EUROPEAN
COMMISSION

Brussels, XXX
SANTE/7048/2020 Rev. 1
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[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending certain Annexes to Regulation (EU) No 142/2011 as regards the requirements for placing on the market of certain insect products and the adaptation of a containment method

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending certain Annexes to Regulation (EU) No 142/2011 as regards the requirements for placing on the market of certain insect products and the adaptation of a containment method

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002[1], and in particular Article 15(1), first subparagraph, points (b), (h), (i) and (j), Article 21(6), first subparagraph, point (d), Article 27, first subparagraph, point (c), Article 31(2), and Article 32(3), first subparagraph, point (a) thereof,

Whereas:

(1) Commission Regulation (EU) No 142/2011[2] lays down public and animal health rules for the placing on the market and export of derived products.

(2) The fast development of the insect producing sector has resulted in a significant amount of insect excrements, which, in the absence of harmonised Union rules, are disposed of differently in each Member State. To ensure the valorisation of insect excrements as fertilisers it is necessary to lay down Union rules.

(3) For the purpose of Regulation (EU) No 142/2011, *"frass"* should be defined as the mixture of insect excrements with parts of dead insects and feeding substrate. Insect larvae, which are commonly used for the production of processed animal protein or for human consumption, live in the frass. A definition of "frass" should be inserted in Annex I to Regulation (EU) No 142/2011 in order to align the requirements for the treatment and placing on the market of frass with the requirements for processed manure. Annex I to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(4) The timely collection of single carcases of non-ruminant farmed animal is not always economically feasible, in particular as regards carcases collected from small farms. Therefore, Chapter V of Annex IX to Regulation 142/2011 provides for containment methods to ensure the safe storage of certain dead non-ruminant farmed animals until collection. The containment method "Hydrolysis with subsequent disposal" currently

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

[2] 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 (OJ L 54, 26.2.2011, p. 1).

only covers carcases of porcine animals. It is appropriate to extend that containment method to also include carcases of poultry and farmed lagomorphs. Point 2 of Section 2.B of Chapter V of Annex IX to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(5) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (Withdrawal Agreement), and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, Regulation (EC) No 1069/2009, as well as the Commission acts based on it, apply to and in the United Kingdom in respect of Northern Ireland after the end of the transition period provided for in the Withdrawal Agreement.

(6) As the transition period provided for in the Withdrawal Agreement ended on 31 December 2020, point 1 of Section 2.B of Chapter V of Annex IX to Regulation (EU) No 142/2011 should be amended in order to replace the reference to the United Kingdom in the list of Member States authorised to apply the containment method by a reference to United Kingdom in respect of Northern Ireland. Furthermore, references to the United Kingdom in Section 2.A of Chapter V of Annex IX to Regulation (EU) No 142/2011 and in Table 3 of Section 11 of Chapter II of Annex XIV to that Regulation should be deleted.

(7) On 8 October 2015, the European Food Safety Authority (EFSA) published a scientific opinion on a risk profile related to the production and consumption of insects as food and feed[3]. Among several insect species, the EFSA assessed silkworms as a possible source for the production of processed animal protein. Sericulture has a long-standing tradition in certain regions of the Union. Since the domestic silkworm consumes only mulberry leaves (*Morus alba* and *Morus nigra*), there is no risk of contamination with feed of animal origin, which is not authorised for the feeding of insects. It should therefore be authorised for processing into processed animal protein intended for the manufacturing of feed for farmed animals, after the silk has been harvested. It is appropriate to add silkworms (*Bombyx mori*) to the list of authorized insect species for the production of processed animal protein intended for the manufacturing of feed for farmed animals. Annex X to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(8) Annex XI to Regulation (EU) No 142/2011 sets out the requirements for the placing on the market of manure. Following the introduction of the definition of "frass" in Annex I to that Regulation, the requirements for the placing on the market of processed frass should ensure safe trade in processed frass. Therefore, the requirements laid down in that Annex should also cover frass. Annex XI to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(9) Member States that currently apply national measures for the processing of frass should align their national measures with the method laid down in Annex XI to Regulation (EU) No 142/2011, as amended by this Regulation. This Regulation should provide for a transitional period of 12 months.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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[3] Scientific Opinion on a Risk profile related to production and consumption of insects as food and feed, The EFSA Journal (2015);13 (10):4257.

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, IX, X, XI and XIV to Regulation (EU) No 142/2011 are amended in accordance with the Annex to this Regulation.

Article 2

Operators approved or registered in a Member State that applies national measures for the processing of frass may continue to apply those national measures for the placing on the market of frass within the concerned Member State until [publication office: insert the date 12 months after the publication]

Article 3

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/7048/2020 ANNEX Rev. 2
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ANNEX

ANNEX

to the

COMMISSION REGULATION

amending certain Annexes to Regulation (EU) No 142/2011 as regards the requirements for placing on the market of certain insect products and the adaptation of a containment method

ANNEX

Annexes I, IX, X XI and XIV to Regulation (EU) No 142/2011 are amended as follows:

1. in Annex I, the following point 61 is added:

'61. '**frass'** means a mixture of excrements derived from farmed insects, the feeding substrate, parts of farmed insects, dead eggs and with a content of dead farmed insects of not more than 5% in volume and not more than 3% in weight.

2. in Annex IX, in Chapter V, Section 2, is amended as follows:

(a) Point A.1 is replaced by the following:

'1. Member States[1] 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 in respect of Northern Ireland.

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.

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(1) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member States include the United Kingdom in respect of Northern Ireland."

(b) points B.1 and B.2 are replaced by the following:

'1. Member States[1] concerned

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

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, poultry or farmed lagomorph species may be used:

(a) Category 2 materials referred to in Article 9, points (f)(i), (ii) and (iii), of Regulation (EC) No 1069/2009;

(b) Category 3 materials referred to in Article 10, point (h), of that Regulation.

