



**Brussels, 29 January 2025
(OR. en)**

**5741/25
ADD 1**

**AGRILEG 13
VETER 12**

COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 27 January 2025

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: D103880/01 ANNEX

Subject: ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending and correcting Regulation (EU) No 142/2011 as regards certain requirements for the placing on the market and imports of animal by-products and derived products not intended for human consumption

Delegations will find attached document D103880/01 ANNEX.

Encl.: D103880/01 ANNEX

EN**ANNEX****Part 1****Amendments to Annexes IV, V, XIV and XV to Regulation (EU) No 142/2011**

Annexes IV, V, XIV and XV to Regulation (EU) No 142/2011 are amended as follows:

- (1) in Annex IV, Chapter IV is amended as follows:
- (a) Section 2 is amended as follows:
- (i) point D(2)(a)(ii) is replaced by the following:
- ‘(ii) in the case of Category 3 materials, other than used cooking oil, any of the processing methods 1 to 5 or processing method 7 or, in the case of material derived from fish, processing methods 1 to 7 as set out in Chapter III;’;
- (ii) in point J(1)(a), the following subpoint is added:
- ‘(iv) used cooking oil of Category 3 material.’;
- (iii) point L(1)(b) is replaced by the following:
- ‘(b) used cooking oil of Category 3 material, rendered fats and fish oil complying with point J(1)(a) of this Section.’;
- (iv) the following points M and N are added:
- ‘M. Production of biodiesel from processed fats derived from Category 1, 2 and 3 animal by- products
1. Starting materials
- For this process, rendered fats of Category 1, 2 or 3 material and used cooking oil of Category 3 material may be used.
2. Processing methods
- Except where fish oil are used which have been produced in accordance with Section VIII of Annex III to Regulation (EC) No 853/2004*, or where rendered fat are used which have been produced in accordance with Section XII of Annex III to Regulation (EC) No 853/2004, the fat fraction derived from animal by-products shall be first processed using:
- (a) in the case of Category 1 or 2 materials, processing method 1 (pressure sterilisation) as set out in Chapter III of this Annex; and
- (b) in the case of Category 3 material, other than used cooking oil, any of the processing methods 1 to 5 or processing method 7 or, in the case of material derived

from fish, processing methods 1 to 7 as set out in Chapter III of this Annex.

3. After processing in accordance with one of the processing methods referred to in point 2, starting materials referred to in point 1 shall be subject to the following steps:
 - (a) a pre-cleaning process for the removal of insoluble impurities in excess of 0,15%. The resulting cleaned liquids obtained from the precleaning process shall be pumped to the biodiesel tank at the establishment where the cleaned liquids are stored, as biodiesel feedstocks, until processing;
 - (b) an acidic esterification/transesterification (1,5% methane sulfonic acid (MSA) w/w; 140°C; 5,5 bar absolute pressure (bara); 4 hours) for conversion of the cleaned feedstock into biodiesel; and
 - (c) fractional distillation: the biodiesel shall be fractionated ($\geq 220^{\circ}\text{C}$; 10 to 35 millibar (mbara)) into multiple refined products, each containing carbon chains of a particular length, resulting in batches of biodiesel with differing specifications.
 4. The competent authority shall assess the HACCP plan which checks and records the main processing parameters of the steps described in points 1, 2 and 3.
- N. Biodiesel production process using rendered fats of Category 1, 2 and 3 animal by- products
1. Starting materials

For this process, a fat fraction derived from animal by-products of Category 1, 2 or 3 materials shall be used.
 2. Processing methods
 - (a) Except where fish oil are used that have been produced in accordance with Section VIII of Annex III to Regulation (EC) No 853/2004, or where rendered fat are used which have been produced in accordance with Sections XII of Annex III to Regulation (EC) No 853/2004, the fat fraction derived from animal by-products shall be first processed using:
 - (i) in the case of Category 1 or 2 materials, processing method 1 (pressure sterilisation) as set out in Chapter III of this Annex; and
 - (ii) in the case of Category 3 material, other than used cooking oil, any of the processing methods 1 to 5 or processing method 7 or, in the case of material derived from fish, processing methods 1 to 7 as set out in Chapter III of this Annex; in the case of fat from ruminant origin, insoluble

impurities in excess of 0,15 % by weight shall be removed.

