signs of disease
			(i) shells from	shellfish with soft tissue or flesh;	
			(ii) the followin	g originating from terrestrial animals:	
			— hatche	ery by-products;	
			— eggs;		
			— egg by	/-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 Ro as referred to in Article 8(a)(iii), (i legory 2 material as referred to in Artic	v) and (v) of Regulation (EC
	(²) and/or	[-		dead animals that did not show that product to humans or animals;]	clinical signs of any disease
II.1.7.		in s	uch a way that they will	f origin or have been preserved in a not spoil between the time of dispate	
(²) ( <sup>6</sup> ) [II.1.8.					
(2) (7)					
<i>either</i> [II.1.8.1.	territory or	r pai	t thereof referred to in	gnment come from animals that have point II.1.1, where vaccination prog ficially controlled in domestic bovine at	rammes against foot-and-mouth

II.	Health inf	ormation		the fee	II.b.		
( <sup>2</sup> ) ( <sup>8</sup> )							
()()							
and/or [II.1.8.2.	The anima meat.]]	al by-prod	ucts in this consi	gnment consist of animal by-products	derived from offal o	or debone	
(²) [II.1.9.	the animal	by-produc	ts described abov	re			
	(²) either	[are deri	ved from other run	ninants than bovine, ovine or caprine ar	nimals.]]		
	(²) or	[are deri	ved from bovine, c	ovine or caprine animals and does not c	ontain and is not deriv	red from:	
		(²) either	continuously	e and caprine materials other than th reared and slaughtered in a country E risk in accordance with Decision 200	or region classified a		
		(²) or		d risk material as defined in point 1 /2001 of the European Parliament and d		lation (EC	
			animals slaught accorda	nically separated meat obtained from b a, except from those animals that wer- ered in a country or region classified a ance with Commission Decision 2007/ b indigenous BSE case,	e born, continuously s posing a negligible	reared an BSE risk i	
			animals nervous into the for thos country	by-product or derived product obtaine which have been killed, after stunni s tissue by means of an elongated ro cranial cavity, or by means of gas injec se animals that were born, continuous or region classified as posing a neglig n 2007/453/EC.]]]	ng, by laceration of d-shaped instrument ted into the cranial ca sly reared and slaugh	the centra introduce vity, except ntered in	
II.1.10	the animal by-products described above:						
	(²) either		ontain milk or milk nimals, other thar	r products of ovine or caprine animal or n fur animals.]	gin or is not intended	for feed fo	
	(²) or			icts of ovine or caprine animal origin ar mals, and the milk or milk products:	id is intended for feed	for farme	
				e and caprine animals which have bee Ilowing conditions are fulfilled:	n kept continuously si	nce birth i	
		(i)	classical se	crapie is compulsorily notifiable;			
		(ii)	an awaren	ess, surveillance and monitoring system	n is in place for classic	al scrapie	
		(iii)		trictions apply to holdings of ovine or of TSE or the confirmation of classical s		e case of	
		(iv)	ovine and	caprine animals affected with classical	scrapie are killed and	destroyed	
		(v)	defined in Health (Ol	g to ovine and caprine animals of mea the Terrestrial Animal Health Code of tl E), of ruminant origin has been banne ntry for a period of at least the precedin	ne World Organisation d and effectively enfo	for Anim	
		(b) origi	nate from holding	s where no official restrictions are impo	sed due to a suspicior	of TSE;	
			od of the preced	gs where no case of classical scrapie ing seven years or, following the cor			

П.	Health information		II.a. Certificate reference No	hain or for trade samples (*		
	(²) either	slaughtered carrying at	nd caprine animals on the holding have d, except for breeding rams of the ARR/A least one ARR allele and no VRQ all least one ARR allele;]	been killed and destroyed c RR genotype, breeding ewe		
	( <sup>2</sup> ) or	destroyed, since the d monitoring, accordance Annex X to	s in which classical scrapie was conf and the holding has been subjected for ate of confirmation of the last classical so including testing with negative results with the laboratory methods set out i Regulation (EC) No 999/2001, of all of th e of 18 months, except ovine animals of t	a period of at least two year crapie case to intensified TSI for the presence of TSE i n point 3.2 of Chapter C on the following animals which ar		
		— animal	s which have been slaughtered for huma	n consumption; and		
			is which have died or been killed on the n the framework of a disease eradication			
Note	25					
Part	l:					
_		e transited t	ignment in the European Union: this box i hrough the European Union; it may be fil n.			
_	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	n: this box is	to be filled in:			
			lucts for uses outside the feed chain: only stored in free zones, free warehouses and			
	<ul> <li>products for trade samples or competent authority where appr</li> </ul>		ne plant in the European Union indicate	ed in the authorisation of th		
_		ading and re	vagons or container and lorries), flight nu eloading in the European Union, the con: ean Union.			
—	Box reference I.19: use the appropriat 04.04; 04.08; 05.05; 05.06, 05.07; 05.		ed System (HS) code under the following I .99, 23.01 or 30.01.	neadings: 04.01; 04.02; 04.03		
_	Box reference I.23: for bulk containers	, the contain	er number and the seal number (if applica	able) must be included.		
—	Box reference I.25: technical use: a production or manufacturing of pet for		er than feeding of farmed animals, oth	er than fur animals, and th		
—	Box reference I.25: for the purposes o	f the certifica	te, 'technical use' includes use as a trade	sample.		
—	Box reference 1.26 and 1.27: except transit or an import certificate.	or trade san	nples, which are not sent in transit, fill in	n according to whether it is		
_	Box reference I.28:					
	<ul> <li>products for the manufacture of veterinary control number of the</li> </ul>		ducts for uses outside the feed chain: Ma stablishment.	anufacturing plant: provide th		
	<ul> <li>products for the particular tech authorisation of the competent a</li> </ul>		udies or analyses: the plant in the Euro re appropriate.	opean Union indicated in th		
	- Species: select from the following	na: Aves Ri	iminantia, Suidae, Mammalia other than	Ruminantia or Suidae, Pesc		

II. a       Certificate reference No       II.b         Part II:       (*)       OJ L 300, 14, 11, 2009, p. 1.       (*)         (*)       OJ L 54, 26, 2, 2011, p. 1.       (*)       OJ L 139, 30, 42004, p. 55.       (*)         (*)       OJ L 139, 30, 42004, p. 55.       (*)       (*)       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 II to Commission Regulation (EC) No 799/2008 (OJ L 236, 23, 8, 2008, p. 1), and         (*)       Annex I to Commission Regulation (EC) No 119/2009 (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 inducted where applicable.         (*)       Only for countries from where the game meat intended for human consumption of the same animal species is authorised for improtation into the European Union.         (*)       Old 1303, 18, 11, 2009, p. 1.         (*)       Out 131, 11, 2009, p. 1.         (*)       Supplementary quarantees to be provided where exports of Part B of Channe I of a Theorem transfer measure in Regulation (EC) No 854/2004 of the European Paritament and of the council (OJ 1, 139, 30, 4, 2004, p. 206), are also permitted.         (*)       Only for certain South American and South	COI	JNTRY		Animal by		e used for purposes outside nain or for trade samples ( <sup>2</sup> )	
<ul> <li>(1) OJ L 300, 14.11 2009, p. 1.</li> <li>(1) OJ L 54, 26.2.2011, p. 1.</li> <li>(1) Delete as appropriate.</li> <li>(2) OJ L 139, 30.4.2004, p. 55.</li> <li>(3) The name and ISO code number of the exporting country as laid down in:</li> <li>Part 1 of Annex II to Commission Regulation (EC) No 206/2010 (OJ L 73, 20.3.2010, p. 1);</li> <li>Annex I to Commission Regulation (EC) No 798/2008 (OJ L 226, 23.8.2008, p. 1), and</li> <li>Annex I to Commission Regulation (EC) No 119/2009 (OJ L 39, 10.2.2009, p. 12).</li> <li>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.</li> <li>(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.</li> <li>(5) OJ L 303, 18.11.2009, p. 1.</li> <li>(6) OJ L 303, 18.11.2009, p. 1.</li> <li>(7) 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.</li> <li>(7) OJ L 130, 18.11.2009, p. 1.</li> <li>(8) Supplementary guarantees to be provided where the material of domestic ruminants originated in the territory of a South American acountry 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 I of Chapter I of Scieton IV of Annex IK Regulation (EC) No 864/2004 of the European Parliament and of the Council (OJ L 139 30.4.2004, p. 206), are also permitted.</li> <li>(9) Only for certain South American and South African countries.</li> <li>(9) Oly L 172, 30.6.2007, p. 84.</li> <li>The signature and the stamp must be in a different colour to that of the printing</li></ul>	П.	Health information	II.a.	Certificate reference			
<ul> <li>(*) OUL 54, 26.2.2011, p. 1.</li> <li>(*) Delete as appropriate.</li> <li>(*) OUL 139, 30.4.2004, p. 55.</li> <li>(*) The name and ISO code number of the exporting country as laid down in:</li> <li>Part 1 of Annex II to Commission Regulation (EU) No 206/2010 (OU L 73, 20.3.2010, p. 1);</li> <li>Annex I to Commission Regulation (EC) No 798/2008 (OU L 226, 23.8.2008, p. 1), and</li> <li>Annex I to Commission Regulation (EC) No 198/2008 (OU L 39, 10.2.2009, p. 12).</li> <li>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.</li> <li>(*) 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.</li> <li>(*) OUL 303, 18.11.2009, p. 1.</li> <li>(*) Ouly 130, 18.11.2009, p. 1.</li> <li>(*) Only for countries for where the game meat intended for human consumption of the same animal species is authorised for importation into the European Union.</li> <li>(*) Ouly 130, 18.11.2009, p. 1.</li> <li>(*) Supplementary guarantees to be provided where the material of domestic ruminants originated in the territory of a South American country op art 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 boving animals, incised in accordance with the requirements of Part I. of Chapter I of Section IV of Annex IK Decyluation (EC) No 854/2004 of the European Parliament and of the Council (OL L 139 30.4.2004, p. 200), are also permitted.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Oul L 172, 30.6.2007, p. 84.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>Note for the person responsible fo</li></ul>	Par	t II:					
<ul> <li>(*) Delete as appropriate.</li> <li>(*) OJ L 139, 30.4 2004, p. 55.</li> <li>(*) The name and ISO code number of the exporting country as laid down in:</li> <li>Part 1 of Annex II to Commission Regulation (EU) No 206/2010 (OJ L 73, 20.3 2010, p. 1);</li> <li>Annex I to Commission Regulation (EC) No 798/2008 (OJ L 226, 23.8.2008, p. 1), and</li> <li>Annex I to Commission Regulation (EC) No 119/2009 (OJ L 39, 10.2.2009, p. 12).</li> <li>In addition the ISO code of territories and parts thereof referred to in the Annexes to Regulations (EU) No 206/2010 (CC) 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.</li> <li>(*) 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.</li> <li>(*) OJ L 303, 18.11.2009, p. 1.</li> <li>(*) 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 meate of domestic ruminants for human consumption is authorised of requirements of Part B. 1 of Chapter I of Section IV of Annex Ito Regulation (EC) No 84/2004 of the European Union.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only 172, 30.6.2007, p. 84.</li> <li>(*) The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Offi</li></ul>	( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.					
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<ul> <li>(*) The name and ISO code number of the exporting country as laid down in:</li> <li>Part 1 of Annex II to Commission Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010, p. 1);</li> <li>Annex I to Commission Regulation (EC) No 798/2008 (OJ L 226, 23.8.2008, p. 1), and</li> <li>Annex I to Commission Regulation (EC) No 119/2009 (OJ L 39, 10.2.2009, p. 12).</li> <li>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.</li> <li>(*) 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.</li> <li>(*) OJL 303, 18.11.2009, p. 1.</li> <li>(*) 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.</li> <li>(*) Only for certain South American countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment in the European Un</li></ul>	( <sup>2</sup> )	Delete as appropriate.					
<ul> <li>Part 1 of Annex II to Commission Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010, p. 1);</li> <li>Annex I to Commission Regulation (EC) No 796/2008 (OJ L 226, 23.8.2008, p. 1), and</li> <li>Annex I to Commission Regulation (EC) No 119/2009 (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 796/2008 and (EC) No 119/2009 referred to in this note (where applicable for the susceptible species concerned) must be included where applicable.</li> <li>(*) 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.</li> <li>(*) Ol L 303, 18.11.2009, p. 1.</li> <li>(*) Supplementary guarantees to be provided where the material of domestic ruminants originated in the territory of a South African country or part thereof from where only maturated and deboned fresh meat of domestic ruminants for human consumption is authorised for seportation 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.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African colur to that of the printing.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the con</li></ul>	( <sup>2a</sup> )	OJ L 139, 30.4.2004, p. 55.					
<ul> <li>Annex I to Commission Regulation (EC) No 798/2008 (OJ L 226, 23.8.2008, p. 1), and</li> <li>Annex I to Commission Regulation (EC) No 119/2009 (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.</li> <li>(*) 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.</li> <li>(*) OL L 303, 18.11.2009, p. 1.</li> <li>(*) 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 Ik Regulation (EC) No 854/2004 of the European Parliament and of the Council (OJ L 139 30.4.2004, p. 206), are also permitted.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) OJ L 147, 31.5.2001, p. 1.</li> <li>(*) OJ L 147, 31.5.2001, p. 1.</li> <li>(*) OL L 172, 30.6.2007, p. 84.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters): Qualification and title: Date: Signature:</li> </ul>	(3)	The name and ISO code number of the exportin	ıg cou	ntry as laid down in:			
<ul> <li>Annex I to Commission Regulation (EC) No 119/2009 (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 119/2008 referred to in this note (where applicable for the susceptible species concerned) must be included where applicable.</li> <li>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.</li> <li>OJ L 303, 18.11.2009, p. 1.</li> <li>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 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.</li> <li>Only for certain South American and South African countries.</li> <li>Only for certain South American and South African countries.</li> <li>OJ L 147, 31.5.2001, p. 1.</li> <li>OJ L 172, 30.6.2007, p. 84.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters): Qualification and title:</li> <li>Date: Signature:</li> </ul>	_	Part 1 of Annex II to Commission Regulation (E	U) No	206/2010 (OJ L 73, 20	.3.2010, p. 1);		
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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.         (*) 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.         (*) OJ L 303, 18.11.2009, p. 1.         (*) 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.         (*) Only for certain South American and South African countries.       (*)         (*) Ol L 147, 31.5.2001, p. 1.       (*)         (*) OJ L 172, 30.6.2007, p. 84.       -         (*) 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.         Official veterinarian/Official inspector       Qualification and title:         Date:       Signature:	_	Annex I to Commission Regulation (EC) No 119	¥2009	(OJ L 39, 10.2.2009, p	. 12).		
for importation into the European Union.         (*)       OJ L 303, 18.11.2009, p. 1.         (*)       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.         (*)       Only for certain South American countries.       (*)         (*)       Only for certain South American and South African countries.       (*)         (*)       OJ L 147, 31.5.2001, p. 1.       (*)         (*)       OJ L 172, 30.6.2007, p. 84.       (*)         (*)       OJ L 172, 30.6.2007, p. 84.       (*)         (*)       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.         Official veterinarian/Official inspector       Qualification and title:         Date:       Signature:		No 798/2008 and (EC) No 119/2009 referred					
<ul> <li>(*) Supplementary guarates 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.</li> <li>(*) Only for certain South American countries.</li> <li>(*) Only for certain South American and South African countries.</li> <li>(*) OJ L 147, 31.5.2001, p. 1.</li> <li>(*) OJ L 172, 30.6.2007, p. 84.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters): Qualification and title:</li> <li>Date: Signature:</li> </ul>	(4)		ntende	ed for human consumpt	ion of the same	animal species is authorised	
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.       (9)         (9)       Only for certain South American and South African countries.       (9)         (10)       U L 147, 31.5.2001, p. 1.       (10)         (10)       OJ L 172, 30.6.2007, p. 84.       (10)         (10)       OJ L 172, 30.6.2007, p. 84.       (11)         (11)       Othe 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.         Official veterinarian/Official inspector       Name (in capital letters):       Qualification and title:         Date:       Signature:       Signature:       Signature:	(5)	OJ L 303, 18.11.2009, p. 1.					
<ul> <li>(*) Only for certain South American and South African countries.</li> <li>(*) OJ L 147, 31.5.2001, p. 1.</li> <li>(*) OJ L 172, 30.6.2007, p. 84.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters): Qualification and title:</li> <li>Date: Signature:</li> </ul>	( <sup>6</sup> )	American or South African country or part the ruminants for human consumption is authorise bovine animals, incised in accordance with the	ereof d for e require	from where only matu exportation to the Europ ements of Part B.1 of C	rated and debo bean Union. The hapter I of Secti	ned fresh meat of domestic whole masseter muscles of on IV of Annex Ito Regulation	
<ul> <li>(*) OJ L 147, 31.5.2001, p. 1.</li> <li>(*) OJ L 172, 30.6.2007, p. 84.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters): Qualification and title:</li> <li>Date: Signature:</li> </ul>	(7)	Only for certain South American countries.					
<ul> <li>OJ L 172, 30.6.2007, p. 84.</li> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters): Qualification and title:</li> <li>Date: Signature:</li> </ul>	( <sup>8</sup> )	Only for certain South American and South Afric	can co	ountries.			
<ul> <li>The signature and the stamp must be in a different colour to that of the printing.</li> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters): Qualification and title:</li> <li>Date: Signature:</li> </ul>	( <sup>9</sup> )	OJ L 147, 31.5.2001, p. 1.					
<ul> <li>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.</li> <li>Official veterinarian/Official inspector</li> <li>Name (in capital letters):</li> <li>Date:</li> <li>Signature:</li> </ul>	(10)	OJ L 172, 30.6.2007, p. 84.					
and must accompany the consignment until it reaches the border inspection post of the point of entry into the European Union. Official veterinarian/Official inspector Name (in capital letters): Date: Signature:	_	The signature and the stamp must be in a differ	ent co	lour to that of the printin	ng.		
Name (in capital letters):     Qualification and title:       Date:     Signature:	_	and must accompany the consignment until it reaches the border inspection post of the point of entry into the European					
Date: Signature:	Offic	cial veterinarian/Official inspector					
•		Name (in capital letters):			Qualification ar	nd title:	
Stamp:		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