This method shall only be applied for the disposal of animals of the porcine, poultry or farmed lagomorph species originating in the same holding provided that this holding is not subject to a prohibition due to a suspected or confirmed outbreak of a serious transmissible disease affecting animals of the porcine, poultry or farmed lagomorph species,

and animals have not been killed for disease control purposes.

(1) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member States include the United Kingdom in respect of Northern Ireland."

3. in Annex X, in Chapter II, in Section 1.A, in point 2, the following point (iv) is added:

'(iv) Silkworm (*Bombyx mori*).';

4. in Annex XI, in Chapter I, Section 2 is amended as follows:

(a) the title and the introductory paragraph are replaced by the following:

'SECTION 2

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

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

(b) the following point (f) is added:

'(f) The placing on the market of frass shall be subject to the conditions set out in points (a), (b), (d) and (e) of this Section.';

4. in Annex XIV, in Chapter II, in Section 11, Table 3 is replaced by the following :

‘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			
		Czechia	Hamburg	FOMA Bohemia, spol. SRO Jana Krušinky 1604 501 04 Hradec Králové, Czechia

United States	Eastman Gelatine Corporation, 227 Washington Street, Peabody, MA, 01960 USA Gelita North America, 2445 Port Neal Industrial Road Sergeant Bluff, Iowa, 51054 USA			
		Czechia	Hamburg	FOMA Bohemia spol. SRO Jana Krušinky 1604 501 04 Hradec Králové, Czechia

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EUROPEAN
COMMISSION

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[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes XIV and XV to Regulation (EU) No 142/2011 as regards imports into and transit through the Union of animal by-products and derived products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes XIV and XV to Regulation (EU) No 142/2011 as regards imports into and transit through the Union of animal by-products and derived products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)[1], and in particular Article 41(3), first and third subparagraphs, and Article 42(2), points (a), (b) and (d), thereof,

Whereas:

(1) Commission Regulation (EU) No 142/2011[2] lays down implementing measures for the public and animal health rules for animal by-products and derived products laid down in Regulation (EC) No 1069/2009, including models of health certificates and the list of third countries authorised for imports into and transit through the Union of consignments of animal by-products and derived products.

(2) In particular, Chapter II of Annex XIV to Regulation (EU) No 142/2011 sets out the specific requirements for the importation into and the transit through the Union of consignments of animal by-products and derived products for uses outside the feed chain for farmed animals other than fur animals. Such consignments are required to comply with, inter alia, the rules set out in Table 2 of Section 1 of that Chapter.

(3) More specifically, row 14 of Table 2 sets out, inter alia, the list of third countries authorised for imports into and transit though the Union of consignments of animal by-products and derived products for uses outside the feed chain, including consignments of fur for the manufacture of derived products, category 3 materials, referred to in Article 10, point (n), of Regulation (EC) No 1069/2009. Certain Member States have requested that row 14 of Table 2 be amended so as to include a list of third countries authorised for imports into the Union of fur for the manufacture of derived products. There is not a list of third countries authorised for imports into the Union of products of fur animals, but Commission Implementing Regulation (EU) 2021/404[3]

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1 OJ L 300, 14.11.2009, p. 1.

2 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 (OJ L 54, 26.2.2011, p. 1).

3 Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products

sets out a list of third countries, territories or zones thereof authorised for the entry into the Union of consignments of fresh meat of ungulates. Following an evaluation of the request by the Member States, it is appropriate to include a list of third countries from which fur for the manufacture of derived products may be imported into the Union in row 14 of Table 2. As the third countries from which the entry into the Union of fresh meat of ungulates is authorised offer a high level of official controls and protection of public and animal health, it is opportune to allow imports of fur for the manufacture of derived products from those third countries.

(4) Annex XIV to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(5) In addition, Chapter 3(F) and Chapter 8 of Annex XV to Regulation (EU) No 142/2011 set out models of health certificates for imports into, or transit through, the Union, of animal by-products for the manufacture of petfood and for those used for purposes outside the feed chain or for trade samples, respectively. Those model health certificates contain among others, the requirement that the animals from which animal by-products are derived must have stayed in a single holding for 40-days before slaughter. From an animal health point of view, such a 40-day pre-slaughter residency period ensures the safety of unprocessed animal by-products when they are imported into the Union. Freedom from foot-and-mouth-disease without practicing vaccination is the most favourable animal health status in accordance with standards of the World Organisation for Animal Health (OIE), and third countries with that animal health status are authorised for imports into the Union and transit through the Union of consignments of fresh meat without such a 40-day residency period, provided that they comply with all other animal health requirements. Certain third countries that are free of foot-and-mouth disease without practicing vaccination have asked the Commission to be authorised for imports into the Union of unprocessed animal by-products without the 40-day pre-slaughter residency period. Animal health conditions for imports of animal by-products should be aligned with animal health requirements for entry into the Union of fresh meat laid down in and Commission Implementing Regulation (EU) 2021/404.

(6) The model health certificates for animal by-products for the manufacture of petfood, set out in Chapter 3(F) of Annex XV to Regulation (EU) No 142/2011, and for animal by-products to be used for purposes outside the feed chain or for trade samples, set out in Chapter 8 of Annex XV to that Regulation, should therefore be amended accordingly.

(7) Furthermore, Chapter V of Annex VIII to Regulation (EU) No 142/2011 provides that derived products of Category 1 or Category 2 material should be permanently marked with a chemical marker to prevent their entry into the feed chain and to ensure official controls of feed. Marking with a chemical marker is not required for Category 3 rendered fats. It is therefore necessary to correct the erroneous wording in the model health certificate set out in Chapter 10(B) of Annex XV to that Regulation for imports of 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 the Union.

(8) Annex XV to Regulation (EU) No 142/2011 should therefore be amended accordingly.

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and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 10).

(9) In order to avoid any disruption of trade, this Regulation should provide for a transitional period during which the commodities concerned by the amendments made to Regulation (EU) No 142/2011, by this Regulation, should continue to be accepted for importation into and transit through the Union, provided that those commodities comply with the requirements laid down in Regulation (EU) No 142/2011 before the amendments made by this Regulation.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes XIV and XV to Regulation (EU) No 142/2011 are amended in accordance with the Annex to this Regulation.