(b) The following biodiesel production process shall consist of a conversion phase of esterification and transesterification in a single step at a temperature of at least 200°C, pressure of at least 70 bar with a retention time of at least 15 minutes, using MgO as a catalyst and in the presence of an alcohol (methanol) followed by vacuum distillation (at $\geq 150^{\circ}\text{C}$, ≤ 10 mbar) of the end-product, biodiesel.

3. The competent authority shall assess the HACCP plan which checks and records the main processing parameters of the steps described in points 1 and 2;

* Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55, ELI: <http://data.europa.eu/eli/reg/2004/853/oj>).’;

(b) in Section 3, in point 2(b), the introductory sentence is replaced by the following:

‘(b) the biodiesel production process referred to in Section 2, points D, M and N, may be.’;

(2) in Annex V, in Chapter I, in Section 1, in point 2, the following point (g) is added:

‘(g) processed frass that has been processed in accordance with Annex XI, Chapter I, Section 2, point (b).’;

(3) Annex XIV is amended as follows:

(a) in Chapter I, in Section 2, point 5(a) is replaced by the following:

‘5. Processed animal protein obtained from farmed insects may be imported into the Union provided that it has been produced in compliance with the following conditions:

(a) the insects belong to one of the following species:

- black soldier fly (*Hermetia illucens*) and common housefly (*Musca domestica*),
- yellow mealworm (*Tenebrio molitor*) and lesser mealworm (*Alphi tobius diaperinus*),
- house cricket (*Acheta domesticus*), banded cricket (*Gryllodes sigillatus*) and field cricket (*Gryllus assimilis*),
- silkworm (*Bombyx mori*).’;

(b) in Chapter II, in Section 1, Table 2 is amended as follows:

(i) in row 12, in the fifth column entitled ‘Third countries’ lists’, point (b) is replaced by the following:

‘(b) In the case of dogchews and petfood other than raw petfood:

Third countries listed in Part 1 of Annex XIII, in Part 1 of Annex XIV, or in Part 1, Section A, of Annex XV to Implementing Regulation (EU) 2021/404, and the following third countries:

(AL) Albania

(EC) Ecuador

(DZ) Algeria

(GE) Georgia (only processed petfood other than canned petfood)

(LK) Sri Lanka

(SA) Saudi Arabia (only processed petfood of poultry origin)

(SV) El Salvador

(TW) Taiwan

(ID) Indonesia (only processed petfood containing processed animal protein of insect origin)

In the case of fish material, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405.’;

- (ii) in row 17, in the third column entitled ‘Raw materials (references to provisions of Regulation (EC) No 1069/2009)’, point (a) is replaced by the following:

‘(a) In the case of materials destined for the production of biodiesel, biodiesel oleochemical products or renewable fuels referred to in points L, M and N of Section 2 of Chapter IV of Annex IV:

Categories 1, 2 and 3 materials referred to in Articles 8, 9 and 10.’;

- (c) in Chapter II, in Section 11, Table 3 is replaced by the following:

Table 3
Imports of photogelatine

<i>Third country of origin</i>	<i>Plants of origin</i>	<i>Member State of destination</i>	<i>Border inspection post of first entry into the Union</i>	<i>Approved photographic factories</i>
Japan	Nitta Gelatin Inc., 2-22 Futamata Yao-City, Osaka 581-0024 Japan Jellice Co., Ltd. 4-1, Sakae 4-Chome, Tagajo-City, Miyagi 985-0833 Japan	The Netherlands	Rotterdam airport Schiphol - Amsterdam	Fujifilm Manufacturing Europe B.V., 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'

;

(4) Annex XV to Regulation (EU) No 142/2011 is amended as follows:

(a) Chapter 1a is replaced by the following:

‘CHAPTER 1a

Health certificate

For processed animal protein derived from farmed insects not intended for human consumption, including mixtures and products other than petfood containing such protein, for dispatch to or for transit through² 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	
							I.10. Region of destination	
	I.11. Place of origin Name Address Name Address Name Address			Approval number Approval number Approval number		I.12. Place of destination Name Address Postcode		
						Custom warehouse <input type="checkbox"/> Approval number		
	I.13. Place of loading			I.14. Date of departure				
I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>					I.22. Number of packages			
I.23. Seal/Container No					I.24. Type of packaging			
I.25. Commodities certified for: Animal feedingstuff <input type="checkbox"/> Technical use <input type="checkbox"/> Organic fertilisers and soil improvers <input type="checkbox"/> Manufacture of petfood <input type="checkbox"/>								
I.26. For transit through EU to third country <input type="checkbox"/> Third country ISO code				I.27. For import or admission into EU <input type="checkbox"/>				
I.28. Identification of the commodities Species (Scientific name) Nature of commodity Approval number of establishments Manufacturing plant Net weight Batch number								