			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				
ent	1.5.	Consignee	I.6. Person responsible for the load in EU				
Ē		Name	Name				
nsig		Address	Address				
ched co		Postcode Tel.	Postcode Tel.				
of dispatched consignment	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO destination code destination				
etails o	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	FOSICOUR				
	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					
	1.18.	Documentation references Description of commodity	I.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:	ł				
		Animal feedingstuff					
	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					
		Nature of commodity Approval number of establishments Manufacturing plant	Number of packages Net weight Batch number				

cou	INTRY				Fish oil not intended for human c material or for purposes outside th								
	Ш.	Health info	orma	ation	II.a. Certificate reference No	II.b.							
		and of the	Cour	ed official veterinarian, declare that I have read ar ncil ( <sup>1a</sup> ) and in particular Article 10 thereof, and Co sof, and certify that the fish oil described above:									
	II.1.	consists of	fish	oil that satisfies the health requirements below;									
Part II: Certification	II.2.	contains ex	clus	ively fish oil not intended for human consumption	n;								
	II.3.			ared and stored in a dedicated fish plant approved egulation (EC) No 1069/2009;	, validated and supervised by the com	petent authority in accordance with							
art II: (	II.4.	has been prepared exclusively with the following animal by-products:											
ä		( <sup>2</sup> ) either	[-	animal by-products arising from the production	of products intended for human consu	imption;]							
		( <sup>2</sup> ) and/or	[-	products of animal origin, or foodstuffs contain consumption for commercial reasons or due to which no risk to public or animal health arise;]									
		(²) and/or	( <sup>2</sup> ) 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 origin consumption;]	ating from plants or establishments i	nanufacturing products for human							
	II.5.	the fish oil:											
			(a)	has been subjected to processing in accordance order to kill pathogenic agents;	with Annex X, Chapter II, Section 3 o	of Regulation (EU) No 142/2011, in							
			(b)	has not been in contact with other types of o	Is including rendered fats from any	species of terrestrial animals, and							
		( <sup>2</sup> ) either	[(c)	is packaged in new containers or in containers t contamination and all precautions taken to prev	hat have been cleaned and disinfected if necessary for the prevention of ant their contamination,]								
		( <sup>2</sup> ) or	[(c)	where bulk transport is intended, the pipe, pump the transportation of the product from the manufa plants have been inspected and found to be cle	cturing plant either directly on to the sl								
		and	(d)	which bear labels indicating 'NOT FOR HUMAN	I CONSUMPTION'.								
	Notes												
	Part I:												
				erson responsible for the consignment in the Eur e 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.	if it is a certificate for transit commodi	ty. The products in transit can only							
				Registration number (railway wagons or containe unloading and reloading.	r and lorries), flight number (aircraft) c	r name (ship); information is to be							
	— Вох	reference I.	19: ເ	use the appropriate HS code: 15.04 or 15.18.									
	— Box	reference I.	23: f	for bulk containers, the container number and the	e seal number (if applicable) should b	e included.							
	— Box	reference I.	25: t	echnical use: any use other than for animal con-	sumption.								
	— Box	reference I.	26 a	nd I.27: fill in according to whether it is a transit	or an import certificate.								
	— Box	reference I.	28: I	Manufacturing plant: provide the registration num	ber of the treatment/processing estab	lishment.							

# **▼**<u>B</u>

COUNTRY	Fish oil not intended for human c material or for purposes outside the									
II. Health information	II.a. Certificate reference No	II.b.								
Part II:										
( <sup>1a</sup> ) OJ L 300, 14.11.2009, p. 1.										
( <sup>1b</sup> ) OJ L 54, 26.2.2011, p. 1.										
( <sup>2</sup> ) Delete as appropriate.										
- The signature and the stamp must be in a different colour to that of	the printing.									
<ul> <li>Note for the person responsible for the consignment in the Europ accompany the consignment until it reaches the border inspection per</li> </ul>		r veterinary purposes and has to								
Official veterinarian/Official inspector										
Name (in capital letters):	Qualification and	title:								
Date:	Signature:									
Stamp:										

# ▼<u>B</u>

## 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

#### COUNTRY:

Veterinary certificate to EU

	l.1.	Consignor		1.2.	Certificate refere	nce No	l.2.a.		
		Name		1.3.	Central compete	nt authority			
		Address		1.4.	Local competent	authority			
		Tel.			_				
	1.5.	Consignee		1.6.	Person responsible for the load in EU				
nent		Name			Name				
ignr		Address			Address				
Part I : Details of dispatched consignment		Postcode			Postcode				
per		Tel.			Tel.				
oatcl	1.7.		Code	1.9.	Country of	ISO	I.10. Region of	Code	
disp		of origin origin			destination	code	destination		
s of									
etai	l.11.	Place of origin		I.12.	Place of destinat	ion			
								_	
Part		Name Approval number					Custom warehouse		
		Address			Name		Approval number		
		Name Approval number			Address				
		Address							
		Name Approval number			Postcode				
	1 1 2	Address		114	Data of dopartur				
	1.13.	Place of loading		1.14.	Date of departur	e			
	I.15.	Means of transport		I.16.	Entry BIP in EU				
		Aeroplane Ship Railway wago	on 🗖						
		Road vehicle 🔲 Other 🗖		1.17.					
		Identification							
		Documentation references							
	I.18.	Description of commodity				I.19. Comm	odity code (HS code)		
							I.20. Quantity		
	1.04	Tomporature of product						koace	
	1.21.	Temperature of product Ambient  Chilled			Frozen 🕻	1	I.22. Number of pac	Lnayes	
	1.23	Seal/Container No			riozen L	J	I.24. Type of packa	aina	
	1.23.						1.24. туре ограска	ying	

1.25.	Commodities cert	ified for:									
	Animal feedingstu	iff 🗖	Manufactu	Manufacture of petfood  Technical use							
1.26.	For transit through	n EU to third countr	у 🗆	I.27. For import or admission into EU							
	Third country	ISO co	ode								
1.28.	I.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					

r						used as feed material				
	н.	Health inform	ation		II.a. Certificate reference No	II.b.				
_		the European	Parliame	ent and of the C	declare that I have read and understor council ( <sup>1a</sup> ), and in particular Article 10 r Chapter II of Annex XIV thereto, and co	thereof, and Commission Regulation				
	II.1.	consist of rend	lered fate	s that satisfy the	health requirements below;					
	II.2.	consist of rend	lered fats	s not intended fo	r human consumption;					
	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 or in accordance with Article 4(2) of Regulation (EC) No 853/2004 of the European Parliament and of the Council ( <sup>3</sup> ), in order to kill pathogenic agents;								
II.2.       consist of rendered fats not intended for human consumption;         II.3.       have been prepared and stored in a plant approved and supervised by the competent authority in accorda Article 24 of Regulation (EC) No 1069/2009 or in accordance with Article 4(2) of Regulation (EC) No 853 the European Parliament and of the Council ( <sup>3</sup> ), in order to kill pathogenic agents;         II.4.       have been prepared exclusively with the following animal by-products:										
( <sup>2</sup> ) <i>either</i> [- carcases and parts of animals slaughtered or, in the case of game, bodies animals killed, and which are fit for human consumption in accordance legislation, but are not intended for human consumption for commercial reason										
		(²) and/or	[-	slaughtered in consumption	t the following parts originating eith n a slaughterhouse and were consi following an ante-mortem inspection c game killed for human consumption in a	idered fit for slaughter for human or bodies and the following parts of				
				COI	rcases or bodies and parts of animals v nsumption in accordance with Union leg ns of disease communicable to humans	gislation, but which did not show any				
				(ii) hea	ads of poultry;					
				inc	les and skins, including trimmings an luding the phalanges and the carpus statarsus bones;					
				(iv) pig	bristles;					
				(v) fea	athers;]					
		(²) and/or	[-	humans or ani after having b	als which did not show any signs of dis imals, obtained from animals that have t een considered fit for slaughter for hu ction in accordance with Union legislatio	been slaughtered in a slaughterhouse man consumption following an ante-				
		(²) and/or	[-		oducts arising from the production including degreased bone, greaves and ig;]					
		(²) and/or	[-	longer intende	nimal origin, or foodstuffs containing pro ed for human consumption for comme I or packaging defects or other defects f	rcial reasons or due to problems of				
		(²) and/or	[-	or derived pro due to probler	eedingstuffs of animal origin, or feeding oducts, which are no longer intended fo ns of manufacturing or packaging defec imal health arises;]	or feeding for commercial reasons or				
		(²) and/or	[-		ta, wool, feathers, hair, horns, hoof cu did not show signs of any disease co					

II.	Health inform	nation	II.a. Certificate reference No II.b.						
	(²) and/or	[-	aquatic animals, and parts of such animals, except sea mammals, which did not show an signs of diseases communicable to humans or animals;]						
	(²) and/or	[-	animal by-products from aquatic animals originating from plants or establishment manufacturing products for human consumption;]						
	(²) and/or	[-	the following material originating from animals which did not show any signs of diseas 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,						
			<ul> <li>egg by-products, including egg shells;</li> </ul>						
			(iii) day-old chicks killed for commercial reasons;]						
II.5.	(²) either	( <sup>2</sup> ) either [- in the case of material of porcine origin, come from a country or part of the territor country free from foot-and-mouth disease for the period of the preceding 24 month free from classical swine fever and African swine fever for the period of the pre 12 months;]							
	(²) and/or	[-	in the case of material of poultry origin, come from a country or part of a territory of country free from Newcastle disease and avian influenza for a period of the precedin 6 months;]						
	(²) and/or	[-	in the case of material of ruminant origin, come from a country or part of a territory of country free from foot-and-mouth disease for the period of the preceding 24 months an 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. durin the relevant period referred to in point II.5, and where the rendered fats derived from 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 owne operator or their representative and, as necessary, the competent authority can monito the operation of the plant; the information must include the particle size, critic: temperature and, as appropriate, the absolute time, pressure profile, raw material feed rat and fat recycling rate.]						
II.6.			t animals, were purified in such way that the maximum levels of remaining total insolubl eed 0,15 % in weight;						
II.7.	the rendered f	ats:							
		(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 necessary for the prevention of contamination, and all precautions have been taken t prevent their contamination;]						
	( <sup>2</sup> ) or	[(b)	where bulk transport is intended, the pipe, pumps and bulk tanks and any other bul container or bulk road tanker used in the transportation of the product from th manufacturing plant either directly on to the ship or into shore tanks or directly to plant have been checked under the responsibility of the competent authority and found to b clean before use;]						

#### COUNTRY Rendered fats not intended for human consumption to be used as feed material П. Health information II.a. Certificate reference No II.b. (<sup>2</sup>) [II.8. the rendered fats described above [is derived from other ruminants than bovine, ovine or caprine animals.]] (<sup>2</sup>) either (<sup>2</sup>) 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.]] (<sup>2</sup>) or specified risk material as defined in point 1 of Annex V to Regulation (EC) [(a) No 999/2001 of the European Parliament and of the Council (4); (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 ( $^5$ ), 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 central 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.]]] II.9. the rendered fats described above: (<sup>2</sup>) either [does not contain milk or milk products of ovine or caprine animal origin or is not intended for feed for farmed animals, other than fur animals.1 [contains milk or milk products of ovine or caprine animal origin and is intended for feed for farmed (2) or animals, other than fur animals, and the milk or milk products: are derived from ovine and caprine animals which have been kept continuously since birth (a) in a country where the following conditions are fulfilled: classical scrapie is compulsorily notifiable; (i) (ii) an awareness, surveillance and monitoring system is in place for classical scrapie: (iii) official restrictions apply to holdings of ovine or caprine animals in the case of a suspicion of TSE or the confirmation of classical scrapie; ovine and caprine animals affected with classical scrapie are killed and (iv)destroyed; (v) 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 vears: originate from holdings where no official restrictions are imposed due to a suspicion of (b) TSE: originate from holdings where no case of classical scrapie has been diagnosed during the (C) preceding seven years or, following the confirmation of a case of classical scrapie:

## COUNTRY Rendered fats not intended for human consumption to be used as feed material П. Health information II.a. Certificate reference No II.b. (2) either [all ovine and caprine animals on the holding have been killed and destroyed or slaughtered, except for breeding rams of the ARRIARR genotype, breeding ewes carrying at least one ARR allele and no VRQ allele and other ovine animals carrying at least one ARR allele;] (2) or [all animals in which classical scrapie was confirmed have been killed and destroyed, and the holding has been subjected for period of at least two years since the date of confirmation of the last classical scrapie case to intensified TSE monitoring, including testing with negative results for the presence of TSE in accordance with the laboratory methods set out in point 3.2 of Chapter C of Annex X to Regulation (EC) No 999/2001, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype: animals which have been slaughtered for human consumption; and animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.]] 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 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: 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 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 or pet 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: Ruminantia, other than Ruminantia Manufacturing plant: provide the registration number of the treatment/processing establishment. Part II: (<sup>1a</sup>) OJ L 300, 14.11.2009, p. 1. (<sup>1b</sup>) OJ L 54, 26.2.2011, p. 1. (<sup>2</sup>) Delete as appropriate. $(^{3})$ OJ L 139, 30.4.2004, p. 55.