Article 2

For a transitional period until 31 May 2022, consignments of animal by-products and of derived products accompanied by a health certificate duly completed and signed in accordance with the appropriate model health certificate set out in Chapter 3(F), Chapter 8 and Chapter 10(B) of Annex XV to Regulation (EU) No 142/2011, in the version applicable before the amendments provided for by Article 1 of this Regulation, shall continue to be accepted for importation into or transit through the Union, provided that such health certificates were duly completed and signed no later than 31 March 2022.

Article 3

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

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ANNEX

Regulation (EU) No 142/2011 is amended as follows:

1. in Annex XIV, Chapter II, Section 1, Table 2, row 14, column ‘third countries’ list’, the following point (d) is added:

‘(d) In the case of fur for the manufacture of derived products:

Third countries listed in Part 1 of Annex XIII to Commission Implementing Regulation (EU) 2021/404* from which the entry into the Union of fresh meat of ungulates is authorised.

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* Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1).’.

2. Annex XV is amended as follows:

(a) Chapter 3(F) is replaced by the following:

‘CHAPTER 3(F)

Health certificate

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

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postcode Tel.		I.6. Person responsible for the load in EU Name Address Postcode Tel.	
I.7. Country of origin	ISO code / I.8. Region of origin / Code	I.9. Country of destination	ISO code / I.10. Region of destination / Code
I.11. Place of origin Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postcode	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Seal/Container No		I.24. Type of packaging	
I.25. Commodities certified for: Manufacture of petfood ☐ Further process ☐ Technical use ☐			
I.26. For transit through EU to third country ☐ Third country ISO code		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY **Animal by-products for the manufacture of petfood**

Part II: Certification

II.	**Health information**	II.a. Certificate reference No	II.b.

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council([1a]) and Commission Regulation (EU) No 142/2011([1b]), and in particular Chapter II of Annex XIV thereto, and certify that the animal by-products described above:

II.1.1. consist of animal by-products that satisfy the animal health requirements below;

II.1.2. have been obtained in the territory of: ……([1c]) from animals:

([2])*either* [that have remained in this territory since birth or for a period of at least three months preceding the date of slaughter or production;]

([2])*or* [that were killed in the wild in this territory([1d]);]

([2])*or* [that are animals of the zoological orders Rodentia or Lagomorpha, aquatic animals or terrestrial or aquatic invertebrates;]

([2])*either* [II.1.3. have been obtained or produced from animals which were not slaughtered or killed to eradicate any epizootic disease, and which

(a) come from holdings where

(i) for the following diseases for which the animals are listed in accordance with Implementing Regulation (EU) 2018/1882, there has been no case/outbreak of rinderpest, Newcastle disease or highly pathogenic avian influenza during the period of the preceding 30 days, nor of classical or African swine fever during the period of the preceding 40 days; nor in the holdings situated in their vicinity within a 10 km radius, during the period of the preceding 30 days; and

(ii) where there has been no case/outbreak of foot-and-mouth disease during the period of the preceding 60 days, nor in the holdings situated in their vicinity within a 25 km radius, during the period of the preceding 30 days; and

([2])*either* [(b) have remained in their holdings of origin for a period of at least 40 days before the date of departure and which have been transported directly to the slaughterhouse without any contact with other animals which did not comply with the same health conditions;]]

([2]) *or* [(b) have remained on holdings under veterinary supervision in the third country or part of the territory of the third country-of origin from which imports of fresh meat of ungulates are authorised without any restrictions in accordance with Implementing Regulation (EU) 2021/404, and at the slaughterhouse

(i) have passed the ante-mortem health inspection during the period of 24 hours preceding the time of slaughter and have shown no evidence of the diseases referred to above for which the animals are susceptible; and

(ii) have been handled 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([4])]]

([2])*or* [II.1.3. have been obtained or produced from animals which were not killed to eradicate any epizootic disease, and which

(a) have been captured and killed in the wild in an area:

(i) in which within a 25 km radius there has been no case/outbreak of any of the following diseases for which the animals are listed in accordance with Implementing Regulation (EU) 2018/1882: foot-and-mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the period of the preceding 30

II. Health information	II.a. Certificate reference No	II.b.

days, nor of classical or African swine fever during the period of the preceding 40 days; and

(ii) situated at a distance of at least 20 km from any country or part of the territory of a country not authorised for export to the European Union of poultry material during the preceding 30 days or of porcine material during the preceding 40 days; and

(b) which after killing were transported within a period of 12 hours following the killing for chilling either to a collection centre and immediately afterwards to a game-handling establishment, or directly to a game-handling establishment;]

II.1.4. have been obtained in an establishment around which, within a radius of 10 km, there has been no case/outbreak of the diseases referred to in point II.1.3 for which the animals are susceptible during the period of the preceding 30 days or, in the event of a case of disease, the preparation of raw material for exportation to the European Union has been authorised only after the removal of all meat, and the total cleaning and disinfection of the establishment under the control of an official veterinarian;

II.1.5. have been obtained and prepared without contact with 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. have been packed in new packaging preventing any leakage and in officially sealed containers bearing the label indicating 'RAW MATERIAL ONLY FOR THE MANUFACTURE OF PETFOOD' and the name and address of the establishment of destination in the European Union;

II.1.7. consist only of the following animal by-products:

([2])*either* [- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed which were deemed fit for human consumption in accordance with Union legislation until irreversibly declared as animal by-products for commercial reasons;]

([2])*and/or* [- carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals;

(ii) heads of poultry;

(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones;

(iv) pig bristles;

(v) feathers;]

([2])*and/or* [- animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

([2])*and/or* [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]

([2])*and/or* [- aquatic animals, and parts of such animals, except sea mammals, which

