

## 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;
- (c) they must come from a third country or part of a third country listed in the column 'third countries' list' of Table 1; and
- (d) they shall be accompanied during transportation to the point of entry into the Union where the veterinary checks take place by the health certificate referred to in the column 'certificates/model documents' of Table 1; or
- (e) they shall be presented at the point of entry into the Union where the veterinary checks take place accompanied by a document corresponding to the model referred to in the 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
1	Processed animal protein	Category 3 materials referred to in Article 10(a), (b), (d), (e), (f), (h), (i),	(a) The processed animal protein must have	(a) In the case of processed animal	Annex XV, Chapter 1.

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		(j), (k), (l) and (m).	been produced in accordance with Section 1 of Chapter II of Annex X; and	fishmeal	proteins excluding fishmeal:
			(b) The processed animal protein shall comply with the additional requirements set out in Section 2 of this Chapter.	(b) In the case of fishmeal: Third countries listed in Annex II to Decision 2006/766/EC.	
2	Blood products for feed material	Category 3 materials referred to in Article 10 (a) and (b)(i).	The blood products must have been produced in accordance with Section 2 of Chapter II of Annex X.	(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	Annex XV, Chapter 4(B).

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					species are authorised.		
					(b) In the case of blood products from other species:		
					Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.		
3	Rendered fats and fish oil	(a) In the case of rendered fats excluding fish oil: Category 3 materials referred to in Article 10(a), (b), (d), (e), (f), (g), (h), (i), (j) and (k).	(a) The rendered fat and the fish oil must have been produced in accordance with Section 3 of Chapter II of Annex X; and	(a) In the case of rendered fats excluding fish oil: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.	(a) In the case of rendered fats excluding fish oil: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.	(a) In the case of rendered fats excluding fish oil: Annex XV, Chapter 10 (A).	(a) In the case of rendered fats excluding fish oil: Annex XV, Chapter 9.
		(b) In the case of fish oil:	(b) The rendered fat shall comply with the additional requirements set out	(b) In the case of fish oil: Third countries listed in Annex II to Decision 2006/766/EC.	(b) In the case of fish oil:	(b) In the case of fish oil:	(b) In the case of fish oil:

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		Category 3 materials referred to in Article 10(e), (f), (i) and (j).	in Section 3 of this Chapter.		
4	Milk, milk-based products and milk-derived products, colostrum, colostrum products	<p>(a) Milk, milk-based products and colostrum products referred to in Article 10(e), (f) and (h).</p> <p>(b) Colostrum, colostrum products from live animals that did not show any signs of disease transmissible through the colostrums to humans or animals.</p>	<p>The milk, milk-based products, colostrum and colostrum products shall comply with the requirements set out in Section 4 of this Chapter.</p>	<p>(a) In the case of milk and milk-based products:</p> <p>Authorised third countries listed in Annex I to Regulation (EU) No 605/2010.</p> <p>(b) In the case of colostrum and colostrum products:</p> <p>Third countries listed as authorised in column 'A' of Annex I to Regulation (EU) No 605/2010.</p>	<p>(a) In the case of milk, milk-based products and milk-derived products:</p> <p>Annex XV, Chapter 2(A).</p> <p>(b) In the case of colostrum and colostrums products:</p> <p>Annex XV, Chapter 2(B).</p>
5	Gelatine and hydrolysed protein	Category 3 materials referred to in Article 10(a), (b), (e), (f),	The gelatine and the hydrolysed protein must have been	(a) Third countries listed in Part	(a) In the case of gelatine:

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

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				(PK) Pakistan (TW) Taiwan.	
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: (KR) South Korea (MY) Malaysia (PK) Pakistan (TW) Taiwan.	Annex XV, Chapter 12.
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: (KR) South Korea (MY) Malaysia (PK) Pakistan (TW) Taiwan.	Annex XV, Chapter 11.
9	Egg products	Category 3 materials referred to in Article 10(e), (f) and (k)(ii).	The egg products must have been produced in accordance with Section 9 of Chapter II of Annex X.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and third countries or	Annex XV, Chapter 15.

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				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.	
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## Section 2

### Imports of processed animal protein

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.

3. Competent authorities must keep a record for at least three years of the results of sampling carried out on all consignments that have undergone sampling.