CO	UNTRY	Rendered fats r	not intended fo	or human consumption to be used as feed material						
п.	Health information	II.a. Certificate reference No	ס	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:									

## 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  $\binom{2}{1}$  the European Union

# COUNTRY:

Veterinary certificate to EU

											-		
	l.1.	Consignor					1.2.	Certificate refere	nce No	l.2.a	i		
		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					
gnm		Address						Address					
nsi													
d C		Postcode						Postcode					
che		Tel.						Tel.					
spat	1.7.	Country of origin	ISO code	1.8.	Region of origin	Code	1.9.	Country of destination	ISO code		Region of lestination	Code	
of di		orongin		1	ongin	1		destination		u	estination		
ails (	111	Place of or	iain				112	Place of destinat	ion				
Deti	1. 1 1.		igin				1.12.	Trace of destinat					
Part I : Details of dispatched consignment		Name		Annro	oval number					Custor	n warehouse		
Pai		Address		/ ippic				Name			val number		
		Name		Appro	oval number			Address		7.6610	Varnanibol		
		Address		, thbic				Address					
		Name		Appro	oval number			Postcode					
		Address											
	I.13.	Place of loa	ading				I.14.	Date of departure	е				
	I.15.	Means of tr	ransport				I.16.	Entry BIP in EU					
			_	_		_							
		Aeroplane			Railway wa	agon 🗖							
		Road vehic		er 📙			I.17.						
		Identificatio											
		Documentation references 8. Description of commodity											
	l.18.								I.19. Comm	odity co	de (HS code)		
											Quantity		
	I.21.	. Temperature of product						I.22. Number of packages				kages	
		Ambient			Chilled C			Frozen	]				
	1.23.	Seal/Conta	iner No							1.24.	Type of packa	ging	

1.25.	Commodities certifie	ed for:				
	Technical use 🗖					
1.26.	For transit through I	EU to third country		I.27. For im	port or admission into EU	
	Third country	ISO code				
1.28.	Identification of the					
		Арр	roval number	of establishm	ents	
(8	Species Manufacturing plant (Scientific name)			Number of packages Net weight		Batch number

	COUNTR	Y				intended for human consumption f rtain purposes outside the feed cha						
	н.	Health inform	ation		II.a. Certificate reference No	II.b.						
		European Par	liament J) No 14	and of the Co	declare that I have read and understo uncil ( <sup>1a</sup> ), and in particular Articles t in particular Chapter II of Annex XIV t	3, 9 and 10 thereof, and Commissi						
_	II.1.	consist of rend	ered fats	not intended fo	r human consumption that satisfy the	health requirements below;						
icatior	II.2.	have been pre	pared ex	clusively with th	e following animal by-products:							
Part II: Certification	( <sup>2</sup> ) [II.2.1.	of Annex IV to	in the case of materials destined for the production of renewable fuels referred to in point L of Section 2 of Chapter IV of Annex IV to Regulation (EU) No 142/2011, biodiesel or oleochemical products, animal by-products referred to in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009;]									
Å	( <sup>2</sup> ) [II.2.2.	of Annex IV to	Regulat	ion (EU) No 142	e production of renewable fuels referre 2/2011, the materials have been prepa lation (EC) No 1069/2009;]							
	( <sup>2</sup> ) [II.2.3.			als destined for epared exclusiv	<sup>-</sup> purposes other than cosmetics, ph ely from:	narmaceuticals or medical devices, t						
		(²) either	[-		oducts containing residues of aut permitted levels referred to in Article ?							
		(²) and/or	[-		animal origin which have been declared unfit for human consumption due to the foreign bodies in those products;]							
		(²) and/or	[-	(EC) No 1069		rred to in Articles 8 and 10 of Regulation ghtered or killed for human consumption, s;]						
		(²) and/or	[-	animals killed	and parts of animals slaughtered or, in the case of game, bodies or parts lled, and which are fit for human consumption in accordance with Un but are not intended for human consumption for commercial reasons;]							
		(²) and/or	[-	in a slaughter an ante-morte	I the following parts originating either f house and were considered fit for sla m inspection or bodies and the follow mption in accordance with Union legisl	ughter for human consumption followi ing parts of animals from game killed						
				consur	ses or bodies and parts of animals nption in accordance with Union legisl ase communicable to humans or anim	ation, but which did not show any sig						
				(ii) heads	of poultry;							
					and skins, including trimmings and sp alanges and the carpus and metacarpu							
				(iv) pig bris	itles;							
				(v) feather	s;]							
		(²) and/or	[-	humans or an after having t	als which did not show any signs of ( imals obtained from animals that hav been considered fit for slaughter for ction in accordance with Union legislat	e been slaughtered in a slaughterhou human consumption following an an						
		(²) and/or	[-		oducts arising from the productio including degreased bone, greaves a ıg;]							

II. Health information				certain purposes outside the feed chain					
II.	Health inform	ation		II.a. Certificate reference No	II.b.				
	(²) and/or	[-	longer intend	animal origin, or foodstuffs containing led for human consumption for comr g or packaging defects or other defect ]	nercial reasons or due to pro	blems o			
	(²) and/or	[-	or derived pro to problems of	feeding stuffs of animal origin, or feed oducts, which are no longer intended fo of manufacturing or packaging defects nal health arises;]	r feeding for commercial reaso	ns or du			
	(²) and/or	[-		nta, wool, feathers, hair, horns, hoof did not show signs of any disease nimals;]					
	(²) and/or	[-		als, and parts of such animals, except ases communicable to humans or anim		show ar			
	(²) and/or	[-		roducts from aquatic animals origir g products for human consumption;]	ating from plants or establ	ishmen			
	(²) and/or	[-		material originating from animals wh le through that material to humans or a		f diseas			
			(i) shells	from shellfish with soft tissue or flesh;					
			(ii) the fol	lowing originating from terrestrial anima	ls:				
			— r	natchery by-products,					
			— 6	eggs,					
			— 6	egg by-products, including egg shells,					
			(iii) day-ol	d chicks killed for commercial reasons;					
	(²) and/or	[-	aquatic and te	errestrial invertebrates other than speci	es pathogenic to humans or an	imals;]			
	(²) and/or	[-	Category 1	parts thereof of the zoological orders material as referred to in Article 8( 9and Category 2 material as referred to	a)(iii), (iv) and (v) of Regulat	ion (E0			
	(²) and/or	[-		ins, hooves, feathers, wool, horns, ha show any signs of disease communica					
	(²) and/or	[-	that material were conside	e from animals which did not show any to humans or animals, which were sla ered fit for slaughter for human c accordance with Union legislation;]]	ightered in a slaughterhouse a	nd whic			
(²) [II.2.4.			ls destined for ical or medical	purposes other than the production devices :	of organic fertilisers or soil ir	nprover			
	( <sup>2</sup> ) either	[-		; material as defined in Article 3(1)(g) rliament and of the Council ( <sup>2b</sup> );]	of Regulation (EC) No 999/20	01 of th			
	(²) and/or	[-		or parts of dead animals containing ) of Regulation (EC) No 999/2001 at the		efined			
	(²) and/or	[-		oducts which have been derived from ent as defined in Article 1(2)(d) of Cour					

COUNTR	RY					Rendered fats not intended for human consumption for certain purposes outside the feed chain					
II.	Healt	h info	rmation		II.a.	Certifica	te reference No		II.b.		
	(²) and	d/or	[-	contamination the permi	ants listed	in Group I Iaid dowr	B(3) of Annex I to by Union legislat	Directive 96	23/EC, if suc	nd environmental ch residues exceed preof, by legislation	
II.3.	the re	ndered	d fats:								
	(a)		nod) as set							te the processing r to kill pathogenic	
	(b)						European Union v 250 mg GTH per			(GTH), so that a ed,	
	(C)	in the case of rendered fats of ruminant origin, insoluble impurities in excess of 0,15% in weight have beer removed,									
	(d)	have	e been tran	sported und	ler conditio	ns which I	prevent their conta	amination, an	d		
	(e)	bear	labels on t	he packagiı	ng or conta	iner indica	ating "NOT FOR H	IUMAN OR A	NIMAL CON	SUMPTION";	
(²) [II.4.				destined for ribed above		ertilisers,	cosmetics, pharm	aceuticals, m	edical device	es or soil improvers	
	(²) eitl	her	[are derive	ed from othe	er ruminant	ts than bo	vine, ovine or cap	rine animals.			
	(²) or		[are derive	ed from bov	vine, ovine o	or caprine	animals and does	s not contain	and is not de	rived from:	
			(²) either	continuou	usly reared	and slaug		try or region of		om animals born, posing a negligible	
			(²) or				I as defined in ropean Parliamen			Regulation (EC)	
				an sla ac	imals, exc aughtered	cept from in a cour with Comr	those animals htry or region cla	that were b issified as p	orn, continu osing a neg	ovine or caprine lously reared and ligible BSE risk in there has been no	
				wh me by bo	nich have b eans of an means of orn, continu	een killed elongated gas injec ously rear	, after stunning, b d rod-shaped inst ted into the crania	by laceration rument introc al cavity, exc ed in a count	of the centra luced into th ept for those ry or region o	or caprine animals I nervous tissue by e cranial cavity, or animals that were classified as posing	
Notes											
Part I:											
is a	certifica	ate for	a commo		ransited thi	rough the				be filled in only if it certificate is for a	

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.

col	UNTRY		Rendered fats		d for human consumption for poses outside the feed chain
Н.	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				ı 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 rel	pading in the European U		
—	Box I.19: use the appropriate Harmonized \$ 15.04; 15.05; 15.06; 15.16 or 15.18.	System	n (HS) code under the follo	owing heading	gs: 04.05; 15.01, 15.02; 15.03;
—	Box reference I.23: for bulk containers, the co	ontaine	r number and the seal num	nber (if applica	ible) must be included.
_	Box reference I.25: technical use: any use ot the production or manufacturing of pet food.	her tha	an feeding of farmed anima	ls, other than	fur animals or pet animals, and
—	Box reference I.26 and I.27: fill in according to	o whet	her it is a transit or an impo	ort certificate.	
—	Box reference I.28:				
	Species: select from the following: Ruminanti	a, othe	er than Ruminantia		
	Manufacturing plant: provide the registration	numbe	r of the treatment/processi	ng establishm	ent.
Part	t II:				
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.				
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.				
(2)	Delete as appropriate.				
( <sup>2a</sup> )	OJ L 125, 23.5.1996, p. 10.				
( <sup>2b</sup> )	OJ L 147, 31.5.2001, p. 1.				
( <sup>2c</sup> )	OJ L 125, 23.5.1996, p. 3.				
( <sup>3</sup> )	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	ferent	colour to that of the printing	I.	
_	Note for the person responsible for the cons and must accompany the consignment until Union.				
Offic	cial veterinarian/Official inspector				
	Name (in capital letters):		C	Qualification a	nd title:
	Date:		S	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

С	o	υ	N	т	R	Y	:

Veterinary certificate to EU

	l.1.	Consignor					1.2.	Certificate refere	ence No	I.2.a.	
		Name					1.3.	Central compete	ent authority	Let"	
		Address					1.4.	Local competen	t authority		
		Tel.									
	1.5.	Consignee					1.6.	Person respons	ible for the loa	ad in EU	
lent		Name						Name			
ignn		Address						Address			
Part I : Details of dispatched consignment		Destands						Destanda			
ed c		Postcode						Postcode			
atch	. 7	Tel.	2		Desire	0.1		Tel.	100		0
lispa	1.7.	Country ISC of origin	) code	I.8.	Region of origin	Code	1.9.	Country of destination	ISO code	I.10. Region of destination	Code
of c											
tails	l.11.	Place of origin					I.12.	Place of destina	ition	1	
å											
art I		Name		Appro	val number					Custom warehous	e 🛛
٩.		Address						Name		Approval number	
		Name		Appro	val number			Address			
		Address									
		Name		Appro	val number			Postcode			
		Address									
	I.13.	Place of loading	9				I.14.	Date of departu	re		
	I.15.	Means of trans	port				I.16.	Entry BIP in EU			
		Aeroplane 🗖	Ship		Railway wa	agon 🗖					
		Road vehicle	] Othe	er 🗖			I.17.				
		Identification									
		Documentation	referenc	ces					-		
	l.18.	Description of c	commodi	ty					I.19. Comm	nodity code (HS code	e)
										I.20. Quantity	
	I.21.	Temperature of	product							I.22. Number of	oackages
		Ambient 🗖			Chilled	]		Frozen			
	1.23.	Seal/Container	No							I.24. Type of pac	kaging

1.25.	Commodities certifie	ed for:				
	Animal feedingstuff		Manufactu	ire of petfood $\Box$	Technical u	use 🗖
1.26.	For transit through E	EU to third country		I.27. For import o	or admission into EU	
	Third country	ISO code				
1.28.	Identification of the		oval number	of establishments		
(5	Species Scientific name)	Manufacturing plant	Number of	f packages	Net weight	Batch number