COUNTRY **Animal by-products for the manufacture of petfood**

II.	**Health information**	II.a. Certificate reference No	II.b.

did not show any signs of diseases communicable to humans or animals;]

([2])*and/or* [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

([2])*and/or* [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;

(ii) the following originating from terrestrial animals:

- hatchery by-products,
- eggs,
- egg by-products, including egg shells;

(iii) day-old chicks killed for commercial reasons;]

([2])*and/or* [- animal by-products from aquatic or terrestrial invertebrates, other than species pathogenic to humans or animals;]

([2])*and/or* [- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8, point (a)(iii), (iv) and (v), of Regulation (EC) No 1069/2009 and Category 2 material as referred to in Article 9, points (a) to (g), of that Regulation;]

([2])*and/or* [- material from animals which have been treated with certain substances which are prohibited by Council Directive 96/22/EC([4a]), the import of the material being permitted in accordance with Article 35, point (a)(ii) of Regulation (EC) No 1069/2009;]

II.1.8. have been deep-frozen at the plant of origin or have been preserved in accordance with European Union legislation in such a way that they will not spoil between dispatch and delivery to the plant of destination in the European Union or during the transit through the European Union;

II.1.9. in the case of raw material derived from animals which have been treated with certain substances prohibited by Directive 96/22/EC for the manufacture of petfood, the import being permitted in accordance with Article 35, point (a)(ii) of Regulation (EC) No 1069/2009:

(a) it has been marked in the third country before entry into the territory of the European 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 in the European Union or during the transit through the European Union, on each outer side of each pallet, in a way that the marking covers at least 70 % of the diagonal length of the frozen block and be of at least 10 cm width;

(b) in the case of material which is not frozen, the raw material has been marked in the third country before entry into the territory of the European 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; and

(c) where the animal by-products are made up of raw material which has been treated as referred to above and other non-treated raw material, all the raw materials have been marked as referred to in point (a) and (b) above.

([2])([5])[II.2. Specific requirements

([2])([6])[II.2.1. The by-products in this consignment come from animals that have been kept in the territory referred to in point (II.1.2), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled

COUNTRY **Animal by-products for the manufacture of petfood**

II. Health information	II.a. Certificate reference No	II.b.

in domestic bovine animals.]

([2])([7])[II.2.2. The by-products in this consignment consist only of animal by-products derived from trimmed offal of domestic ruminants, which have maturated at an ambient temperature of more than + 2 °C for a period of at least three hours, or in the case of masseter muscles of bovine animals and deboned meat of domestic animals, for a period of at least 24 hours.]]

([2])[II.3. the animal by-products for the manufacture of petfood contains or is obtained from animal-by products of ruminant origin and:

([2])*either* [originate from a country or region, which is classified as posing a negligible bovine spongiform encephalopathy (BSE) risk in accordance with Commission Decision 2007/453/EC([8]), and in which there has been no indigenous BSE case;]]

([2])*or* [originate from a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC in which there has been an indigenous BSE case, and the animal by-products or derived products were derived from animals born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code, has been effectively enforced in that country or region, and

([2])*either* [are derived from ruminants other than bovine, ovine or caprine animals.]]]

([2])*or* [are derived from bovine, ovine or caprine animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC.]]]

([2])*or* [do not contain:

(a) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council([9]);

(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 Decision 2007/453/EC, in which there has been no indigenous BSE case,

(c) animal by-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.]]]

Notes

Part I:

- Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for a commodity to be imported into the European Union.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. Products in transit may only be stored in free zones, free warehouses and custom warehouses.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number

II.	**Health information**	II.a. Certificate reference No	II.b.

(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 Harmonized System (HS) code: 05.04; 05.06; 05.07; 05.11.91 or 05.11.99; 23.01; 41.01.

– Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be included.

– Box reference I.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the production or manufacturing of petfood.

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

– Box reference I.28:

  - species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or Suidae, Pesca, Mollusca, Crustacea, invertebrates other than Mollusca and Crustacea;
  - manufacturing plant: provide the veterinary control number of the approved establishment.

Part II:

([1a]) OJ L 300, 14.11.2009, p. 1.

([1b]) OJ L 54, 26.2.2011, p. 1.

([1c]) The name and ISO code number of the exporting country as laid down in:

  - Part 1 of Annex XIII to Commission Implementing Regulation (EU) 2021/404 (OJ L 114, 31.3.2021, p. 1);
  - Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404, and
  - Part 1 of Annex I to Commission Regulation (EC) No 119/2009 (OJ L 39, 10.2.2009, p. 12).

In addition the ISO code of regionalisation in the abovementioned Annexes (where applicable for the susceptible species concerned) must be included.

([1d]) Only for countries from which game meat intended for human consumption of the same animal species is authorised for importation into the European Union.

([2]) Delete as appropriate.

([3]) Excluding raw blood, raw milk, hides and skins, hooves and horn, pig bristles and feathers (see relevant specific certificates in that Annex for the import of these products).

([4]) OJ L 303, 18.11.2009, p. 1.

([4a]) OJ L 125, 23.5.1996, p. 3.

([5]) Supplementary guarantees to be provided when the material of domestic ruminants originated in the territory of a South American or South African country or part thereof from where only maturated and deboned fresh meat of domestic ruminants for human consumption is permitted for exportation to the European Union. The whole masseter muscles of bovine animals, incised in accordance with Section IV, Chapter I, Part B.1, 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 countries.

([8]) OJ L 172, 30.6.2007, p. 84.

([9]) OJ L 147, 31.5.2001, p. 1.

– The signature and the stamp must be in a different colour to that of the printing.

– Note for the person responsible for the consignment in the European Union: this certificate is only for veterinary purposes and must accompany the consignment until it reaches the border inspection post of the European Union.