COUNTRY

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

Part II: Certification

II. Health information	II.a. Certificate reference No	II.b.
<p>I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1069/2009 of the European Parliament and of the Council^(1a) and in particular Article 10 thereof, and Commission Regulation (EU) No 142/2011^(1b), and in particular Section 1 of Chapter II of Annex X, and Chapter I of Annex XIV thereto and certify that:</p>		
<p>II.1. the processed animal protein derived from farmed insects or product described above contains exclusively processed animal protein not intended for human consumption that:</p>		
<p>(a) has been prepared and stored in an establishment or plant approved and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009, and</p>		
<p>(b) has been prepared exclusively from farmed insects of the following species: ⁽²⁾ either [- black soldier fly (<i>Hermetia illucens</i>);] ⁽²⁾ and/or [- common housefly (<i>Musca domestica</i>);] ⁽²⁾ and/or [- yellow mealworm (<i>Tenebrio molitor</i>);] ⁽²⁾ and/or [- lesser mealworm (<i>Alphitobius diaperinus</i>);] ⁽²⁾ and/or [- house cricket (<i>Acheta domestica</i>);] ⁽²⁾ and/or [- banded cricket (<i>Gryllodes sigillatus</i>);] ⁽²⁾ and/or [- field cricket (<i>Gryllus assimilis</i>).] ⁽²⁾ and/or [- silkworm (<i>Bombyx mori</i>).]</p>		
<p>and</p>		
<p>(c) has been processed by method [1]-[2]-[3]-[4]-[5]-[7]⁽²⁾ as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011;</p>		
<p>and</p>		
<p>(d) the substrate for the feeding of farmed insects shall only contain products of non-animal origin or the following products of animal origin of Category 3 material:</p> <ul style="list-style-type: none"> - fishmeal; - blood products from non-ruminants; - di and tricalcium phosphate of animal origin; - hydrolysed proteins from non-ruminants; - hydrolysed proteins from hides and skins of ruminants; - gelatine and collagen from non-ruminants; - eggs and egg products; - milk, milk based-products, milk-derived products, and colostrum; - honey; - rendered fats; 		
<p>and</p>		
<p>(e) the substrate for the feeding of insects and the insects or their larvae have not been in contact with any other materials of animal origin than those referred to in point (d) and the substrate did not contain manure, catering waste or other waste.</p>		
<p>II.2. the competent authority examined a random sample immediately prior to dispatch and found it to comply with the following standards⁽³⁾:</p>		
<p>Salmonella: Absence in 25 g: n = 5, c = 0, m = 0, M = 0</p>		
<p>Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1g;</p>		
<p>II.3. the product has undergone all precautions to avoid recontamination with pathogenic agents after treatment;</p>		
<p>II.4. the end product:</p>		

COUNTRY

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

II. Health information	II.a. Certificate reference No	II.b.
<p>(²) <i>either</i> [was packed in new or sterilised bags,]</p> <p>(²) <i>or</i> [was transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected before use,]</p> <p>which bear labels indicating ‘NOT FOR HUMAN CONSUMPTION / PROCESSED INSECT PROTEIN – SHALL NOT BE USED IN FEED FOR FARMED ANIMALS, EXCEPT AQUACULTURE, FUR ANIMALS, PORCINE ANIMALS AND POULTRY’;</p> <p>II.5. the end product was stored in enclosed storage;</p> <p>(²)II.6. the processed animal protein or product described above contains or is derived from animal-by products of ruminant origin and:</p> <p style="padding-left: 40px;">(²) <i>either</i> [originates from a country or region, which is classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC, and in which there has been no indigenous BSE case, and]</p> <p style="padding-left: 40px;">(²) <i>or</i> [originates 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-product or derived product were derived from animals born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, as defined in the World Organisation for Animal Health (WOAH) Terrestrial Animal Health Code, has been effectively enforced in that country or region, and]</p> <p style="padding-left: 40px;">(²) <i>either</i> [is derived from other ruminants than bovine, ovine or caprine animals.]</p> <p style="padding-left: 40px;">(²) <i>or</i> [is derived from bovine, ovine or caprine animals and does not contain and is not derived from:</p> <p style="padding-left: 80px;">(²) <i>either</i> [bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Decision 2007/453/EC.]</p> <p style="padding-left: 80px;">(²) <i>or</i> [(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⁽⁴⁾;</p> <p style="padding-left: 120px;">(b) mechanically separated meat obtained from bones of bovine, ovine or caprine animals, except from those animals that were born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk in accordance with Commission Decision 2007/453/EC⁽⁵⁾, in which there has been no indigenous BSE case,</p> <p style="padding-left: 120px;">(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.]</p> <p>II.7. the processed animal protein or product described above:</p> <p style="padding-left: 40px;">(²) <i>either</i> [does not contain milk or milk products of ovine or caprine animal origin or is not intended for feed for farmed animals, other than fur animals.]</p>		