COL	INTRY				ot intended for human consumption ial or for purposes outside the feed chair
П.	Health informati	ion	II.a	. Certificate reference No	II.b.
	the European I	Parliament 011 ( <sup>1b</sup> ), a	and of the Cou	incil (1a), and in particular Article 10	od Regulation (EC) No 1069/2009 o thereof, and Commission Regulation d certify that the gelatine/collagen ( <sup>2</sup>
II.1.	consists of gela	atine/collag	en (²) that satist	y the health requirements below;	
II.2.	consist exclusiv	vely of gela	atine/collagen (2)	not intended for human consumption	n;
II.3.				approved and supervised by the co 09, in order to kill pathogenic agents;	mpetent authority in accordance with
II.4.	has been prepa	ared exclu	sively with the fo	llowing animal by-products:	
	( <sup>2</sup> ) either		animals killed,		ne case of game, bodies or parts o sumption in accordance with Unior on for commercial reasons;]
	( <sup>2</sup> ) and/or		slaughtered in consumption fol	a slaughterhouse and were cons	her from animals that have beer idered fit for slaughter for humar or bodies and the following parts o cccordance with Union legislation:
		1	consump	•	nich are rejected as unfit for human slation, but which did not show an animals;
			(ii) heads of	poultry;	
		1			ting thereof, horns and feet, including rpus bones, tarsus and metatarsus
			(iv) pig bristle	95;	
			v) feathers;	l	
	(²) and/or	-		cluding degreased bone, greaves an	of products intended for human d centrifuge or separator sludge fron
	( <sup>2</sup> ) and/or		onger intended	for human consumption for comme	oducts of animal origin, which are no rcial reasons or due to problems o from which no risk to public or anima
	(²) and/or	-	or derived produ due to problems	icts, which are no longer intended for	gstuffs containing animal by-product: or feeding for commercial reasons o ts or other defects from which no risl
	(²) and/or			and parts of such animals, except s s communicable to humans or anima	ea mammals, which did not show an ls;]
	(²) and/or			ucts from aquatic animals origina roducts for human consumption;]	ting from plants or establishment
II.5.	the gelatine/col	llagen (²):			
			and in particula		nder satisfactory hygiene conditions ace in a dedicated room, and only

II.	Health info	rmation		II.a.	Certificate reference No		chai
			Wrappings 'GELATINE/		packages containing gelatine GEN(2) SUITABLE FOR ANIMAL		
	(²) either	[(b)	Category 3 more rinses	material , involv followe	atine, was produced by a proc was subjected to a treatment wi ing pH adjustment, extraction b d by purification by means of filtra	ith acid by heati	or alkali, followed by one oing one or several times i
	( <sup>2</sup> ) or	[(b)	Category 3	material Ili follov	agen, was produced by a proc was subjected to a treatment inv ved by one or more rinses, filtr	olving w	vashing, pH adjustment usin
(²) [II.6.	in the case	e of gelatine/o	collagen (²) fro	m mate	rials other than hides and skins		
	(²) either	[is derived f	rom other rum	inants t	han bovine, ovine or caprine anima	als.]]	
	(²) or	[is derived f	rom bovine, o	vine or o	caprine animals and does not cont	tain and	is not derived from:
		(²) either	continuously	reared	I caprine materials other than and slaughtered in a country or re nce with Decision 2007/453/EC.]]		
		(²) or			sk material as defined in point I of the European Parliament and (		
			anim slaug acco	als, ex phtered rdance	y separated meat obtained from cept from those animals that w in a country or region classified with Commission Decision 2007/ Is BSE case,	vere boi l as pos	rn, continuously reared an sing a negligible BSE risk i
			anim tissu cavit that class	als whice by me y, or by were b	roduct or derived product obtain thave been killed, after stunning eans of an elongated rod-shaped in means of gas injected into the cra- born, continuously reared and s is posing a negligible BSE r 2.]]	g, by lac instrume anial ca slaughte	eration of the central nervou ent introduced into the crania vity, except for those animal red in a country or regio
11.7.	in the case	e of gelatine/o	collagen (²) fro	m mate	rials other than hides and skins de	escribed	above:
	(²) either		ontain milk or nals, other tha		oducts of ovine or caprine animal imals.]	origin o	or is not intended for feed fo
	(²) or				of ovine or caprine animal origin and the milk or milk products:	and is	intended for feed for farme
					d caprine animals which were kep ions are fulfilled:	t continu	uously since birth in a countr
		(i)	class	ical scr	apie is compulsorily notifiable;		
		(ii)	an a	warenes	ss, surveillance and monitoring sys	stem is i	n place for classical scrapie;
		(iii)		al restri icion of	ctions apply to holdings of ovine	or capr	rine animals in the case of

II.	Health information	1	II.a.	Certificate reference No	ll.b.
		(iv)	ovine and ca	prine animals affected with classic	al scrapie are killed and destroyed;
		(v)	defined in th Health (OIE)	e Terrestrial Animal Health Code	neat-and-bone meal or greaves, a of the World Organisation for Anima nned and effectively enforced in th ling seven years;
	(b)	originate fr	om holdings wh	ere no official restrictions are impo	sed due to a suspicion of TSE;
	(c)			here no case of classical scrapie has a scrapie has or, following the confirmation or	as been diagnosed during the perio a case of classical scrapie:
		(²) either	slaughtered, carrying at	except for breeding rams of the	have been killed and destroyed of ARR/ARR genotype, breeding ewe RQ allele and other ovine animal
		(²) or	destroyed, a since the da monitoring, accordance Annex X to F	nd the holding has been subjected te of confirmation of the last class including testing with negative m with the laboratory methods set	confirmed have been killed an d for a period of at least two year ical scrapie case to intensified TS soults for the presence of TSE i out in point 3.2 of Chapter C o Il of the following animals which ar Is of the ARR/ARR genotype:
			— animal	s which have been slaughtered for	human consumption; and
				s which have died or been killed n the framework of a disease eradi	on the holding but which were no cation campaign.]]
Notes	3				
Part I	:				
(		odity to be	transited throug	gh the European Union; it may b	his box is to be filled in only if it is e filled in if the certificate is for
				to be filled in only if it is a certifica nouses and custom warehouses.	te for transit commodity. Products
i		e case of ur	nloading and re	loading in the European Union, th	ght number (aircraft) or name (shi e consignor must inform the borde
	Box I.19: use the appro	oriate Harmo	onized System	(HS) code under the following head	lings: 35.03 or 35.04.
- 1	Box reference I.23: for b	oulk containe	ers, the containe	er number and the seal number (if a	applicable) must be included.
				r than feeding of farmed animal	s, other than fur animals, and th
-	Box reference I.25: teo production or manufactu				
1 1	production or manufactu	uring of pet f	ood.	ther it is a transit or an import certif	icate.

col	JNTRY			collagen not intended for human as feed material or for purposes outside the feed chain
н.	Health information	II.a.	Certificate reference No	II.b.
Pari	: II:			
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.			
( <sup>1b</sup> )	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	plour to that of the printing.	
_	Note for the person responsible for the con- and must accompany the consignment until			ate is only for veterinary purposes
Offic	cial veterinarian/Official inspector			
	Name (in capital letters):		Qualificat	ion and title:
	Date:		Signature	:
	Stamp:			

#### CHAPTER 12

#### Health certificate

For hydrolysed protein, dicalcium phosphate and tricalcium phosphate not intended for human consumption to be used as feed material or for uses outside the feed chain, intended for dispatch to or for transit through  $(^2)$  the European Union

#### COUNTRY:

#### Veterinary certificate to EU

	l.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.	
		Name					1.3.	Central compete	ent authority		
		Address					1.4.	Local competent	authority		
		Tel.									
	1.5.	Consignee					1.6.	Person responsi	ble for the loa	ad in EU	
Jent		Name						Name			
ignn		Address						Address			
cons		Postcode						Postcode			
hed		Tel.						Tel.			
Part I : Details of dispatched consignment	I.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
ils											
Deta	1.11.	Place of or	igin				1.12.	Place of destinat	tion		
 t		Name		Appro	val number					Custom warehouse	
Ра		Address						Name		Approval number	_
		Name		Appro	val number			Address			
		Address									
		Name		Appro	val number			Postcode			
		Address									
	I.13.	Place of lo	ading				I.14.	Date of departur	e		
	1.15.	Means of t	ransport				1.16.	Entry BIP in EU			
		Aeroplane	Ship		Railway wa						
		Road vehic			Rallway wa	ayon 🗖	1.17.				
		Identificatio									
			ation referend	ces							
	l.18.		n of commodi						I.19. Comm	nodity code (HS code)	)
								L		I.20. Quantity	
	I.21.	Temperatu	re of product	:						I.22. Number of pa	ackages
		Ambient	]		Chilled <b>C</b>	]		Frozen C	כ		
	1.23.	Seal/Conta	ainer No							I.24. Type of pack	aging

1.25.	Commodities cert	ified for:				
	Animal feedingstu	iff 🗖	Manufactu	re of petfood $\Box$	Technical us	e 🗖
I.26.	For transit through	n EU to third count	ry 🗖	I.27. For import or a	admission into EU	
	Third country	ISO c	ode			
1.28.	Identification of th	e commodities	Approval number	of establishments		
(Sci	Species entific name)	Nature of commodity	Manufacturing plant	Number of packages	Net weight	Batch number

	COUNT	ſRY				phosphate not inten	calcium phosphate and tricalciu ded for human consumption to b or for uses outside the feed chai			
	П.	Health in	formation			II.a. Certificate reference No	II.b.			
	-	the Europ (EU) No	ean Parliame 142/2011 ( <sup>1t</sup>	ent and o °), and	of the Co in partic	eclare that I have read and understoo uncil ( <sup>1a</sup> ), and in particular Article 10 th ular Chapter I of Annex XIV thereto nosphate ( <sup>2</sup> ) described above:	nereof, and Commission Regulatio			
u	II.1.	consists o below;	of hydrolysed	protein	/dicalcium	phosphate/tricalcium phosphate (2) the second	hat satisfy the health requirement			
rtificati	II.2.	consists e consumpt		hydroly	/sed prote	in/dicalcium phosphate/tricalcium pho	osphate (2) not intended for huma			
Part II: Certification	II.3.					t approved and supervised by the com 09, in order to kill pathogenic agents;	npetent authority in accordance wi			
å	11.4.	has been	prepared exc	lusively	with the fe	llowing animal by-products:				
	-	(²) either	slaughtered	lor,int ninaco	the case cordance	hosphate derived from defatted bone of game, bodies or parts of animals with Union legislation, but are not in	killed, and which are fit for huma			
		(²) or	[in the case	of other	r materials					
			(²) either	[-	of anim	and parts of animals slaughtered or, i als killed, and which are fit for huma gislation, but are not intended for h ]]	n consumption in accordance wi			
			(²) and/or	[-	slaughte consum of anim	arcases and the following parts originating either from animals that have be laughtered in a slaughterhouse and were considered fit for slaughter for hum consumption following an ante-mortem inspection or bodies and the following pa of animals from game killed for human consumption in accordance with Uni egislation:				
					COI	cases or bodies and parts of animals w isumption in accordance with Union leg ns of disease communicable to humans	gislation, but which did not show a			
					(ii) hea	ads of poultry;				
					inc	es and skins, including trimmings an uding the phalanges and the carpus tatarsus bones;				
					(iv) pig	bristles;				
					(v) fea	thers;]]				
			(²) and/or	[-	blood to slaughte	animals which did not show any signs humans or animals obtained from anim rhouse after having been conside ption following an ante-mortem insp n;]]	nals that have been slaughtered in red fit for slaughter for hum			
			(²) and/or	[-	consum	by-products arising from the production, including degreased bone, gre om milk processing;]]	•			
			(²) and/or	[-	are no l problem	of animal origin, or foodstuffs contain onger intended for human consumption s of manufacturing or packaging defect or animal health arise;]]	n for commercial reasons or due			

II.	Health int	formatio	on			II.a.	Certificate reference No	II.b.			
		(²) and	d/or	[-	product comme	s or rcial r	derived products, which are	r feedingstuffs containing animal I no longer intended for feeding anufacturing or packaging defects nimal health arises;]]			
		(²) and	d/or	[-	live ani	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	d/or	[-			als, and parts of such animals, ns of diseases communicable to	except sea mammals, which did i humans or animals;]]			
		(²) and	d/or	[-			oducts from aquatic animals orig g products for human consumption	inating from plants or establishme on;]]			
		(²) and	d/or	[-			material originating from anima municable through that material t	als which did not show any signs o humans or animals:			
					(i) sh	ells fr	om shellfish with soft tissue or fle	sh;			
					(ii) th	e follo	wing originating from terrestrial a	nimals:			
						hato	chery by-products,				
					_	egg	IS,				
					_		by-products, including egg shells	S.			
							chicks killed for commercial reas				
II.5.	the hydrol	veed pr	atoin/di	calciur		-	icalcium phosphate $(^2)$ :	0110,11			
n.ə.	the right of										
		(a)	CONS particu	UMPT ular the	ION' an e wrappi	d was ng an	s stored and transported under s	abels indicating 'NOT FOR HUM, atisfactory hygiene conditions, and dicated room, and only preservativ			
	(²) either	[(b)					protein, was produced by a proce raw Category 3 material.	ess involving appropriate measures			
			produ	ced in ing the	a proces	sing p	plant dedicated only to hydrolysed	from ruminants hides and skins, w I proteins production, using a proce brining, liming and intensive washi			
			(i)	temp	erature	of moi		han 11 for more than 3 hours at by heat treatment at a temperature ar ; or			
			(ii)				e material to a pH of 1 to 2, follow t at a temperature of more than 1	red by a pH of more than 11, follow 40 °C for 30 minutes at 3 bar.]			
	(²) or	[(b)	in the	case c	of dicalciu	ım ph	osphate, was produced by a proc	cess that:			
			(i)	and	treated v	/ith di		rushed and degreased with hot wa num concentration of 4 % and a pH			

II.	Health inf	formation		II.a.	Certificate reference No	II.b.	
		(iii)			precipitate, with an inlet tempe /een 30 °C and 65 °C.]	rature of 65 °C to 325 °C and an en	
	(²) or	[(b) in the	case of tricalc	um pho	osphate, was produced by a pro	cess ensuring:	
		(i)			pone-material is finely crushed a less than 14 mm),	and degreased in counter-flow with ho	
		(ii)	the continuo	us cook	ting with steam at 145 °C during	30 minutes at 4 bars,	
		(iii)	the separati centrifugatio		he protein broth from the hyd	roxyapatite (tricalcium phosphate) b	
		(iv)	the granulat 200 °C.]	ion of f	the tricalcium phosphate after	drying in a fluidised bed with air a	
(²) [II.6.	the hydrol	ysed protein/d	icalcium phosp	nate/tric	calcium phosphate (²) describec	labove	
	( <sup>2</sup> ) <i>either</i> [is derived from other ruminants than bovine, ovine or ca					nals.]]	
	(²) or	[is derived from bovine, ovine or caprine animals and does not contain and is not derived from:					
		(²) either	continuously	reared		n those derived from animals borr rry or region classified as posing 07/453/EC.]]	
		(²) or			material as defined in point of the European Parliament and	1 of Annex V to Regulation (EC of the Council $(^3)$ ;	
			animal slaugh accord	s, exce tered ir ance w	ept from those animals that with a country or region classified	n bones of bovine, ovine or caprin were born, continuously reared an d as posing a negligible BSE risk i /453/EC ( <sup>4</sup> ), in which there has bee	
			animal tissue cavity, that w classif	s which by mea or by m ere bo	have been killed, after stunnin ins of an elongated rod-shaped neans of gas injected into the c rn, continuously reared and posing a negligible BSE	ined from bovine, ovine or caprin g, by laceration of the central nervou instrument introduced into the crania ranial cavity, except for those animal slaughtered in a country or regio risk in accordance with Decisio	
II.7.	the hydrol	ysed protein/d	icalcium phosp	nate/tric	calcium phosphate (²) describec	l above:	
	(²) either		ntain milk or n als, other than			Il origin or is not intended for feed fo	
	( <sup>2</sup> ) or				ovine or caprine animal origir d the milk or milk products:	and is intended for feed for farme	
					caprine animals which have b conditions are fulfilled:	een kept continuously since birth in	
		(i)	classical scr	apie is c	compulsorily notifiable;		
		(ii)	an awarenes	is, surv	eillance and monitoring system	is in place for classical scrapie;	
		(iii)	official restri	ctions a	pply to holdings of ovine or cap	rine animals in the case of a suspicio	