COUNTRY **Animal by-products for the manufacture of petfood**

II. Health information	II.a. Certificate reference No	II.b.
Official veterinarian/Official inspector Name (in capital letters): Qualification and title: Date: Signature: Stamp:		

’;

(b) Chapter 8 is replaced by the following:

‘CHAPTER 8

Health certificate

For animal by-products to be used for purposes outside the feed chain or for trade samples[(2)], intended for dispatch to or for transit through([2]) the European Union

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment				
	I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
			I.3. Central competent authority	
			I.4. Local competent authority	
	I.5. Consignee Name Address Postcode Tel.		I.6. Person responsible for the load in EU Name Address Postcode Tel.	
	I.7. Country of origin / ISO code / I.8. Region of origin / Code		I.9. Country of destination / ISO code / I.10. Region of destination / Code	
	I.11. Place of origin Name / Approval number Address Name / Approval number Address Name / Approval number Address		I.12. Place of destination Custom warehouse ☐ Name / Approval number Address Postcode	
	I.13. Place of loading		I.14. Date of departure	
	I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references		I.16. Entry BIP in EU I.17.	
	I.18. Description of commodity		I.19. Commodity code (HS code)	
			I.20. Quantity	
	I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	

I.23. Seal/Container No	I.24. Type of packaging
I.25. Commodities certified for: Technical use ☐	
I.26. For transit through EU to third country ☐ Third country ISO code	I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples(2)

Part II: Certification

II. Health information	II.a. Certificate reference No	II.b.

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council([1a]), and Commission Regulation (EU) No 142/2011([1b]), and in particular Chapter II of Annex XIV thereto, and certify that the animal by-products described above

([2])*either* [are trade samples which consist of animal by-products intended for particular studies or analyses as referred to in the definition of trade samples in point 39 of Annex I to Regulation (EU) No 142/2011, that bear the label 'TRADE SAMPLE NOT FOR HUMAN CONSUMPTION'.]

([2])*or* [satisfy the animal health requirements set out in point II.1.];

II.1. The animal by products described above

II.1.1. have been

([2])*either* [(a) obtained from materials imported from a third country, territory or part thereof:……..……([3]) authorised to export fresh meat to the European Union;]

([2])*and/or* [(b) obtained in the exporting third country, territory or part thereof:……..……([3]) from animals that

either:

(i) have remained in that third country, territory or part thereof eligible to export fresh meat to the European Union since birth or for a period of at least the preceding three months before the date of slaughter; and/or

(ii) were killed in the wild in that third country, territory or part thereof([4]);]

([2])*and/or* [(c) derived from eggs, milk, rodents, lagomorphs, or aquatic animals or terrestrial or aquatic invertebrates;]

([2])[II.1.2. in the case of materials other than materials derived from eggs, milk, rodents, lagomorphs, wool grease, aquatic animals, terrestrial or aquatic invertebrates and unprocessed furs, have been obtained from animals:

([2])*either* [(a) coming from holdings:

(i) where, for the following diseases for which the animals are susceptible, there has not been any case/outbreak of rinderpest, swine vesicular disease, Newcastle disease or highly pathogenic avian influenza during the period of the preceding 30 days, nor of classical or African swine fever during the period of the preceding 40 days; nor in the holdings situated in their vicinity within a 10 km radius, during the period of the preceding 30 days; and

(ii) where there has not been any case/outbreak of foot-and-mouth disease during the period of the preceding 60 days, nor in the holdings situated in their vicinity within a 25 km radius, during the period of the preceding 30 days; and

(b) which:

(i) were not killed to eradicate any epizootic disease;

[([2])*either*

(ii) remained on their holdings of origin for a period of at least 40 days before the date of departure and which were transported directly to the slaughterhouse without contact with other animals which did not comply with the same health conditions;

([2])*or*

(ii) have remained on holdings under veterinary supervision in the

COUNTRY **Animal by-products to be used for purposes outside the feed chain or for trade samples(2)**

II. Health information	II.a. Certificate reference No	II.b.

third country or part of the territory of the third country of origin from which imports of fresh meat of ungulates are authorised without any restrictions in accordance with Commission Implementing Regulation (EU) 2021/404]

(iii) at the slaughterhouse, passed the ante-mortem health inspection during the period of 24 hours before the time of slaughter and showed no evidence of the diseases referred to above for which the animals are susceptible; and

(iv) were handled in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Union legislation and complied with requirements at least equivalent to those laid down in Chapters II and III of Council Regulation (EC) No 1099/2009([5])]

([2])*or* [(a) captured and killed in the wild in an area:

(i) where within a 25 km radius there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot-and-mouth disease, rinderpest, Newcastle disease or highly pathogenic avian influenza during the period of the preceding 30 days nor of classical or African swine fever during the period of the preceding 40 days; and

(ii) that is situated at a distance that exceeds 20 km from the borders separating another territory of a third country or part thereof, which is not authorised at these dates for the exportation of such material to the European Union; and

(b) which after killing were transported within a period of 12 hours for chilling either to a collection centre and immediately afterwards to a game establishment, or directly to a game establishment;]]

([2])[II.1.3. in the case of materials other than materials derived from fish or invertebrates caught in the wild, have been obtained in an establishment around which, within a radius of 10 km, there has been no case/outbreak of diseases referred to in point II.1.2 for which the animals are susceptible during a period of the preceding 30 days or, in the event of a case/outbreak of one of those diseases, the preparation of raw material for exportation to the European Union was authorised only after the removal of all meat, and the total cleaning and disinfection of the establishment under the control of an official veterinarian;]

II.1.4. have been obtained and prepared without contact with other material which does not comply with the conditions required above, and it has been handled so as to avoid contamination with pathogenic agents;

II.1.5. have been packed in new packaging which prevents any leakage or in packaging which has been cleaned and disinfected before use and, in the case of consignments shipped other than via parcel post, in containers sealed under the responsibility of the competent authority, bearing the label indicating 'ANIMAL BY-PRODUCTS ONLY FOR THE MANUFACTURE OF DERIVED PRODUCTS FOR USES OUTSIDE THE FEED CHAIN' and the name and address of the establishment of destination in the European Union;

II.1.6. consist only of the following animal by-products:

([2])*either* [- carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed which were deemed fit for human consumption in accordance with Union legislation until irreversibly declared as animal by-products for commercial reasons;]

([2])*and/or* [- carcases and the following parts originating either from animals that were slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection

II. Health information	II.a. Certificate reference No	II.b.

or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcases or bodies and parts of animals which were rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals;

(ii) heads of poultry;

(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones;

(iv) pig bristles;

(v) feathers;]

(2)*and/or* [- animal by-products from poultry and lagomorphs slaughtered on the farm as referred to in Article 1(3), point (d), of Regulation (EC) No 853/2004 of the European Parliament and of the Council(2a), which did not show any signs of disease communicable to humans or animals;]

(2)*and/or* [- blood of animals which did not show any signs of disease communicable through blood to humans or animals, obtained from animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

(2)*and/or* [- animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

(2)*and/or* [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2)*and/or* [- petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

(2)*and/or* [- blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

(2)*and/or* [- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

(2)*and/or* [- animal by-products from aquatic animals originating from establishments or plants manufacturing products for human consumption;]

(2)*and/or* [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;

(ii) the following originating from terrestrial animals:

- hatchery by-products;
- eggs;
- egg by-products, including egg shells;

COUNTRY **Animal by-products to be used for purposes outside the feed chain or for trade samples(2)**

II. Health information	II.a. Certificate reference No	II.b.

(iii) day-old chicks killed for commercial reasons;]

([2])*and/or* [- animal by-products from aquatic or terrestrial invertebrates, other than species pathogenic to humans or animals;]

([2])*and/or* [- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8, point (a)(iii), (iv) and (v), of Regulation (EC) No 1069/2009 and Category 2 material as referred to in Article 9, points (a) to (g), of that Regulation;]

([2])*and/or* [- furs originating from dead animals that did not show clinical signs of any disease communicable through that product to humans or animals;]

II.1.7. have been deep-frozen at the plant of origin or have been preserved in accordance with European Union legislation in such a way that they will not spoil between the time of dispatch and the time of delivery to the plant of destination.

([2])([6])[II.1.8.

([2])([7])

either[II.1.8.1.The animal by-products in this consignment come from animals that have been obtained in the country, territory or part thereof referred to in point II.1.1, where vaccination programmes against foot-and-mouth disease are regularly carried out and officially controlled in domestic bovine animals.]]

([2])([8])

and/or[II.1.8.2.The animal by-products in this consignment consist of animal by-products derived from offal or deboned meat.]]

([2])[II.1.9. the animal by-products described above

([2])*either* [are derived from other ruminants than bovine, ovine or caprine animals.]]

([2])*or* [are 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 bovine spongiform encephalopathy (BSE) risk in accordance with Commission Decision 2007/453/EC([9]).]]

([2])*or* [(a) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council([10]);

(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 Decision 2007/453/EC, 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.1.10 the animal by-products described above:

([2])*either* [do not contain milk or milk products of ovine or caprine animal origin or are

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples(2)

II. Health information	II.a. Certificate reference No	II.b.

not intended for feed for farmed animals, other than fur animals.]

([2])*or* [contain milk or milk products of ovine or caprine animal origin and are intended for feed for farmed animals, other than fur animals, and the milk or milk products:

(a) are derived from ovine and caprine animals which have been kept continuously since birth in a country where the following conditions are fulfilled:

(i) classical scrapie is compulsorily notifiable;

(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 transmissible spongiform encephalopathy (TSE) or the confirmation of classical scrapie;

(iv) ovine and caprine animals affected with classical scrapie are killed and 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 years;

(b) originate from holdings where no official restrictions are imposed due to a suspicion of TSE;

(c) originate from holdings where no case of classical scrapie has been diagnosed during the period of the preceding seven years or, following the confirmation of a case of classical scrapie:

([2])*either* [all ovine and caprine animals on the holding have been killed and destroyed or slaughtered, except for breeding rams of the ARR/ARR genotype, breeding ewes carrying at least one ARR allele and no VRQ allele and other ovine animals carrying at least one ARR allele;]

([2])*or* [all animals in which classical scrapie was confirmed have been killed and destroyed, and the holding has been subjected for a 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 Chapter C, point 3.2, 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

COUNTRY **Animal by-products to be used for purposes outside the feed chain or for trade samples(2)**

II. Health information	II.a. Certificate reference No	II.b.

European Union; it may be filled in if the certificate is for a commodity to be imported into the European Union.

- Box reference I.11: In the case of consignments for trade samples or analyses: indicate the name and address of the establishment only.
- Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority.
- Box reference I.12: Place of destination: this box is to be filled in for the following products:
  - products for the manufacture of derived products for uses outside the feed chain: only if it is a certificate for a transit commodity. Products in transit may only be stored in free zones, free warehouses and custom warehouses.
  - products for trade samples or analyses: the plant in the European Union indicated in the authorisation of the competent authority where appropriate.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In the case of unloading and reloading in the European Union, the consignor must inform the border inspection point of the point of entry into the European Union.
- Box reference I.19: use the appropriate Harmonized System (HS) code under the following headings: 04.01; 04.02; 04.03; 04.04; 04.08; 05.05; 05.06, 05.07; 05.11.91; 05.11.99, 23.01 or 30.01.
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) must be included.
- Box reference I.25:
  - technical use: any use other than feeding of farmed animals, other than fur animals, and the production or manufacturing of petfood;
  - for the purposes of the certificate, 'technical use' includes use as a trade sample.
- Box reference I.26 and I.27: except for trade samples, which are not sent in transit, fill in according to whether it is a transit or an import certificate.
- Box reference I.28:
  - products for the manufacture of derived products for uses outside the feed chain: Manufacturing plant: provide the veterinary control number of the approved establishment;
  - products for the particular technological studies or analyses: the plant in the European Union indicated in the authorisation of the competent authority where appropriate;
  - species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia or Suidae, Pesca, Mollusca, Crustacea, invertebrates other than Mollusca and Crustacea.