COUNTRY

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

II. Health information	II.a. Certificate reference No	II.b.
<p>(²) <i>or</i></p> <p>II.8.</p> <p>(²) <i>either</i></p> <p>(²)(⁶) <i>or</i></p>	<p>[contains milk or milk products of ovine or caprine animal origin and is intended for feed for farmed animals, other than fur animals, which:</p> <p>(a) are derived from ovine and caprine animals which have been kept continuously since birth in a country where the following conditions are fulfilled:</p> <p>(i) classical scrapie is compulsorily notifiable;</p> <p>(ii) an awareness, surveillance and monitoring system is in place for classical scrapie;</p> <p>(iii) official restrictions apply to holdings of ovine or caprine animals in the case of a suspicion of TSE or the confirmation of classical scrapie;</p> <p>(iv) ovine and caprine animals affected with classical scrapie are killed and destroyed;</p> <p>(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 WOA, of ruminant origin has been banned and effectively enforced in the whole country for a period of at least the preceding seven years;</p> <p>(b) originate from holdings where no official restrictions are imposed due to a suspicion of TSE;</p> <p>(c) originate from holdings where no case of classical scrapie has been diagnosed during a period of at least the preceding seven years or, following the confirmation of a case of classical scrapie:</p> <p>(²) <i>either</i>[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;]</p> <p>(²) <i>or</i> [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:</p> <ul style="list-style-type: none"> - 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.] 	

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

II. Health information	II.a. Certificate reference No	II.b.
analyses carried out in accordance with the methods set out in Annex VI to Commission Regulation (EC) No 152/2009 ⁽⁷⁾ .]		
Notes		
Part I:		
<ul style="list-style-type: none"> - Box reference I.6: Person responsible for the consignment in the European Union: this box is required to be filled in only if it is a certificate for a commodity to be transited through the European Union; it may be filled in if the certificate is for a commodity to be imported into the European Union. - Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for a transit commodity. Products in transit shall only be stored in free zones, free warehouses and custom warehouses. - Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading. - Box reference I.19: use the appropriate HS code: 05.11, 23.01 or 23.09. - Box reference I.25: technical use: any use other than feeding of farmed animals, other than fur animals, and the production or manufacturing of pet food. - Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate. - Box reference I.28: Species: insects, specify its scientific name. 		
Part II:		
^(1a) OJ L 300, 14.11.2009, p. 1.		
^(1b) OJ L 54, 26.2.2011, p. 1.		
⁽²⁾ Delete as appropriate.		
⁽³⁾ Where:		
n = number of samples to be tested;		
m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;		
M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and		
c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less.		
⁽⁴⁾ OJ L 147, 31.5.2001, p. 1.		
⁽⁵⁾ OJ L 172 30.6.2007, p. 84.		
⁽⁶⁾ The person responsible for the load referred to in Box I.6 shall ensure that, if the processed animal protein or product described in this health certificate is intended to be used for the production of feed for non-ruminant farmed animals, other than fur animals, the consignment shall be analysed, in accordance with the methods set out in Annex VI to Regulation (EC) No 152/2009, in order to verify the absence of unauthorised constituents of animal origin. The information on the result of such analysis shall be attached to this health certificate when presenting the consignment at an EU Border Inspection Post.		
⁽⁷⁾ OJ L 54, 26.2.2009, p. 1.		
<ul style="list-style-type: none"> - The signature and the stamp shall 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 shall accompany the consignment until it reaches the border inspection post. 		