4. Where a consignment imported into the Union proves to be positive for salmonella or where it does not meet the microbiological standards for enterobacteriaceae set out in Chapter I of Annex X, it must either:
- (a) be dealt with in accordance with the procedure laid down by Article 17(2) (a) of Directive 97/78/EC; or
  - (b) reprocessed in a processing plant or decontaminated by a treatment authorised by the competent authority. The consignment must not be released until it has been treated, tested for salmonella or enterobacteriaceae, as necessary, by the competent authority in accordance with Chapter I of Annex X, and a negative result obtained.

### *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-and-mouth disease for the previous 24 months and free from rinderpest for the previous 12 months; or
- (d) where there has been an outbreak of one of the diseases referred to in points (a), (b) and (c) during the relevant period referred to in those points, have been subjected to one of the following heat treatments:
  - (i) at least 70 °C for at least 30 minutes; or
  - (ii) at least 90 °C for at least 15 minutes.

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

### *Section 4*

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

- A. The following requirements shall apply to the importation of milk, milk-based products, milk-derived products, colostrum and colostrum products:



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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.
  2. 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.

## 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;
- (c) they must come from a third country or part of a third country listed in the column 'third countries' list' of Table 2; and
- (d) they shall be accompanied during transportation to the point of entry into the Union where the veterinary checks take place by the health certificate or other document, as applicable, referred to in the column 'certificates/ model documents' of Table 2; or
- (e) they shall be presented at the point of entry into the Union where the veterinary checks take place accompanied by a document corresponding to the model referred to in the column 'certificates/ model documents' of Table 2.

*TABLE 2*

<b>No</b>	<b>Product</b>	<b>Raw materials (reference to provisions of Regulation (EC) No 1069/2009)</b>	<b>Import and transit conditions</b>	<b>Third countries' lists</b>	<b>Certificates/ model documents</b>
1	Processed manure, derived products from processed	Category 2 material referred to in Article 9(a).	The processed manure, the derived products from	Third countries listed in: (a) Part 1 of	Annex XV, Chapter 17.

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	manure and guano from bats		processed manure and the guano from bats must have been produced in accordance with Section 2 of Chapter I of Annex XI.	(b) Annex II to Regulation (EU) No 206/2010; Annex I to Decision 2004/211/EC; or Part 1 of Annex I to Regulation (EC) No 798/2008.	
2	Blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals	Category 1 material referred to in Article 8(c) and (d) and Category 3 material referred to in Article 10(a), (b), (d) and (h).	The blood products must have been produced in accordance with Section 2.	The following third countries: (a) in the case of untreated blood products of ungulates: Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 from which imports	(a) In the case of untreated blood products: Annex XV, Chapter 4 (C). In the case of treated blood products: Annex XV, Chapter 4 (D).



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				(c)	No 798/2008. Japan. in the case of untreated blood products of other animals: Third countries listed either in Part 1 of Annex II to Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008, or in Part 1 of Annex I to Regulation (EC) No 119/2009.
				(d)	Japan. in the case of treated blood products of

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				any species: Third countries listed in Part 1 to Annex II of Regulation (EU) No 206/2010, in Part 1 of Annex I to Regulation (EC) No 798/2008 or in Part 1 of Annex I to Regulation (EC) No 119/2009. Japan.	
3	Blood and blood products from equidae	Category 3 materials referred to in Article 10(a), (b), (d) and (h).	The blood and the blood products shall comply with the requirements set out in Section 3.	The following third countries: (a) in the case of blood that has been collected in accordance with point 1 of Chapter IV	Annex XV, Chapter 4(A).



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				<p>been treated in accordance with point 2(b)(ii) of Chapter IV of Annex XIII: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat of domestic equidae.</p>	
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	Annex XV, Chapter 5(A).



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				(EU) No 206/2010, from which Member States authorise imports of fresh meat from the same species.	
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.	<p>(a) In the case of treated hides and skins of ungulates:</p> <p>Third countries or parts of third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010.</p> <p>(b) In the case of treated hides and skins of ruminants that are intended for dispatch to the European Union and which have</p>	<p>(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:</p> <p>Annex XV, Chapter 5(B).</p> <p>(b) In the case of treated hides and skins of ruminants and of equidae that</p>