CO	UNTRY		phosphate not inte	dicalcium phosphate and trica ended for human consumptior al or for uses outside the feed	ı to be
II.	Health information	II.a.		II.b.	
	(iv) ovine and cap	orine a	animals affected with classical so	crapie are killed and destroyed;	
	in the Terrest of ruminant o	rial A rigin	e and caprine animals of meat- nimal Health Code of the World has been banned and effective re preceding seven years;	Organisation for Animal Health	(OIE)
	(b) originate from holding	s wh	ere no official restrictions are imp	posed due to a suspicion of TSE	;
			ere no case of classical scrapie ars or, following the confirmation		perioc
	slaughtere	ed, ex t leas	caprine animals on the holding coept for breeding rams of the it one ARR allele and no VRQ a R allele;]	ARR/ARR genotype, breeding	ewes
	and the ho confirmati testing wi laboratory No 999/20	olding on of ith ne meth 001, c	which classical scrapie was confi has been subjected for a period the last classical scrapie case to egative results for the presen tods set out in point 3.2 of Cha of all of the following animals w imals of the ARR/ARR genotype	d of at least two years since the of o intensified TSE monitoring, inc ice of TSE in accordance wi pter C of Annex X to Regulation which are over the age of 18 m	date o cluding th the n (EC)
	— anima	ls wh	ich have been slaughtered for h	uman consumption; and	
			ich have died or been killed on t ork of a disease eradication cam		illed ir
Not	es				
Par	t I:				
_	Box reference I.6: Person responsible for the or it is a certificate for a commodity to be transit commodity to be imported into the European U	ed th	rough the European Union; it m		
—	Box reference I.12: Place of destination: this b in transit can only be stored in free zones, free				oducts
—	Box reference I.15: Registration number (railw information is to be provided in case of unload			flight number (aircraft) or name	(ship)
_	Box reference I.19: use the appropriate HS co	de: 0{	5.08, 28.35.25; 28.35.26, 29.22;	35.02; 35.03 or 35.04.	
_	Box reference I.23: for bulk containers, the cor	ıtaine	r number and the seal number (	if applicable) must be included.	
_	Box reference I.25: technical use: any use production or manufacturing of pet food.	other	r than feeding of farmed anim	als, other than fur animals, ar	nd the
_	Box reference I.26 and I.27: fill in according to	whet	her it is a transit or an import cer	rtificate.	
_	Box reference I.28:				
	<ul> <li>Species: select from the following: Aves Mollusca, Crustacea, invertebrates other</li> </ul>			er than Ruminantia or Suidae, I	Pesca

COUNTRY			phosphate n	ot intended f	um phosphate and tricalcium or human consumption to be r uses outside the feed chain		
н.	Health information	II.a.	Certificate reference No		II.b.		
	<ul> <li>Nature of commodity: specify if hydrol</li> </ul>	lysed pr	otein, dicalcium phosphat	e or tricalcium	phosphate.		
	— Manufacturing plant: provide the registration number of treatment/processing establishment.						
Part	: II:						
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.						
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.						
( <sup>2</sup> )	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 d	ifferent	colour to that of the printir	ıg.			
_	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	cial 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  $\binom{2}{}$  the European Union

cou	UNTRY Veterinary certificate to EU										
	1.1.	Consignor				1.2.	Certificate	e reference	e No	1.2.a.	
		Name Address				I.3. Central competent authority					
		Tel.				I.4. Local competent authority					
ŧ	1.5.	Consignee				I.6. Person responsible for the load in EU					
mei		Name				Name					
ign		Address					Address				
suo											
о р		Postcode					Postcode	•			
che		Tel.					Tel.				
Part I: Details of dispatched consignment	1.7.	Country of origin	ISO code	I.8. Region of origin	Code	1.9.	Country destination		SO code	I.10. Region of destination	Code
etails	l.11.	Place of origin				I.12.	Place of	destination	n		1
art I: De		Name Address		Approval number			Name Address			Custom warehouse Approval number	
а.		Name Address		Approval number			Postcode	9			
		Name Address		Approval number			1 0010000				
	I.13.	. Place of loading				I.14. Date of departure					
	l.15.	15. Means of transport				l.16.	Entry BIF	o in EU			
		Aeroplane 🗌	Ship 🗌		on 🗖						
		Road vehicle	Other [			1.17.					
		Identification									
		Documentation refe									
	1.18.	Description of com	modity			I.19. Commodity code (HS code)					
									1.20.	Quantity	
	1.21.	Temperature of pro	oduct			I.22. Number of packages					
		Ambient 🔲		Chilled		Froze	n 🗖				
	1.23.	Seal/Container No							1.24.	Type of packaging	
	I.25.	Commodities certifi	ed for:								
		Technical use 🗌									
	1.26.	For transit through	EU to third	country	]	1.27.	For impo	rt or admi	ssion into I	EU C	]
		Third country		ISO code							
	1.28.	Identification of the	commoditie	S		1					
		Species (Scientific name)	Ν	lature of commodity		Appro		er of estal cturing pla	blishments ant	Net	weight

# ▼<u>B</u>

ou	NTRY			Apiculture by-products intended	exclusively for use in apiculture	
	Ш.	Health info	ormation	II.a. Certificate reference No	II.b.	
		and of the	rsigned official veterinarian, declare that I have read ar Council ( <sup>1a</sup> ) and in particular Article 10 thereof, and Co thereof, and certify that the apiculture by-products de	ommission Regulation (EU) No 142/20		
	II.1.	come from with:	an area where the diseases mentioned below are o	fficially notifiable and which is not sub	oject to any restrictions associated	
_		(a) America	an foulbrood ( <i>Paenibacillus larvae larvae</i> );			
atio		(b) Acarios	is ( <i>Acarapis woodi</i> (Rennie));			
ertific		(c) Small h	ive beetle (Aethina tumida); and			
Part II: Certification		(d) Tropilae	elaps mites ( <i>Tropilaelaps</i> spp.);			
Part	II.2.	have been				
		( <sup>2</sup> ) either	[subjected to a temperature of - 12 $^\circ\!\text{C}$ or lower for	at least 24 hours.]		
		( <sup>2</sup> ) or	[in the case of wax refined or processed in accorda Annex IV to Regulation (EU) No 142/2011]	ance with processing method 1-2-3-4-	5-7 ( <sup>2</sup> ) as set out in Chapter III of	
	Notes					
	Part I:					
			6: Person responsible for the consignment in the Eur ay be filled in if the certificate is for import commodil		n only if it is a certificate for transit	
	<ul> <li>Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competer authority.</li> </ul>					
<ul> <li>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 transle stored in free zones, free warehouses and custom warehouses.</li> </ul>				ty. The products in transit can only		
	<ul> <li>Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is provided in the event of unloading and reloading.</li> </ul>				r name (ship); information is to be	
	— Box	reference I.	19: use the appropriate HS code: 05.11.99 and spec	cify the commodity as listed under not	e Box reference I.28.	
	— 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	or an import certificate.		
	— Box	reference I.	28: Nature of commodity: means honey, beeswax, ro	oyal jelly, propolis or pollen used in be	ee-keeping;	
	Part II:					
	( <sup>1a</sup> ) OJ	J L 300, 14.	11.2009, p. 1.			
	( <sup>1b</sup> ) OJ	J L 54, 26.2.	2011, p. 1.			
	( <sup>2</sup> ) De	elete as app	ropriate.			
	— The	signature a	nd 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 accompany the consignment until it reaches the border inspection post.					
	Official	veterinarian/	Official inspector			
	Nar	me (in capita	al letters):	Qualification and	title:	
	Dat	e:		Signature:		
	Sta	mp:				

# **▼**<u>B</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  $\binom{2}{}$  the European Union

cou	NTR	1	Veterinary certificate to E				
	1.1.	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	<ul> <li>I.6. Person responsible for the load in EU</li> <li>Name</li> <li>Address</li> </ul>				
shed co		Postcode Tel.	Postcode Tel.				
f dispato	1.7.	Country of origin ISO code 1.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination				
ails o	l.11.	Place of origin	I.12. Place of destination				
t I: Deta		Name Approval number Address	Name Custom warehouse Address Approval number				
Part		Name Approval number Address	Postcode				
		Name Approval number Address					
	l.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	l.17.				
		Identification Documentation references					
	l.18.	Description of commodity	I.19. Commodity code (HS code)				
			I.20. Quantity				
	1.21.	Temperature of product Ambient Chilled	I.22. Number of packages				
	1.23.	Seal/Container No	I.24. Type of packaging				
	I.25.	Commodities certified for:					
		Technical use					
	1.26.	For transit through EU to third country	I.27. For import or admission into EU				
	1.28.	Identification of the commodities					
		Species Approval number of establishments (Scientific name) Manufacturing plant	Number of packages Net weight Batch number				

# ▼<u>M4</u>

▼<u>M4</u>

cou	INTRY			Fat derivatives not intended for outside the feed chain	human consumption to be used					
	П.	Health inform	nation	II.a. Certificate reference No	II.b.					
		and of the C	gned official veterinarian, declare that I have read an ouncil ( <sup>1a</sup> ) and in particular Article 10 thereof, and Cr thereto, and certify that the fat derivatives describe	ommission Regulation (EU) No 142/2						
Part II: Certification	II.1.	consist of fat	derivatives that satisfy the health requirements belo	ow;						
	II.2.	consist of fat	derivatives intended for purposes outside the feed	I chain, other than in cosmetics, ph	armaceuticals and medical devices;					
	II.3.		epared and stored in a plant approved, validated an C) No 1069/2009, in order to kill pathogenic agents		ority in accordance with Article 24 of					
Pai	II.4.	have been pr	repared from rendered fats exclusively produced fro	m the following materials:						
	II.4.1.			rivatives are intended for uses outside the feed chain, other than in organic fertilisers, soil improvers, cosmetics, d medical devices, the following Category 1 materials:						
		(²) either	[- the following material:							
			(i) specified risk material;							
			(ii) entire bodies or parts of dead animals conta	aining specified risk material at the t	ime of disposal;]					
		(²) and/or	[- animal by-products which have been derived fro Article 1(2)(d) of Directive 96/22/EC or Article 2		ted to illegal treatment as defined in					
		( <sup>2</sup> ) and/or [- animal by-products containing residues of other substances and environmental contaminants listed in Group B Annex I to Directive 96/23/EC, if such residues exceed the permitted levels laid down by Union legislation or, absence thereof, by legislation of the Member State of importation;]								
	II.4.2.	. in case the fat derivatives are intended for use in organic fertilisers or soil improvers or other uses outside the feed chain, other than i cosmetics, pharmaceuticals and medical devices, the following Category 2 materials:								
		( <sup>2</sup> ) either	[- animal by-products containing residues of author to in Article 15(3) of Directive 96/23/EC;]	ised substances or contaminants exe	ceeding the permitted levels referred					
		(²) and/or	[- products of animal origin which have been decla those products;]	red unfit for human consumption due	to the presence of foreign bodies in					
		(²) and/or	[- animals and parts of animals, other than those re other than being slaughtered or killed for huma							
	II.4.3.	the following Category 3 materials:								
		( <sup>2</sup> ) either	[- carcases and parts of animals slaughtered or, in human consumption in accordance with Union reasons;]							
		( <sup>2</sup> ) and/or	[- carcases and the following parts originating eithe considered fit for slaughter for human consumpti of animals from game killed for human consum	ion following an ante-mortem inspect	ion or bodies and the following parts					
			<ul> <li>carcases or bodies and parts of animals whi legislation, but which did not show any sign</li> </ul>							
			(ii) heads of poultry;							
			<li>(iii) hides and skins, including trimmings and spl metacarpus bones, tarsus and metatarsus</li>		ng the phalanges and the carpus and					
			(iv) pig bristles;							
			(v) feathers;]							
		( <sup>2</sup> ) and/or	[- blood of animals which did not show any signs from animals that have been slaughtered in a s consumption following an ante-mortem inspection	slaughterhouse after having been co	insidered fit for slaughter for human					
		( <sup>2</sup> ) and/or	[- animal by-products arising from the production or greaves and centrifuge or separator sludge from		sumption, including degreased bone,					

▼<u>M4</u>

# Fat derivatives not intended for human consumption to be used outside the feed chain

COUNT	RY	outside the feed chain	
II.	Health infor	ion II.a. Certificate reference No II.b.	
	(²) and/or	products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defe which no risk to public or animal health arises;]	
	(²) and/or	petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, w no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging de 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 sho of any disease communicable through that product to humans or animals;]	w signs
	(²) and/or	aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of c communicable to humans or animals;]	lisease
	(²) and/or	animal by-products from aquatic animals originating from plants or establishments manufacturing products for consumption;]	humar
	(²) and/or	the following material originating from animals which did not show any signs of disease communicable throu material to humans or animals:	ugh tha
		(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.	in case of fa	rivatives produced from animal by-products referred to in point II.4.1 and point II.4.2:	
	(a) have bee	roduced using the following methods:	
	(²) either	[transesterification or hydrolysis at least 200 °C, under corresponding appropriate pressure, for 20 minutes (glyce acids and esters)]	rol, fatty
	(²) or	[saponification with NaOH 12M (glycerol and soap):	
		( <sup>2</sup> ) <i>either</i> [in a batch process at 95 °C for three hours;]	
		( <sup>2</sup> ) or [in a continuous process at 140 °C, 2 bars (2000 hPa) for eight minutes;]]	
	( <sup>2</sup> ) or	[hydrogenation at 160 °C at 12 bars (12000 hPa) pressure for 20 minutes;]	
		d in new containers or in containers that have been cleaned, and all precautions are taken to prevent its conta abels indicating "NOT FOR HUMAN OR ANIMAL CONSUMPTION";	minatior
II.6.		ivatives produced from animal by-products referred to in point II.4.3, the fat derivatives have been produced in acc processing methods [1]-[2]-[3]-[4]-[5]-[6]-[7] ( <sup>2</sup> ) referred to in Chapter III of Annex IV to Regulation (EU) No 14	
Notes			
Part I:			
		rson responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate fo filled in if the certificate is for import commodity.	or transi
		ace of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit o as, free warehouses and custom warehouses.	can only
		egistration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be prov I reloading, the consignor must inform the BIP of entry into the EU.	rided. Ir
		ropriate Harmonized System (HS) code under the following headings: 15.16 or 15.08.	