COUNTRY

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

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

‘;

(b) Chapter 17 is replaced by the following:

‘CHAPTER 17

Health certificate

For processed manure, derived products from processed manure, processed frass and processed guano from bats intended for dispatch to or for transit through² the European Union

COUNTRY		Veterinary certificate to the EU		
Part I: Description of consignment	I.1 Consignor/Exporter Name Address Country ISO country code	I.2 Certificate reference	I.2a IMSOC reference	
		I.3 Central Competent Authority	QR CODE	
		I.4 Local Competent Authority		
	I.5 Consignee/Importer Name Address Country ISO country code	I.6 Operator responsible for the consignment Name Address Country ISO country code		
	I.7 Country of origin ISO country code	I.9 Country of destination ISO country code		
	I.8 Region of origin Code	I.10 Region of destination Code		
	I.11 Place of dispatch Name Registration/Approval No Address Country ISO country code	I.12 Place of destination Name Registration/Approval No Address Country ISO country code		
	I.13 Place of loading	I.14 Date and time of departure		
	I.15 Means of transport <input type="checkbox"/> Aircraft <input type="checkbox"/> Vessel <input type="checkbox"/> Railway <input type="checkbox"/> Road vehicle Identification	I.16 Entry Border Control Post		
		I.17 Accompanying documents Type Code Country ISO country code Commercial document reference		
I.18 Transport conditions	<input type="checkbox"/> Ambient	<input type="checkbox"/> Chilled	<input type="checkbox"/> Frozen	

I.19 Container number/Seal number		Seal No	
Container No			
I.20 Certified as or for			
<input type="checkbox"/> Organic fertilizers and soil improvers			
I.21 <input type="checkbox"/> For transit		I.22 <input type="checkbox"/> For internal market	
Third country	ISO country code	I.23 <input type="checkbox"/> For re-entry	
I.24 Total number of packages		I.25 Total quantity	
		I.26 Total net weight/gross weight (kg)	
I.27 Description of consignment			
Approval number of establishments			
Species (Scientific name)	Nature of commodity	Manufacturing plant	Number of packages
			Net weight
			Batch number

COUNTRY		Processed manure, derived products from processed manure, processed frass and processed guano from bats		
Part II: Certification	II. Health information		II.a Certificate reference	
			II.b IMSOC reference	
	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. come from a plant for the manufacture of products for purposes other than feeding to farmed animals, a biogas plant or a composting plant approved by the competent authority of the third country meeting the special conditions laid down in Regulation (EC) No 1069/2009 and in Regulation (EU) No 142/2011;			
	II.2 ⁽²⁾ have been subjected to:			
	[a heat treatment process of at least 70 °C for at least 60 minutes;] or			
	[in the case of processed manure, derived products from processed manure and processed guano from bats an equivalent treatment validated and authorised by the importing Member State in accordance with the specific conditions laid down in Regulation (EC) No 1069/2009 and in Regulation (EU) No 142/2011 as follows:			
			
			
];			
II.3. are:				
(a) free from Salmonella (no salmonella in 25 g treated product);				
(b) free from Escherichia coli or from Enterobacteriaceae (based on the aerobic count: less than 1 000 cfu per gram of treated product); and				
have been subjected to reduction in spore-forming bacteria and toxin formation;				
II.4. are not urine hunting lures derived from cervids;				
II.5. are securely enclosed in:				
(a) well-sealed and insulated containers, or				
(b) properly sealed packs (plastic bags or 'big bags').				
Notes				
Part I:				
<ul style="list-style-type: none"> • Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity. • Box reference I.11 and I.12: Approval number: the registration number of the establishment or plant, which has been issued by the competent authority. 				

- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit shall only be stored in free zones, free warehouses and custom warehouses.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in the event of unloading and reloading.
- Box reference I.19: for bulk containers, the container number and the seal number (if applicable) shall be given.
- Box reference I.20: technical use: any use other than for animal consumption.
- Box reference I.21, I.22 and I.23: fill in according to whether it is a transit, an import certificate or re-entry.
- Box reference I.27: Nature of commodity: enter if processed manure, derived products from processed manure, processed frass or guano from bats.

Part II:

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

(^{1b}) OJ L 54, 26.2.2011, p. 1.

(²) Delete as appropriate.

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

Official veterinarian/Official inspector

Name (in capital letters)

Date

Qualification and title

Stamp

Signature

‘;

Part 2
Correction to Annex XIV to Regulation (EU) No 142/2011

In Annex XIV, in Chapter II, in Section 1, in Table 2, in row 14, in the fifth column entitled ‘Third countries lists’, point (b) is corrected and replaced by the following:

‘(b) In the case of animal by-products for the manufacture of pharmaceuticals:

Third countries listed in Part 1 of Annex XIII or in Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404; and in Annexes I, V, and VI to Implementing Regulation (EU) 2021/405.

In the case of material from fish, third countries listed in Annex IX to Implementing Regulation (EU) 2021/405.’.