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<p>been kept separate for 21 days or will undergo transport for 21 uninterrupted days before importation:</p> <p>Any third country.</p>	<p>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:</p> <p>The official declaration set out in Annex XV, Chapter 5(C).</p> <p>(c) In the case of treated hides and skins of ungulates which comply with the requirements set out in Section 4,</p>
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					point 2: No certificate is required.
6	Game trophies and other preparations from animals	Category 2 materials referred to in Article 9, point (f) derived from wild animals not suspected of being infected with a disease communicable to humans or animals and Category 3 material referred to in Article 10(a), (b)(i), (iii) and (v) and (n).	The game trophies and other preparations shall comply with the requirements set out in Section 5.	(a) In the case of game trophies and other preparations referred to in Section 5, point 2:  Any third country.  (b) In the case of game trophies and other preparations referred to in Section 5, point 3:  (i) Game trophies from birds: Third countries listed in Part 1 of Annex I to Regulation (EC) No	(a) In the case of game trophies referred to in Section 5, point 2: Annex XV, Chapter 6(A).  (b) In the case of game trophies referred to in Section 5, point 3: Annex XV, Chapter 6(B).  (c) In the case of game trophies referred to in Section 5, point 1: No certificate is required.

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				special remarks for fresh meat.
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.	<p>(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.</p> <p>(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</p>

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				to the date of importation.	
8	Untreated wool and hair	Category 3 materials referred to in Article 10 (h) and (n).	The untreated wool and hair must be (a) securely enclosed in packaging and dry; and (b) sent directly to a plant producing derived products for uses outside the feed chain or a plant carrying out intermediate operations, under conditions which prevent the spreading of pathogenic agents.	Any third country.	For imports of untreated wool and hair, no health certificate is required.
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.
10	Apiculture by-products	Category 3 materials	(a) In the	(a) In the	(a) In the

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	<p>referred to in Article 10 (e).</p>	<p>case of apiculture by-products intended for use in apiculture, other than beeswax in the form of honey and the apiculture by-products have been subjected to a temperature of - 12°C or lower temperature for at least 24 hours, or</p> <p>(i) The following country: Cameroon.</p> <p>(b) In the case of beeswax for purposes other than feeding to farmed animals:</p> <p>(ii) In the case of beeswax, the material has been processed in accordance with any of</p>	<p>case of apiculture by-products intended for use in apiculture: Annex XV, Chapter 13.</p> <p>(b) In the case of beeswax for purposes other than feeding to farmed animals:</p> <p>A commercial document attesting the refinement or processing.</p> <p>Any third country.</p>	<p>case of apiculture by-products intended for use in apiculture: Annex XV, Chapter 13.</p> <p>(b) In the case of beeswax for purposes other than feeding to farmed animals:</p> <p>A commercial document attesting the refinement or processing.</p>
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			of the processing methods 1 to 5 or processing method 7, as set out in Chapter III of Annex IV before importation.		
11	Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) for uses other than as feed material, organic fertiliser or soil improver	Category 3 materials referred to in Article 10(a) (b)(i) and (iii), (e) and (h).	The products shall comply with the requirements set out in Section 7.	Any third country.	The products shall be accompanied by: (a) a commercial document as set out in Section 7, point 2; and (b) a declaration of the importer in accordance with Annex XV, Chapter 16 in at least one official language of

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					the Member State through which the consignment first enters the Union and in at least one official language of the Member State of destination.
12	Petfood, including dogchews	<p>(a) In the case of processed petfood and of dogchews:</p> <p>Materials referred to in Article 35(a) (i) and (ii).</p> <p>(b) In the case of raw petfood:</p> <p>Materials referred to in Article 35(a) (iii).</p>	<p>The petfood and the dogchews must have been produced in accordance with Chapter II of Annex XIII.</p>	<p>(a) In the case of raw petfood:</p> <p>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.</p>	<p>(a) In the case of canned petfood: Annex XV, Chapter 3(A).</p> <p>(b) In the case of processed petfood other than canned petfood: Annex XV, Chapter 3(B).</p> <p>(c) In the case of dogchews: Annex XV, Chapter 3(C).</p>

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				<p>In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.</p> <p>(b) In the case of dogchews and petfood other than raw petfood:</p> <p>Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries:</p> <p>(JP) Japan (EC) Ecuador (LK) Sri Lanka (TW) Taiwan</p>	<p>(d) In the case of raw petfood: Annex XV, Chapter 3(D).</p>
13	Flavouring innards for the manufacture of petfood	Materials referred to in Article 35(a)	The flavouring innards must have been produced in accordance with Chapter III of Annex XIII.	Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which Member States authorise imports of fresh meat from the	Annex XV, Chapter 3(E).