#### Fat derivatives not intended for human consumption to be used 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: (<sup>1a</sup>) OJ L 300, 14.11.2009, p. 1. (<sup>1b</sup>) 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(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  $\binom{2}{}$  the European Union

I.1. Consignor       I.2. Certificate reference No       I.2.a.         Name       Address       I.3. Central competent authority         Tel.       I.4. Local competent authority         I.5. Consignee       I.6. Person responsible for the load in EU         Name       Address         Address       Postcode         Tel.       Tel.         I.5. Consignee       Address         Postcode       Postcode         Tel.       Postcode         Tel.       I.6. Person responsible for the load in EU         Name       Address         Postcode       Postcode         Tel.       Tel.         I.7. Country of origin       ISO code       I.8. Region of origin         Code       I.9. Country of       ISO code       I.10. Region of			
Address     1.3. Central competent authority       Tel.     1.4. Local competent authority			
Tel.			
1.5.     Consignee     1.6.     Person responsible for the load in EU       Name     Name       Address     Address       Person     Postcode       Tel     Tel			
Name     Name       Address     Address       Postcode     Postcode       Tel     Tel			
Tel     Address       Address     Address       Postcode     Postcode       Tel     Tel			
V     Postcode       V     Tel			
Instruction         Instruction	Code		
Initial         Initial <t< td=""><td></td></t<>			
Interview     Approval number     Name     Custom warehouse       Address     Address     Address	ו		
Address Postcode			
Name Approval number Address			
I.13. Place of loading I.14. Date of departure	I.14. Date of departure		
I.15. Means of transport I.16. Entry BIP in EU			
Aeroplane 🗌 Ship 🗌 Railway wagon 🗌			
Road vehicle Other I	1.17.		
Identification Documentation references			
I.18. Description of commodity     I.19. Commodity code (HS code)       15.16.10			
I.20. Quantity			
I.21. Temperature of product I.22. Number of packages			
Ambient Chilled Frozen			
I.23. Seal/Container No I.24. Type of packaging			
I.25. Commodities certified for:			
Animal feedingstuff  Technical use			
I.26. For transit through EU to third country	]		
Third country ISO code			
I.28. Identification of the commodities			
Species Nature of commodity Approval number of establishments Number of Net weight Batch (Scientific name) Manufacturing plant packages	number		

# ▼<u>B</u>

cou	NTRY			Fat derivatives not intended for hu feed or outside the feed chain	man consumption to be used as
	П.	Health inf	ormation	II.a. Certificate reference No	II.b.
		Parliament	ersigned official veterinarian, declare that I have ; and of the Council ( <sup>1a</sup> ) and in particular Article <sup>-</sup> Annex XIV, Chapter II thereof, and certify that the f	10 thereof, and Commission Regulation	
	II.1.	consist of	fat derivatives that satisfy the health requirements	below;	
ication	II.2.	consist of	fat derivatives not intended for human consumptior	n;	
Part II: Certification	II.3.		prepared and stored in a plant approved, validated on (EC) No 1069/2009, in order to kill pathogenic		ority in accordance with Article 24
Part	11.4.	have been	prepared from rendered fats exclusively produced	from the following Category 3 materia	als:
		( <sup>2</sup> ) either	[- carcases and parts of animals slaughtered or, in human consumption in accordance with Union I reasons;]		
		( <sup>2</sup> ) and/or	[- carcases and the following parts originating eithe considered fit for slaughter for human consumpti of animals from game killed for human consump	on following an ante-mortem inspectior	or bodies and the following parts
			<ul> <li>(i) carcases or bodies and parts of animals whi- legislation, but which did not show any sign</li> </ul>		
			(ii) heads of poultry;		
			<ul> <li>(iii) hides and skins, including trimmings and spli metacarpus bones, tarsus and metatarsus b</li> </ul>		
			(iv) pig bristles;		
			(v) feathers;]		
		( <sup>2</sup> ) and/or	[- blood of animals which did not show any signs from animals other than ruminants that have be slaughter for human consumption following an a	en slaughtered in a slaughterhouse af	ter having been considered fit for
		( <sup>2</sup> ) and/or	[- animal by-products arising from the production of greaves and centrifuge or separator sludge from		nption, including degreased bone,
		(²) and/or	[- products of animal origin, or foodstuffs contain consumption for commercial reasons or due to which no risk to public or animal health arise;]		
		( <sup>2</sup> ) and/or	[- petfood and feedingstuffs of animal origin, or fee no longer intended for feeding for commercial re- defects from which no risk to public or animal h	asons or due to problems of manufactu	
		( <sup>2</sup> ) and/or	[- blood, placenta, wool, feathers, hair, horns, hoof any disease communicable through that product		animals that did not show signs of
		( <sup>2</sup> ) and/or	[- aquatic animals, and parts of such animals, exanicable to humans or animals;]	cept sea mammals, which did not sho	w any signs of diseases commu-
		( <sup>2</sup> ) and/or	[- animal by-products from aquatic animals origin consumption;]	ating from plants or establishments n	nanufacturing products for human
		(²) and/or	[- the following material originating from animals material to humans or animals:	which did not show any signs of dis	ease communicable through that
			(i) shells from shellfish with soft tissue or flesh;		

# **▼**<u>B</u>

COUNTR	Υ	Fat derivatives not intended for hu feed or outside the feed chain	man consumption to be used as
П.	Health information	II.a. Certificate reference No	II.b.
	(ii) the following originating from terrestrial a	nimals:	
	- hatchery by-products,		
	— eggs,		
	— egg by-products, including egg shells;	;	
	(iii) day-old chicks killed for commercial reas	sons;]	
II.5.	are packaged in new containers or in containers which to cleaned, and all precautions are taken to prevent its cont		CONSUMPTION', that have been
Notes			
Part I:			
	reference I.6: Person responsible for the consignment in the modity; it may be filled in if the certificate is for import comm		n only if it is a certificate for transit
	reference I.11 and I.12: Approval number: the registration nu ority.	mber of the establishment or plant, which	has been issued by the competent
	reference I.12: Place of destination: this box is to be filled in tored in free zones, free warehouses and custom warehouse		ty. The products in transit can only
	reference I.15: Registration number (railway wagons or contr ided in case of unloading and reloading.	ainer and lorries), flight number (aircraft) o	r name (ship); information is to be
— Box	reference I.23: for bulk containers, the container number an	d the seal number (if applicable) should b	e 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 tra-	ansit or an import certificate.	
— Box	reference I.28: Manufacturing plant: provide the registration	number of treatment/processing establishr	nent.
Part II:			
( <sup>1a</sup> ) OJ	L 300, 14.11.2009, p. 1.		
( <sup>1b</sup> ) OJ	L 54, 26.2.2011, p. 1.		
( <sup>2</sup> ) De	lete as appropriate.		
— The	signature and the stamp must be in a different colour to that	at of the printing.	
	o for the person responsible for the consignment in the E mpany the consignment until it reaches the border inspection		r veterinary purposes and has to
Official	veterinarian/Official inspector		
Nam	e (in capital letters):	Qualification ar	nd title:
Date		Signature:	
Stam	p:		

# 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

.00	NTR		Veterinary certificate to EL					
	l.1.	Consignor Name Address	1.2. Certificate reference No     1.2.a.       1.3. Central competent authority					
		Addiess						
		Tel.	I.4. Local competent authority					
dispatched consignment	I.5.	Consignee Name Address	I.6. Person responsible for the load in EU Name Address					
g		Postcode Tel.	Postcode Tel.					
atch	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code					
disp			destination destination					
ails of	l.11.	Place of origin	I.12. Place of destination					
Part I: Details		Name Approval number Address	Name Custom warehouse					
Part I		Name Approval number Address	Address Approval number					
		Name Approval number Address						
	l.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 Identification	l.17.					
		Documentation references						
	l.18.	Description of commodity	I.19. Commodity 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 certified for:						
		Animal feedingstuff	use 🗌					
	1.26.	For transit through EU to third country	I.27. For import or admission into EU					
	1.28.	Identification of the commodities	1					
		Approval number of establishments Number of pa Manufacturing plant	ckages Net weight Batch number					

# ▼<u>M4</u>

▼	M4	

JNTRY			Egg products not intended for he used as feed	uman consumption that could b						
11.	Health infor	mation	II.a. Certificate reference No	II.b.						
	and of the Co	igned official veterinarian, declare that I have read ouncil ( <sup>1a</sup> ) and in particular Article 10 thereof, and ( hereto, and certify that the egg products describe	Commission Regulation (EU) No 142/20							
II.1.	consist of eg	gg products that satisfy the health requirements b	elow;							
II.2.	consist exclu	usively of egg products not intended for human co	onsumption;							
II.3.		repared and stored in a plant, approved, validated EC) No 1069/2009 or Article 4(2) of Regulation (EC iic agents;								
11.4.	have been p	prepared (derived) exclusively with the following a	nimal by-products:							
	( <sup>2</sup> ) <i>either</i> [- animal by-products arising from the production of products intended for human consumption;]									
-	( <sup>2</sup> ) and/or	[- products of animal origin, or foodstuffs cont consumption for commercial reasons or due which no risk to public or animal health arise	to problems of manufacturing or packa							
	(²) and/or	<ul> <li>the following material originating from terrestr that material to humans or animals:</li> </ul>	rial animals which did not show any sign	s of disease communicable through						
		— hatchery by-products,								
		— eggs,								
	— egg by-products, including egg shells;]									
II.5.	have been s	ubjected to processing:								
	(²) either	[in accordance with processing method No 142/2011;]	( <sup>4</sup> ) as set out in Chapte	er III of Annex IV to Regulation (EU)						
	( <sup>2</sup> ) or	[in accordance to a method and parameters wh out in Chapter I of Annex X, to Regulation (EU)		th the microbiological standards set						
	(²) or	[in accordance with Section X, Chapters I and	II of Annex III to Regulation (EC) No 85	3/2004;]						
II.6.	have been e following sta	examined by the competent authority taking a ran ndards ( $^{5}$ ):	dom sample immediately prior to dispa	tch and found it to comply with the						
	Salmonella:	absence in 25g: n = 5, c = 0, m = 0, M	$\Lambda = 0,$							
	Enterobacter	riaceae: n = 5, c = 2, m = 10, M = 300 in 1 gra	m;							
11.7.		standards on residues of substances that are harn dangerous or harmful to animal health;	mful or might alter the organoleptic chara	cteristics of the product or make its						
II.8.	the end proc	duct was:								
	(²) either	[packed in new or sterilised bags,]								
	( <sup>2</sup> ) or	[transported in bulk in containers or other means approved by the competent authority before use		d and disinfected with a disinfectant						
	and which b	ear labels indicating "NOT FOR HUMAN CONSU	IMPTION";							
11.9.	the end proc	duct was stored in enclosed storage;								
II.10.	the product I	has undergone all precautions to avoid contamina	ation with pathogenic agents after treatn	nent.						
Notes		- ·	· ·							
Part I:										

# ▼<u>M4</u>

		used as feed	
II.	Health information	II.a. Certificate reference No	II.b.
	ox reference I.12: Place of destination: this box is to be filled in only a stored in free zones, free warehouses and custom warehouses.	/ if it is a certificate for transit commod	ity. The products in transit can only
	ox reference I.15: Registration number (railway wagons or containe ase of unloading and reloading, the consignor must inform the BIP		r name (ship) is to be provided. In
— Во	ox I.19: use the appropriate Harmonized System (HS) code under	the following headings: 04.08, 23.09 o	r 35.02.
— Во	ox reference I.23: for bulk containers, the container number and th	e seal number (if applicable) should b	e included.
— Во	ox reference I.25: technical use: any use other than for animal con	sumption.	
— Во	ox reference I.26 and I.27: fill in according to whether it is a transit	t or an import certificate.	
Part	11:		
( <sup>1a</sup> ) (	OJ L 300, 14.11.2009, p. 1.		
( <sup>1b</sup> ) (	DJ L 54, 26.2.2011, p. 1.		
( <sup>2</sup> ) [	Delete as appropriate.		
(3)	DJ L 139, 30.4.2004, p. 55.		
( <sup>4</sup> ) I	nsert method 1 to 5 or 7 as applicable.		
( <sup>5</sup> ) \	Where:		
r	n = number of samples to be tested;		
r	<ul> <li>threshold value for the number of bacteria; the result is consid m;</li> </ul>	ered satisfactory if the number of bacte	eria in all samples does not exceed
١	M = maximum value for the number of bacteria; the result is consid or more; and	lered unsatisfactory if the number of ba	cteria in one or more samples is M
c	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 bacteria
— Tł	ne 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 European l e consignment until it reaches the border inspection post.	Jnion: this certificate is only for veterina	ry purposes and has to accompany
Officia	al veterinarian/Official inspector		
Na	ame (in capital letters):	Qualificat	tion and title:
Di	ate:	Signature	ə:
St	amp:		

#### **Model declaration**

Declaration by the importer of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for use other than as feed material, organic fertilisers or soil improvers for dispatch to the European Union

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

I, the undersigned, declare that the following products  $(^{1})$ :

(a) bones and bone products (excluding bone meal);

(b) horns and horn products (excluding horn meal);

(c) hooves and hoof products (excluding hoof meal);

are intended to be imported by me into the Union, and I declare that these products will not be diverted at any stage for any use in food, feed material, organic fertilisers or soil improvers and will be conveyed directly for the purpose of further processing or treatment to:

Name: Ac	Idress:
Furthermore, I declare that the product does not contain and is V to Regulation (EC) No 999/2001 or mechanically separate animals.	
The importer:	
Name: Ad	idress:
Done at	on
(place)	(date)
Signature	
	- Entry Decomposit (OVED) analytical for in Annow III to

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)

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

 $<sup>\</sup>left(^{2}\right)$  The signature and the stamp must be in a different colour to that of the printing.