Part II:

(1a) OJ L 300, 14.11.2009, p. 1.

(1b) OJ L 54, 26.2.2011, p. 1.

(2) Delete as appropriate.

(2a) OJ L 139, 30.4.2004, p. 55.

(3) The name and ISO code number of the exporting country as laid down in:

- Part 1 of Annex XIII to Commission Implementing Regulation (EU) 2021/404 (OJ L 114, 31.3.2021, p. 1);
- Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404, 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 Implementing Regulation (EU) 2021/404 and to Regulation (EC) No 119/2009 referred to in this note (where applicable for the susceptible species concerned) must be included where applicable.

(4) Only for countries from where the game meat intended for human consumption of the same animal species is authorised for importation into the European Union.

COUNTRY

Animal by-products to be used for purposes outside the feed chain or for trade samples(2)

II. Health information	II.a. Certificate reference No	II.b.

(5) OJ L 303, 18.11.2009, p. 1.

(6) Supplementary guarantees to be provided where the material of domestic ruminants originated in the territory of a South American or South African country or part thereof from where only maturated and deboned fresh meat of domestic ruminants for human consumption is authorised for exportation to the European Union. The whole masseter muscles of bovine animals, incised in accordance with the requirements of Section IV, Chapter I, Part B.1, 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.

(7) Only for certain South American countries.

(8) Only for certain South American and South African countries.

(9) OJ L 172, 30.6.2007, p. 84.

(10) OJ L 147, 31.5.2001, p. 1.

- The signature and the stamp must be in a different colour to that of the printing.
- Note for the person responsible for the consignment in the 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:

’;

(c) Chapter 10(B) is replaced by the following:

‘CHAPTER 10(B)

Health certificate

For rendered fats not intended for human consumption to be used for certain purposes outside the feed chain, intended for dispatch to or for transit through([2]) the European Union

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postal code Tel.		I.6. Person responsible for the load in EU Name Address Postal code Tel.	
I.7. Country of origin / ISO code	I.8. Region of origin / Code	I.9. Country of destination / ISO code	I.10. Region of destination / Code
I.11. Place of origin Name / Approval number Address Name / Approval number Address Name / Approval number Address		I.12. Place of destination Custom warehouse ☐ Name / Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentation references		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Seal/Container No		I.24. Type of packaging	
I.25. Commodities certified for: Technical use ☐			
I.26. For transit through EU to third country ☐ Third country / ISO code		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (scientific name)	Approval number of establishments: Manufacturing plant	Number of packages	Net weight	Batch number

COUNTRY

Rendered fats not intended for human consumption for certain purposes outside the feed chain

Part II: Certification

II.	**Health information**	II.a. Certificate reference No	II.b.

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([1a]), and in particular Articles 8, 9 and 10 thereof, and Commission Regulation (EU) No 142/2011([1b]), and in particular Chapter II of Annex XIV thereto, and certify that the rendered fats described above:

II.1. consist of rendered fats not intended for human consumption that satisfy the health requirements below;

II.2. have been prepared exclusively with the following animal by-products:

([2])[II.2.1. in the case of materials destined for the production of renewable fuels referred to in Chapter IV, Section 2, point L, 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;]

([2])[II.2.2. in the case of materials destined for the production of renewable fuels referred to in Chapter IV, Section 2, point J, of Annex IV to Regulation (EU) No 142/2011, the materials have been prepared exclusively from animal by-products referred to in Articles 9 and 10 of Regulation (EC) No 1069/2009;]

([2])[II.2.3. in the case of materials destined for purposes other than cosmetics, pharmaceuticals or medical devices, the materials have been prepared exclusively from:

([2])*either* [- animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels referred to in Article 15(3) of Council Directive 96/23/EC([2a]);]

([2])*and/or* [- products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;]

([2])*and/or* [- animals and parts of animals, other than those referred to in Articles 8 and 10 of Regulation (EC) No 1069/2009, that died other than being slaughtered or killed for human consumption, including animals killed for disease control purposes;]

([2])*and/or* [- carcasses and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Union legislation, but are not intended for human consumption for commercial reasons;]

([2])*and/or* [- carcasses and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Union legislation:

(i) carcasses or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of disease communicable to humans or animals;

(ii) heads of poultry;

(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones;

(iv) pig bristles;

(v) feathers;]

([2])*and/or* [- blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]

([2])*and/or* [- animal by-products arising from the production of products intended for

COUNTRY **Rendered fats not intended for human consumption for certain purposes outside the feed chain**

II.	**Health information**	II.a. Certificate reference No	II.b.

human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]

([2])*and/or* [- products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

([2])*and/or* [- petfood and feeding stuffs of animal origin, or feeding stuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]

([2])*and/or* [- blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]

([2])*and/or* [- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]

([2])*and/or* [- animal by-products from aquatic animals originating from plants or establishments manufacturing products for human consumption;]

([2])*and/or* [- the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;

(ii) the following originating from terrestrial animals:

- hatchery by-products,
- eggs,
- egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;]

([2])*and/or* [- aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;]

([2])*and/or* [- animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8, point (a)(iii), (iv) and (v), of Regulation (EC) No 1069/2009 and Category 2 material as referred to in Article 9, points (a) to (g), of that Regulation;]

([2])*and/or* [- hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals;]

([2])*and/or* [- adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Union legislation;]]

([2])[II.2.4. in the case of materials destined for purposes other than the production of organic fertilisers or soil improvers, cosmetics, pharmaceutical or medical devices :

([2])*either* [- specified risk material as defined in Article 3(1), point (g), of Regulation (EC) No 999/2001 of the European Parliament and of the Council[(2b)];]

([2])*and/or* [- entire bodies or parts of dead animals containing specified risk material as defined in Article 3(1), point (g), of Regulation (EC) No 999/2001 at the time of disposal;]