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				same species and where only bone in meat is authorised. In the case of flavouring innards from fish materials, third countries listed in Annex II to Decision 2006/766/EC.
14	Animal by-products for the manufacture of petfood other than raw petfood and of derived products for uses outside the feed chain	<p>(a) Category 3 materials referred to in Article 10 (a) (k).</p> <p>(b) In the case of materials for the manufacture of petfood, Category 1 materials referred to in Article 8(c).</p> <p>(c) In the case of fur for the manufacture</p>	The products shall comply with the requirements set out in Section 8.	<p>(a) In the case of animal by-products for the manufacture of petfood: In the case of animal by-products from bovine, ovine, caprine, porcine and equine animals, including farmed and wild animals: Third countries or parts of</p> <p>(a) In the case of animal by-products for the manufacture of processed petfood: Annex XV, Chapter 3(F).</p> <p>(b) In the case of animal by-products for the manufacture of products for uses outside the feed chain for farmed animals:</p>

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		of derived products, Category 3 materials referred to in Article 10(n).		third country listed in Part 1 of Annex II to Regulation (EU) No 206/2010, from which imports of fresh meat for human consumption is authorised. (ii) Raw material from poultry including ratites: Third countries or parts of third countries from which Member States authorise imports of fresh poultrymeat, which are listed in Part 1 of Annex I to	Annex XV, Chapter 8.
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					Regulation (EC) No 798/2008.
			(iii)	Raw material from fish: Third countries listed in Annex II to Decision 2006/766/ EC.	
			(iv)	Raw material from other wild land mammals and leporidae: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EC) No 798/2008.	
			(b)	In the case of animal	

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by-  
products  
for  
the  
manufacture  
of  
pharmaceuticals:

Third  
countries  
listed in Part  
1 of Annex II  
to Regulation  
(EU) No  
206/2010,  
in Part 1 of  
Annex I to  
Regulation  
(EC) No  
798/2008 or  
in Part 1 of  
Annex I to  
Regulation  
(EC) No  
119/2009, and  
the following  
third  
countries:

(JP)  
Japan  
(PH)  
Philippines  
(TW)  
Taiwan.

(c) In  
the  
case  
of  
animal  
by-  
products  
for  
the  
manufacture  
of  
products  
for  
uses  
outside  
the  
feed  
chain  
for

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				<p>farmed animals, other than pharmaceuticals:</p> <p>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.</p>	
15	Animal by-products for use as raw petfood	Category 3 materials referred to in Article 10 (a), (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, from which Member States authorise imports of fresh meat from the same species and where	Annex XV, Chapter 3(D).



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				only bone in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.	
16	Animal by-products for use in feed for fur animals	Category 3 materials referred to in Article 10 (a), 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 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).
17	Rendered fats for certain purposes outside the feed chain for farmed animals	(a) In the case of materials destined to	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	Annex XV, Chapter 10(B).

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	<p>the production of biodiesel:</p> <p>Category 1, 2 and 3 materials referred to in Articles 8, 9 and 10.</p> <p>(b) In the case of materials destined to organic fertilisers and soil improvers:</p> <p>Category 2 materials referred to in Article 9(c), (d) and f(i) and Category 3 materials referred to in Article 10, other than points (c) and (p).</p> <p>(c) In the case of materials destined to other purposes:</p> <p>Category 1 materials referred to in Article 8(b), (c) and (d), Category 2 materials referred to in</p>	<p>case of fish materials, third countries listed in Annex II to Decision 2006/766/EC.</p>
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		Article 9 (c), (d) and (f)(i) and Category 3 materials referred to in Article 10 other than points (c) and (p).			
18	Fat derivatives	<p>(a) In the case of fat derivatives for uses outside the feed chain for farmed animals:</p> <p>Category 1 materials referred to in Article 8(c) and (d), Category 2 materials referred to in Article 9(c), (d) and (f)(i) and Category 3 materials referred to in Article 10(a), (b), (d), (e), (f), (g), (h), (i), (j), and (k).</p> <p>(b) In the case of fat derivatives for use as</p>	The fat derivatives shall comply with the requirements set out in Section 10.	Any third country.	<p>(a) In the case of fat derivatives for uses outside the feed chain for farmed animals:</p> <p>Annex XV, Chapter 14(A).</p> <p>(b) In the case of fat derivatives for use as feed or for uses outside the feed chain for farmed animals:</p> <p>Annex XV, Chapter 14(B).</p>

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		feed or for uses outside the feed chain:  Category 3 materials referred to in Article 10.			
19	Photogelatine	Category 1 materials referred to in Article 8(b) and Category 3 materials referred to in Article 10.	The imported photogelatine shall comply with the requirements set out in Section 11.	Photogelatine may only be imported from establishments of origin in the United States and in Japan that are authorised in accordance with Section 11.	Annex XV, Chapter 19.
20	Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, for the production of organic fertilisers or soil improvers	Category 3 materials referred to in Article 10(a), (b), (h) and (n).	The products shall comply with the requirements set out in Section 12.	Any third country.	Annex XV, Chapter 18.