# 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

		Consignor Name Address Tel. Consignee Name		I.3.	Central o	e reference competent a		l.2.a.		
	.5.	Address Tel. Consignee				competent a	uthority			
- 	.5.	Consignee		1.4.		I.3. Central competent authority				
	.5.	Consignee			Local co	mpetent aut	hority			
		Name		1.6.	Person r	esponsible	for the loa	ad in EU		
me			Name							
nsign		Address			Address					
		Postcode		Postcod	в					
chec		Tel.			Tel.					
dis	.7.	Country of origin ISO code	I.8. Region of origin Code	1.9.	Country destinati		ISO code	I.10. Region of destination	Code	
ls of										
I: Details	.11.	Place of origin	1.12.	Place of	destination					
Part I: I		Name Address	Name Custom warehouse Address Approval number							
		Name Address	Approval number		Postcode	e				
		Name Address	Approval number							
	.13.	Place of loading	I.14. Date of departure							
Ī	.15.	Means of transport		l.16.	Entry Bl	P in EU				
		Aeroplane 🗌 Ship 🗌	Railway wagon 🔲							
		Road vehicle Other		l.17.	1.17.					
		Documentation references		I.19. Commodity code (HS code)						
I	.18.	Description of commodity								
							1.20.	Quantity		
1	.21.	Temperature of product	_	I.22. Number of packages						
		Ambient 🔲	Chilled 🗌	Frozer	ח 🗆		_			
	.23.	Seal/Container No					1.24.	Type of packaging		
1	.25.	Commodities certified for:								
		Technical use								
1	.26.	For transit through EU to third	country	1.27.	For impo	ort or admis	sion into <b>I</b>	EU		
		Third country	ISO code							
Ī	.28.	Identification of the commoditie	s							
		Species (Scientific name)	Nature of commodity			al number o Manufacturi		nments	Net weight	

со	UNTRY		Processed manure, derived produ guano from bats	icts from processed manure and
	П.	Health information	II.a. Certificate reference No	II.b.
		I, the undersigned official veterinarian, declare that I have read a and of the Council ( <sup>1a</sup> ) and in particular Article 9 thereof, and Co Chapter II thereof, and certify that the processed manure, the de above:	ommission Regulation (EU) No 142/20	11 ( <sup>1b</sup> ), and in particular Annex XIV,
tion	II.1.	come from a plant for the manufacture of products for purposes approved by the competent authority of the third country meeting Regulation (EU) No 142/2011;		
II: Certification	II.2.( <sup>2</sup> )	have been subjected to:		
°		[a heat treatment process of at least 70 $^{\circ}\mathrm{C}$ for at least 60 minu	tes;] or	
Part		[an equivalent treatment validated and authorised by the import Regulation (EC) No 1069/2009 and in Regulation (EU) No 142/ $$		the specific conditions laid down in
				;
	II.3.	are:		
	-	(a) free from Salmonella (no salmonella in 25 g treated produc	t);	
		(b) free from Escherichia coli or from Enterobacteriaceae (base and	d on the aerobic count: less than 1 00	00 cfu per gram of treated product);
		have been subjected to reduction in spore-forming bacteria and	I toxin formation;	
	11.4.	are securely enclosed in:		
		(a) well-sealed and insulated containers; or		
		(b) properly sealed packs (plastic bags or 'big bags').		
	Notes			
	Part I:			
		reference I.6: Person responsible for the consignment in the Eu modity; it may be filled in if the certificate is for import commodi		n only if it is a certificate for transit
		reference I.11 and I.12: Approval number: the registration number ority.	er of the establishment or plant, which	has been issued by the competent
		reference I.12: Place of destination: this box is to be filled in only stored in free zones, free warehouses and custom warehouses.	<i>i</i> if it is a certificate for transit commo	lity. The products in transit can only
		reference I.15: Registration number (railway wagons or containe rided in the event of unloading and reloading.	er and lorries), flight number (aircraft) (	or name (ship); information is to be
	— Box	reference I.23: for bulk containers, the container number and th	e seal number (if applicable) should b	be 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.	
	— Box	reference I.31: Nature of commodity: enter if processed manure	, derived products from processed ma	anure or guano from bats.
	Part II:			
	( <sup>1a</sup> ) O	J L 300, 14.11.2009, p. 1.		
	( <sup>1b</sup> ) O.	J L 54, 26.2.2011, p. 1.		

col	INTRY	Processed manure, derived prod guano from bats	ucts from processed manure and					
11.	Health information	II.a. Certificate reference No	II.b.					
(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 Europ accompany the consignment until it reaches the border inspection po		for veterinary purposes and has to					
Off	cial veterinarian/Official inspector							
	Name (in capital letters):	Qualification a	nd title:					
	Date:	Signature:						
	Stamp:							

# 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

#### COUNTRY:

# Veterinary certificate to EU

	l.1.	Consignor					1.2.	Certificate refere	ence No	l.2.a.		
		Name						I.3. Central competent authority				
		Address						I.4. Local competent authority				
		Tel.										
	5						1.6.	Person responsi	ible for the loa	ad in EU		
lent		Name						Name				
Part I : Details of dispatched consignment		Address						Address				
onsi												
ed c		Postcode						Postcode				
tch		Tel.						Tel.				
lispé	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	
of c												
tails	I.11.	Place of or	igin				I.12.	Place of destina	tion	1		
: De												
art I		Name		Appro	val number					Custom warehouse		
ď.		Address						Name		Approval number		
		Name		Appro	val number			Address				
		Address										
		Name		Appro	val number			Postcode				
		Address										
	I.13.	Place of lo	ading				I.14.	Date of departur	е			
	I.15.	Means of t	ransport				I.16.	Entry BIP in EU				
			·									
		Aeroplane	Ship		Railway wa	agon 🗖						
		Road vehic	cle 🛛 Othe	er 🗖			I.17.	Number(s) of CI	TES			
		Identificatio	on									
		Documenta	ation referen	ces								
	I.18.	Descriptior	n of commod	ity					I.19. Comn	nodity code (HS code)		
										05.07		
										I.20. Quantity		
	I.21.	Temperatu	re of product	t						I.22. Number of pa	ckages	
		Ambient	]		Chilled C	]		Frozen <b>C</b>	]			
	1.23.	Seal/Conta	ainer No							I.24. Type of packa	aging	

1.25.	Commodities certified for:						
	Further process	Technical	Technical use 🛛				
1.26.	6. For transit through EU to third country		I.27. For import or admission into EU				
	Third country	ISO code					
1.28.	28. Identification of the commodities Approval number of establishments						
	Species Manufacturing ( (Scientific name)		Net weight	Batch number			

	COUNTR	Y						ves and ho	of products, exc	, excluding horn meal uding hoof meal, inte ertilisers or soil impro	nded
	н.	Health inf	formation			II.a.	Certificat	e reference	No	II.b.	
		the Europ particular	ean Parliam	nent and f Annex 3	of the C XIV therete	ouncil o, and	( <sup>1a</sup> ), and certify tha	Commissior t the horns	n Regulation (EU	ation (EC) No 1069/20 ) No 142/2011 ( <sup>1b</sup> ), a s, excluding horn meal	nd in
c	II.1.	originate f	ate from animals								
Part II: Certification		(²) either						ter undergoi an consump		nspection, and were fit,	, as a
art II: Ce		(²) or	[that did n animals;]	ot show	clinical s	igns o	f any dise	ase commu	unicable through	that product to huma	ns or
å	II.2 <i>.</i>		rn products, ire of at least		and hoof	produc	cts must h	ave underg	one a heat treatr	nent for one hour at a	core
	II.3.	horns mus	st have been	removed	d without o	pening	the crania	al cavity;			
	II.4.	at any st contamina		cessing,	storage o	or trar	isport eve	ry precautio	on must have b	een taken to avoid c	cross-
	II.5.	the horns packed:	and horn p	roducts,	excluding	horn	meal, and	hooves an	d hoof products,	excluding hoof meal,	were
		(²) either	[in new pac	ckaging c	or containe	ers;]					
		(²) or	[in vehicles authority;]	s or bulk	container	s disin	fected pric	er to loading	using a product	approved by the comp	oetent
			'NOT FOR I							r-product ( <sup>3</sup> ) and bear l ress of the establishme	
	(²)[II.6.	The horns above	and horn pr	roducts, e	excluding	horn n	neal, and h	ooves and	hoof products, ex	cluding hoof meal desc	cribed
		(²) either	[is derived	from othe	er ruminan	its thai	n bovine, o	vine or capr	ine animals.]]		
		(²) or	[is derived	from bov	ine, ovine	or cap	rine anima	ls and does	not contain and i	s not derived from:	
			(²) either	continu	uously rea	red an	d slaughte		ntry or region clas	erived from animals ssified as posing a negl	
			(²) or	[(a)	specified No 999/2	risk 2001 of	material a the Europ	s defined i ean Parliam	n point 1 of Ar ent and of the Co	nex V to Regulation uncil (⁴);	(EC)
				(b)	animals, slaughtei accordar	excep red in nce wit	ot from th a country	ose animal or region o	s that were born classified as posi	of bovine, ovine or ca n, continuously reared ng a negligible BSE ri <sup>5</sup> ), in which there has	i and isk in
				(c)	animals v tissue by cavity, or that wer	which l mean by me e born as	have been is of an elc eans of ga n, continu posing a	killed, after ongated rod- s injected in ously reare	stunning, by lace shaped instrumen to the cranial cav d and slaughter	n bovine, ovine or ca ration of the central ne nt introduced into the c ity, except for those an ed in a country or n accordance with Dea	rvous ranial imals egion

COI	JNTRY	excluding horn meal, and uding hoof meal, intended ertilisers or soil improvers					
н.	Health information	II.a.	Certificate reference N	10	II.b.		
Not	es						
Par	:1:						
—	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.						
	Box reference I.12: Place of destination: this be in transit must only be stored in free zones, free				transit commodity. Products		
-	Box reference I.15: Registration number (railwainformation is to be provided in the event of unl				per (aircraft) or name (ship);		
_	Box reference I.23: for bulk containers, the con	tainer	number and the seal nu	umber (if applicabl	e) must be given.		
_	Box reference I.25: technical use: any use othe	r thar	n for animal consumptior	۱.			
_	Box reference I.26 and I.27: fill in according to	wheth	ner it is a transit or an im	port certificate.			
_	Box reference I.28: Nature of commodity.						
Par	t II:						
( <sup>1a</sup> )	OJ L 300, 14.11.2009, p. 1.						
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.						
( <sup>2</sup> )	Delete as appropriate.						
(3)	Type of product: horns, horn products, hooves,	hoof	products.				
(4)	OJ L 147, 31.5.2001, p. 1.						
( <sup>5</sup> )	OJ L 172, 30.6.2007, p. 84.						
	The signature and the stamp must be in a diffe	rent c	olour 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	cial veterinarian/Official inspector						
	Name (in capital letters):			Qualification and	d title:		
	Date:			Signature:			
1	Stamp:						

# Health certificate

For gelatine not intended for human consumption to be used by the photographic industry, intended for dispatch to the European Union

CUU	NTRY									Veterinary certific	ate to EU
	l.1.	Consignor				1.2.	Certificat	e reference l	No	I.2.a.	
		Name Address				1.3.	Central c	competent au	thority		
		Tel.				1.4.	Local co	mpetent auth	ority		
ant	l.5.	Consignee				1.6.	Person r	esponsible f	or the load	in EU	
Ĕ		Name					Name				
Isigr		Address					Address				
COL		Postcode					Postcode	9			
Itched		Tel.					Tel.	-			
s of dispatched consignment	1.7.	Country of origin	ISO code	I.8. Region of origin	Code	1.9.	Country destinati		SO code	I.10. Region of destination	Code
Part I: Details	l.11.	Place of origin	1			1.12.	Place of	destination		I	
Part I:		Name Address		Approval number			Name Address			Custom warehouse  Approval number	I
		Name Address		Approval number							
		Name		Approval number			Postcode	Э			
	112	Address Place of loading				1.14	Date of o	doporturo			
	1.13.	Flace of loading				1.14.	Date of t	leparture			
	l.15.	Means of transport			_	I.16.	Entry BI	⊃ in EU			
		Aeroplane 🗌 Road vehicle 🔲	Ship 🗌 Other 🗌		n 🔲						
		Identification		<b>_</b>		1.17.	Number(	s) of CITES			
		Documentation refer	ences								
	l.18.	Description of comm	nodity			1		I.19. Comm	odity code	(HS code)	
									1.20. Q	uantity	
										<b>,</b>	
	I.21.	Temperature of proc Ambient	duct	Chilled		Frozei	n 🗖		1.22. N	umber of packages	
	1.23.	Seal/container No							I.24. Ty	ype of packaging	
	1.25.	Commodities certifie	d for:								
		Technical use 🗌									
	I.26.					1.27.	For impo	rt or admissi	on into EU		
	1.28.	Identification of the	commodities	;		I					
		Species (Scientific name)		Approval number of Manufacturin		ents		N	et weight	Batch n	umber

UNTRY		Gelatine not intended for human consumption to be used by photographic industry									
11.	Health information	II.a. Certificate reference No II.b.									
		and understood Regulation (EC) No 1069/2009 of the European Parliament and hereof, and Commission Regulation (EU) No 142/2011 ( <sup>1b</sup> ), and in particular An aphic gelatine described above:									
II.1.	consists exclusively of photographic gelatine for pho	otographic uses and is not intended for any other purpose;									
UII.2.		ed and supervised by the competent authority in accordance with Article 23 duce gelatine for food, feed or other uses intended for dispatch to the Europe									
	has been prepared with Category 3 animal by-produ	has been prepared with Category 3 animal by-products and/or bovine vertebral column classified as Category 1 material;									
и Ш.4.	has been wrapped, packaged in new containers, st satisfactory hygiene conditions;	tored and transported in sealed, leak-proof labelled containers in a vehicle un									
II.5.	has been produced by a process ensuring that the	raw material is:									
	( <sup>3</sup> ) either treated by pressure sterilisation as referre	ed to in definition No 19 of Article 3 of Regulation (EC) No 1069/2009 ( <sup>2</sup> );									
	( <sup>3</sup> ) or subjected to:										
-		ays, washing with water and treatment with an alkaline solution for at least 20 daterial purified by means of filtration and sterilised at 138-140 $^\circ C$ for 4 seconds									
	(ii) treatment with alkali for at least two the pH must be adjusted and the m	days, washing with water and treatment with an acid solution for 10-12 hor aterial purified by means of filtration and sterilised at 138-140 $^\circ C$ for 4 secon									
II.6.	has been wrapped and packaged in wrappings PHOTOGRAPHIC INDUSTRY ONLY'.	and packages carrying the words 'PHOTOGRAPHIC GELATINE FOR T									
Notes	5										
Part	l:										
	ox reference I.5: The intended destination of the photog ingdom.	graphic gelatine can only be the Czech Republic, the Netherlands or the Uni									
— Во	ox reference I.9: Country of destination: only applicable fo	or the Czech Republic, the Netherlands or the United Kingdom.									
	ox reference I.11 and I.12: Approval number: the registrati uthority.	ion number of the establishment or plant, which has been issued by the compet									
	ox reference I.15: Registration number (railway wagons or ovided in the event of unloading and reloading.	r container and lorries), flight number (aircraft) or name (ship); information is to									
— во	ox reference I.23: Identification of container/seal number:	only where applicable.									
— Во	ox reference I.25: technical use: any use other than for a	nimal consumption.									
Part	И:										
( <sup>1a</sup> ) (	OJ L 300, 14.11.2009, p. 1.										
( <sup>1b</sup> )	OJ L 54, 26.2.2011, p. 1.										
(2)	Pressure sterilisation (method 1) is also referred to in Ch.	apter III of Annex IV to Regulation (EU) No 142/2011 as follows:									
.	'Reduction										
	using appropriate equipment, set so that the particle	essed is more than 50 millimetres, the animal by-products must be reduced in s size after reduction is no greater than 50 millimetres. The effectiveness of ecorded. If checks disclose the existence of particles larger than 50 millimetre the process is resumed.									