([2])*and/or* [- animal by-products which have been derived from animals which have been submitted to illegal treatment as defined in Article 1(2), point (d), of Council Directive 96/22/EC[(2c)] or Article 2, point (b), of Directive

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96/23/EC;]

([2])*and/or* [- animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted levels laid down by Union legislation or, in the absence thereof, by legislation of the Member State of importation;]]

II.3. the rendered fats:

(a) have been subjected to processing in accordance with method ..... (indicate the processing method) as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011, in order to kill pathogenic agents,

[([2])(b) of Category 1 and 2 materials have been marked before dispatch to the European Union with glyceroltriheptanoate (GTH), so that a homogenous minimum concentration of at least 250 mg GTH per kilogramme fat is achieved,]

(c) in the case of rendered fats of ruminant origin, insoluble impurities in excess of 0,15 % in weight have been removed,

(d) have been transported under conditions which prevent their contamination, and

(e) bear labels on the packaging or container indicating "NOT FOR HUMAN OR ANIMAL CONSUMPTION";

([2])[II.4. in the case of materials destined for organic fertilisers, cosmetics, pharmaceuticals, medical devices or soil improvers the rendered fats described above

([2])*either* [are derived from other ruminants than bovine, ovine or caprine animals.]

([2])*or* [are 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 bovine spongiform encephalopathy (BSE) risk in accordance with Commission Decision 2007/453/EC([3]).]

([2])*or* [(a) specified risk material as defined in point 1 of Annex V to Regulation (EC) No 999/2001;

(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 Decision 2007/453/EC, 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.]]]

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.

COUNTRY

Rendered fats not intended for human consumption for certain purposes outside the feed chain

II. Health information	II.a. Certificate reference No	II.b.

- Box reference I.11: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority.
- Box reference I.12:
  - approval number: the registration number of the establishment or plant, which has been issued by the competent authority;
  - place of destination: this box is to be filled in only if it is a certificate for a transit commodity. Products in transit may only be stored in free zones, free warehouses and custom warehouses.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In the case of unloading and reloading in the European Union, the consignor must inform the border inspection post of the point of entry into the European Union.
- Box I.19: use the appropriate Harmonized System (HS) code under the following headings: 04.05; 15.01, 15.02; 15.03; 15.04; 15.05; 15.06; 15.16 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 petfood.
- 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:

(1a) OJ L 300, 14.11.2009, p. 1.

(1b) OJ L 54, 26.2.2011, p. 1.

(2) Delete as appropriate.

(2a) OJ L 125, 23.5.1996, p. 10.

(2b) OJ L 147, 31.5.2001, p. 1.

(2c) OJ L 125, 23.5.1996, p. 3.

(3) OJ L 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:

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EUROPEAN
COMMISSION

Brussels, XXX
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[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) No 142/2011 as regards conditions for exports of certain organic fertilisers and soil improvers containing Category 2 materials

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) No 142/2011 as regards conditions for exports of certain organic fertilisers and soil improvers containing Category 2 materials

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002[1], and in particular Article 32(3)(a) and the second subparagraph of Article 43(3) thereof,

Whereas:

(1) Commission Regulation (EU) No 142/2011[2] lays down public and animal health rules for placing on the market and export of derived products, including organic fertilisers and soil improvers.

(2) Chapter V of Annex XIV to Regulation (EU) No 142/2011 provides for rules on exports of amongst others processed manure. Processed manure may be used as a component to exclude the subsequent use of organic fertilisers and soil improvers containing meat-and-bone meal (MBM) of Category 2 materials for feeding purposes. The rules on export of processed manure should be amended to allow the export of processed manure contained as mixing component in MBM of Category 2 materials.

(3) The export of certain organic fertilisers and soil improvers containing MBM of Category 2 materials should be authorised without the channelling referred to in Article 48(4) of Regulation (EU) No 1069/2009, where the use of such organic fertilisers and soil improvers for feeding purposes is excluded due to their composition or packaging. Organic fertilisers and soil improvers should be mixed with processed manure or other prescribed components to exclude the subsequent use for feeding purposes. The rules for the export of organic fertilisers and soil improvers containing MBM of Category 2 materials are to be set out in Chapter V of Annex XIV to Regulation (EU) No 142/2011.

(4) Annex VIII of Regulation (EU) No 142/2011 provides for labelling requirements for organic fertilisers and soil improvers placed on the Union market. In case of the export to third countries, labelling should be in one of the official languages of the third country of destination.

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1 OJ L 300, 14.11.2009, p. 1.

2 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 (OJ L 54, 26.2.2011, p. 1).

(5) Annex XIV to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Chapter V of Annex XIV to Regulation (EU) No 142/2011 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

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ANNEX

In Regulation (EU) No 142/2011, Annex XIV, Chapter V, the table shall be amended as follows:

(a) row 1 is replaced by the following:

'1	Processed manure; Organic fertilizers, compost or digestion residues from biogas transformation containing no other animal by-products or derived products than processed manure; Processed animal protein containing processed manure as a mixing component or meat-and-bone meal of Category 2 materials containing processed manure as a mixing component	The following derived products 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: – Processed manure; – Organic fertilizers, compost or digestion residues from biogas transformation containing no other animal by-products or derived products than processed manure; – Processed manure as a mixing component in processed animal protein or meat-and-bone meal of Category 2 materials.‘

(b) the following row 4 is added as follows:

‘4	Organic fertilisers and soil improvers containing meat-and-bone meal of Category 2 materials	Organic fertilisers and soil improvers containing meat-and-bone meal of Category 2 materials referred to in points 1, 2, 3 and 5 of Section 1 of Chapter II of Annex XI that meet the requirements therein, which are packaged in ready-to-sell packages of not more than 50 kg in weight for use by the final consumer with a content of (a) not more than 90 % in volume of meat-and-bone meal of Category 2 material; (b) at least 10 % in volume of processed manure, processed urine, lime, mineral fertilisers, or any other mixing

		component referred to in point 3(b) of Section 1 of Chapter II to Annex XI.’