## *Section 2*

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

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

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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.
2. The blood from which blood products for the manufacture of derived products for uses outside the feed chain for farmed animals are produced must have been collected:
  - (a) in slaughterhouses approved in accordance with Union legislation;
  - (b) in slaughterhouses approved and supervised by the competent authority of the third country; or
  - (c) from live animals in facilities approved and supervised by the competent authority of the third country.
- 3.1. 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

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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:

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- (i) 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:

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 either in:
  - (a) slaughterhouses
    - (i) approved in accordance with Regulation (EC) No 853/2004; or
    - (ii) approved and supervised by the competent authority of the third country; or
  - (b) facilities approved and furnished with a veterinary approval number and supervised by the competent authority of the third country for the purpose of collecting blood from equidae for the production of blood products for purposes other than feeding.
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,

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after splitting the head in the median plane and excising the nasal septum;

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



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- (c) they have undergone all precautions to avoid recontamination with pathogenic agents.
- 2. 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:

- 1. 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**

1. Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) may be imported to produce derived products for uses outside the feed chain if:
  - (a) the products are dried before export to the Union and not chilled or frozen;
  - (b) the products are conveyed only by land and sea from their third country of origin direct to a border inspection post of entry into the Union and are not transhipped at any port or place outside the Union;
  - (c) following the document checks provided for in Directive 97/78/EC, the products are conveyed directly to the registered establishment or plant of destination.

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2. Each consignment must be accompanied by a commercial document stamped by the competent authority supervising the establishment of origin, including the following information:
  - (a) the third country of origin;
  - (b) the name of the establishment or plant of production;
  - (c) the nature of the product (dried bone/dried bone product/dried horns/dried horn products/dried hooves/dried hoof products), and
  - (d) confirmation of the fact that the product was:
    - (i) derived from healthy animals slaughtered in a slaughterhouse;
    - (ii) dried for a period of 42 days at an average temperature of at least 20 °C;
    - (iii) heated for one hour to at least 80 °C to the core before drying;
    - (iv) ashed for one hour to at least 800 °C to the core before drying;
    - (v) underwent an acidification process such that the pH was maintained at less than 6 to the core for at least one hour before drying, andis 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:

1. the animal by-products have been deep-frozen at the plant of origin or have been preserved in accordance with Union legislation in such a way to prevent spoiling between dispatch and delivery to the establishment or plant of destination;
2. the animal by-products have undergone all precautions to avoid contamination with pathogenic agents;
3. the animal by-products were packed in new packaging preventing any leakage 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;

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

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TABLE 3

**Imports of photogelatine**

<b>Third country of origin</b>	<b>Plants of origin</b>	<b>Member State of destination</b>	<b>Border inspection post of first entry into the Union</b>	<b>Approved photographic factories</b>
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

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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
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2. Once the photogelatine has entered the Member State of destination, it shall not be traded between Member States but shall only be used in the approved photographic factory in the same Member State of destination and solely for photographic production purposes.
3. Following the 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.



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- (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
2. 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 redispached 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.

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## 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) redispached 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.

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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) redispached 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'.
2. The materials shall be directly delivered to an approved or registered establishment or plant for the manufacture of derived products, other than the products referred to in point 1.
3. Unused or surplus materials shall be used or disposed of in accordance with Article 12 of Regulation (EC) No 1069/2009.

## Section 2

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

1. The competent authority may authorise the import of the following materials for purposes other than feeding to farmed land animals, except for feeding to fur animals, provided there is no unacceptable risk for the transmission of diseases communicable to humans or animals:
  - (a) animal by-products from aquatic animals and derived products from aquatic animals;
  - (b) aquatic invertebrates and derived products from aquatic invertebrates;
  - (c) terrestrial invertebrates, including any of their transformation forms, such as larvae, and derived products therefrom;
  - (d) products generated by the animals referred to in points (a), (b) and (c), such as fish eggs;
  - (e) Category 3 material comprising of animals and parts thereof of the zoological orders of Rodentia and Lagomorpha.
2. 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.