COUN	ITRY	Gelatine not intended for human consumption to be used by th photographic industry				
П.	Health information	II.a. Certificate reference No	II.b.			
	Time, temperature and pressure					
	<ol> <li>The animal by-products with the particle size of no greater thar for at least 20 minutes without interruption at a pressure (absolu all air in the sterilisation chamber and the replacement of the a sole process or as a pre- or post-process sterilisation phase.</li> </ol>	ite) of at least 3 bars. The pressure m	ust be produced by the evacuation of			
	3. The processing may be carried out in batch or continuous sys	stems.'				
( <sup>3</sup> )	Delete as appropriate.					
— т	he signature and the stamp must be in a different colour to that o	of the printing.				
	lote for the person responsible for the load in the European Unior onsignment until it reaches the factory of destination from the bor		purposes and has to accompany the			
Offici	ial veterinarian/Official inspector					
Na	ame (in capital letters):	Qualification	and title:			
Da	ate:	Signature:				
Sta	amp:					

# 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	INTRY	<i>'</i> :			Veterinary certificate to EU
	l.1.	Consignor	1.2.	Certificate reference No	l.2.a.
		Name	1.3.	Central competent authority	
		Address	1.4.	Local competent authority	
		Tel.			
	1.5.	Consignee	1.6.	Person responsible for the loa	ad in EU
nent		Name		Name	
ignn		Address		Address	
suo:		Destende		Postcode	
led o		Postcode Tel.		Tel.	
atch	1.7.	Country ISO code I.8. Region of Code	1.9.	Country of ISO	I.10. Region of Code
disp	1.7.	of origin origin	1.0.	destination code	destination
Part I : Details of dispatched consignment					
etail	I.11.	.11. Place of origin		Place of destination	
<u> </u>					
Part		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	
	I.15.	Means of transport	I.16.	Entry BIP in EU	
		Aeroplane 🛛 Ship 🖾 Railway wagon 🗖			
		Road vehicle 🗖 Other 🗖	I.17.		
		Identification			
		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 packages
		Ambient Chilled		Frozen 🗖	
	1.23.	Seal/Container No			I.24. Type of packaging

1.25.	Commodities certified for:							
	Technical use 🗖							
I.26.	For transit through EU to thi	rd country	I.27. For import or admission into EU					
	Third country	ISO code						
1.28.	I.28. Identification of the commodities Approval number of establishments							
	Species Manufacturing plant (Scientific name)		Net weight	Batch number				
L								

	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				
	П.	Health	n inform	ation	II.a.	Certificate reference No	II.b.
	DEC	LARATION					
	trans	sited through	the Euro		e defir	eferred to above is intended to be ition of an intermediate product pro ticular that:	
ıtion	(1) it is intended for the manufacture of:						
rtifica	( <sup>2</sup> ) <i>either</i> [- medicinal products,]						
Part II: Certification		(²) and/or	[- v	eterinary medicinal products	,]		
Part		(²) and/or	[- m	nedical devices for medical a	nd ve	erinary purposes,]	
		(²) and/or	[- a	ctive implantable medical de	vices,	]	
		(²) and/or	[- ir	n vitro diagnostic medical dev	/ices f	or medical and veterinary purposes	,]
		(²) and/or	[- la	aboratory reagents,]			
		(²) and/or	[- c	osmetic products;]			
	(2)	(2) its design, transformation and manufacturing stages have been sufficiently completed in order to qualify the material directly or as a component of a product intended for that purpose, except for the fact that it requires 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 a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, an active implantable medical devices, an in vitro diagnostic medical device for medical and veterinary purposes or a cosmetic product in accordance with the European Union legislation ( <sup>1b</sup> ) applicable to those products or as a laboratory reagent;					
	(3)	(3) it has been derived from:					
		(²) either	<ul> <li>material which may have originated from animals submitted to an illegal treatment as defined in Article 1(2)(d) of Council Directive 96/22/EC (<sup>2a</sup>) or in Article 2(b) of Council Directive 96/23/EC (<sup>2b</sup>);]</li> </ul>				
		(²) and/or	a	carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]			
		(²) and/or	s n	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			of animals which are rejected as tion, but which did not show any sig	
			(i	i) heads of poultry;			
			(i			trimmings and splitting thereof, I nd metacarpus bones, tarsus and	
			(i	v) pig bristles;			
			(\	/) feathers;]			

	UNTRY			Intermediate products to be used for products, veterinary medicinal p medical and veterinary purpose devices, in vitro diagnostics me veterinary purposes, laboratory reag	products, medical devices fo s, active implantable medica dical devices for medical and	
II.	Health	n infoi	mation	II.a. Certificate reference No	II.b.	
	(²) and/or	[-	animals obtained from anima	b ot show any signs of disease communicat Is other than ruminants that have been sl d fit for slaughter for human consumpi Union legislation;]	laughtered in a slaughterhouse	
	(²) and/or	[-		m the production of products intended for d centrifuge or separator sludge from milk		
	(²) and/or	[-	intended for human consum	r foodstuffs containing products of anim- ption for commercial reasons or due to fects from which no risk to public or animal	problems of manufacturing o	
	(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	[-		rs, hair, horns, hoof cuts and raw milk or ease communicable through that product t		
	(²) and/or	[-	aquatic animals, and parts or diseases communicable to hu	f such animals, except sea mammals, wh imans or animals;]	hich did not show any signs o	
	(²) and/or	[-	<ul> <li>animal by-products from aquatic animals originating from plants or establishmen products for human consumption;]</li> </ul>			
	(²) and/or	[-	<ul> <li>the following material originating from animals which did not show any signs of dis through that material to humans or animals:</li> </ul>		signs of disease communicable	
			(i) shells from shellfish with	n soft tissue or flesh;		
			(ii) the following originating	from terrestrial animals:		
			— hatchery by-produ	cts,		
			— eggs,			
			— egg by-products, i	ncluding egg shells;		
			(iii) day-old chicks killed for	commercial reasons;]		
	(²) and/or	[-	animal by-products from aqua or animals;]	atic or terrestrial invertebrates other than	species pathogenic to humans	
	(²) and/or	[-		the zoological orders of Rodentia and La rticle 8(a)(iii), (iv) and (v) and Categor n (EC) No 1069/2009;]		
	(²) and/or	[-	products derived from or gene	erated by:		
				rts of such animals, except sea mammals le to humans or animals,	s, which did not show any signs	
			<ul> <li>aquatic or terrestrial invention</li> </ul>	ertebrates other than species pathogenic t	to humans or animals,	
			Category 1 material as	reof of the zoological orders of Roder referred to in Article 8(a)(iii), (iv) and (' ) to (q) of Regulation (EC) No 1069/2009;]	v) and Category 2 material as	

COI	UNTRY				produ and v	cts, veterinary medic eterinary purposes, a agnostics medical de	inal products, me ictive implantable vices for medical a	nanufacture of medicinal dical devices for medical medical devices, in vitro and veterinary purposes, s, and cosmetic products
П.	Health	info	rmatio	on	II.a.	Certificate reference	No	II.b.
	(²) and/or	[-		nals and parts of animal 069/2009,	s, othe	er than those referred t	o in Article 8 or Art	ticle 10 of Regulation (EC)
			(i)	that died other than b killed for disease contr			d for human consu	Imption, including animals
			(ii)	foetuses;				
			(iii)	oocytes, embryos and	semei	n which are not destine	d for breeding purp	ooses; and
			(iv)	dead-in-shell poultry;]				
	(²) and/or	[-	anim	nal by-products other tha	an Cat	egory 1 material or Cat	egory 3 material;]	
(4)	4) its outer packaging is labelled 'FOR 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 / COSMETIC PRODUCTS ONLY' and it is not intended to be diverted at any stage within the European Union for any other use;							
(5)	the consignr point I.12 of t				to the	place of destination	in the European	Union as indicated under
	(²) either	de me	vices edical o	for medical and veteri	nary p veteri	ourposes, active impla nary purposes, laborat	antable medical de ory reagents or cos	edicinal products, medical evices, in vitro diagnostic smetic products, which has
	( <sup>2</sup> ) or [an establishment or plant which has been approved in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they may only be dispatched to an establishment or plant referred to in the preceding indent of this point.]							
Not	es							
—	2007/275/EC	c of 1	7 April		of anim	als and products to be	subject to controls	ith Commission Decision at border inspection posts
—	Box referenc	e I.25	5: tech	nical use: any use other	than f	or animal consumption	I.	
( <sup>1a</sup> )	OJ L 54, 26.2	2.201	1, p. 1					
( <sup>1b</sup> )								
( <sup>2</sup> )	Delete as ap	propr	riate.					
( <sup>2a</sup> )	OJ L 125, 23	.5.19	96, p.	3.				
( <sup>2b</sup> )	OJ L 125, 23	.5.19	96, p.	10.				
The	importer							
	Name (in cap	oital l	etters)	:			Address:	
	Date:						Signature:	

# Model declaration

Declaration by the importer of untreated wool and hair referred to in Article 25(2)(e) for import to the European Union

cou	NTR	Y:				
	l.1.	Consignor Name	I.2. Certificate reference No I.2.a.			
		Address Tel.	I.3. Central competent authority			
ent		тө.	I.4. Local competent authority			
signm	1.5.	Consignee Name	I.6. Person responsible for the load in EU Name			
S		Address	Address			
of dispatched consignment		Country Tel.	Postcode Tel.			
s of dis <sub>l</sub>	1.7.	Country of origin ISO code I.8. Region of origin Code	I.9. Country of ISO code I.10. Region of Code destination			
etails	1 4 4	Place of origin	I.12. Place of destination			
Part I: Details	1.11.	Name Approval number Address	Name Approval number Address			
		Country	Postal code / Region			
	l.13.	Place of loading Address	I.14. Date of departure			
	l.15.	Means of transport	I.16. Entry BIP in EU			
		Aeroplane Ship Railway wagon	Name Unit no			
		Road vehicle Other I Identification	I.17. No(s) of CITES			
	l.18.	Description of commodity	I.19. Commodity code (HS code)			
			I.20. Quantity			
	I.21.	Temperature of product Ambient	1.22. Number of packages			
	1.23.	Seal/Container No	1.24. Type of packaging			
	1.25.	Commodities certified for:				
		Further process				
	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				
		Nature of commodity	Net weight			

# ▼<u>M2</u>

▼<u>M2</u>

	OUNTRY:		Wool and hair referred to in Articl (EU) No 142/2011	e 25(2)(e) of Regulation			
Γ	II. Health information		II.a. Certificate reference No	II.b.			
	DECLARATION						
	I, the undersigned, dec	lare that the untreated wool (1) and/or hai	ir (1) is produced from animals other	than those of the porcine specie			
5	(a) at least 21 days before the date of entry into the Union;						
erunca	(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						
		the third country or region thereof referred d goats, of sheep pox and goat pox in a					
j	Notes:						
1	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.						
	Part I:						
-	- Box reference I.11 & I.12: Approval number: the registration number of the esatblishment or plant, which has been issued by the compter authority.						
-	- Box reference I.19:	Use the appropriate Harmonised System 5101 or 5102	(HS) code of the World Customs Org	anisation of the following heading			
-	- 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:						
	<sup>(1)</sup> Delete as appropriate.						
( <sup>2</sup> ) The signature must be in colour different to that of the printing.							
	The importer						
	The importer						
1	The importer Name (in capital letters):		Addr	ess:			
2				ess: ature:			

#### ANNEX XVI

## **OFFICIAL CONTROLS**

## CHAPTER I

# OFFICIAL CONTROLS IN PROCESSING PLANTS

#### Section 1

#### Supervision of the production

1. 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:

- (i) 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.
- 2. 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

1. Access to lists of registered and approved establishments, plants and operators

In order to assist Member States in making up-to-date lists of registered and approved establishments, plants and operators available to other Member States and to the public, the Commission shall provide a website which shall contain links to the national websites provided by each Member State, as referred to in point 2(a).

- 2. Format for national websites
  - (a) Each Member State shall provide the Commission with a linking address to a single national website containing the master list of 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.
- 3. 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) 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.
- The competent authority shall carry out official controls at collection centres in order to verify compliance with this Regulation.

# ▼<u>M4</u>

#### 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.

# ▼<u>B</u>

## 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) № 1069/2009)					
Name and address of applicant	Approval or registration number ( <sup>2</sup> )				
Name and address of place(s) of origin	Approval or registration number(s) ( <sup>2</sup> )				
Name and address of consignor (1)	Approval or registration number ( <sup>2</sup> )				
Name and address of place(s) of destination(s) ( <sup>3</sup> )	Approval or registration number(s) ( <sup>3</sup> )				
Animal by-products/derived products ( <sup>4</sup> ) Category 1 material consisting of: (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 1 to Directive 2002/32/EC destined for detoxification in an approved establishment	Intended use (4)         Disposal as a waste         Processing         Combustion         Incineration or co-incineration in ABP approved establishments or plants         Application to land         Transformation into biogas         Composting         Establishment for intermediate activities         Petfood ( <sup>5</sup> )         Production of biodiesel or other biofuels         For feeding to ( <sup>6</sup> ):         For the manufacture of the following derived products ( <sup>7</sup> ) ( <sup>2</sup> ):				
Indicate the quantity of animal by-products/derived products (volur	Destined for detoxification in an approved establishment ( <sup>2</sup> )  ne or mass) ( <sup>2</sup> ) ( <sup>8</sup> ):				

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: The materials have been processed according to the following method ( <sup>9</sup> ):	Species of origin (information should correspond to the indication of species in DOCOM/CD ( <sup>12</sup> )):
The materials have been marked with GTH. In the case of fish oil intended for detoxification, processing metho	ld.
I, the undersigned, declare that the above information is factually correct.	
(Signature: name, date, contact details: telephone, fax (if applicable), e-mail)	
The dispatch of the consignment is:  refused.  accepted.  accepted subject to the application of pressure sterilisation (method 1) to the materials and GTH marking.  accepted subject to the following conditions for the dispatch ( <sup>2</sup> ):	
This authorisation is valid until	( <sup>11</sup> )
(Date, stamp and signature of the competent authority)	
<ul> <li>places of destination The size of the box may be extended to include decision of the competent authority, responsible for the place(s) of des (*) Tick as appropriate.</li> <li>(*) Tick as appropriate.</li> <li>(*) In the case of petfood produced with Category 1 material, importer 1069/2009.</li> <li>(*) Specify in accordance with Article 18 of Regulation (EC) No 1069/2009.</li> <li>(*) Specify intended uses, such as for the manufacture of fur, organic fertitient of the case of</li></ul>	ed from third countries, referred to in Article 8(c) of Regulation (EC) No ). lisers/soil improvers, taxidermy, etc. ider (microchip), if available, or the unique life number as defined in Article

- (a) Specify one of the processing methods referred to in Chapter III or Chapter IV of Annex IV to Regulation (EU) No 142/2011.
   (<sup>10</sup>) For the competent authority: tick as appropriate.
   (<sup>11</sup>) Insert date of expiration of authorisation.
   (<sup>12</sup>) DOCOM: commercial document in TRACES form/CD: commercial document.

## 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.

# ▼<u>M9</u>