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From:	European Commission
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To:	General Secretariat of the Council
No. Cion doc.:	D033683/04 Annex 1
Subject:	ANNEX to the COMMISSION REGULATION (EU) No …/.. amending Regulation (EU) No 142/2011 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

Delegations will find attached document D033683/04 Annex 1.

Encl.: D033683/04 Annex 1

EUROPEAN
COMMISSION

Brussels, XXX
SANCO/7115/2012 Rev. 1 ANNEX
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[…](2014) XXX draft

ANNEX 1

ANNEX

to the

COMMISSION REGULATION (EU) No …/..

amending Regulation (EU) No 142/2011 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

ANNEX

Annexes I, III, IV, V, VI, IX, X, XI, XII, XIV, XV and XVI to Regulation (EU) No 142/2011 are amended as follows:

(1) Annex I is amended as follows:

(a) point 35 is replaced by the following:

"35. '**intermediate product'** means a derived product:

(a) which is intended for uses within the manufacturing of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products as follows:

(i) as material in a manufacturing process or in the final production of a finished product;

(ii) in validation or verification during a manufacturing process; or

(iii) in quality control of a finished product;

(b) whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in point (a);

(c) which however requires some further manufacturing or transformation, such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device for medical and veterinary purposes, active implantable medical device, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagent or cosmetic products;"

(b) point 39 is replaced by the following:

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

(c) point 58 is replaced by the following:

"58. **‘processing plant’** means premises or facilities for the processing of animal by-products as referred to in Article 24(1)(a) of Regulation (EC) No 1069/2009, in which animal by-products are processed in accordance with Annex IV and/or Annex X;"

(d) the following point is added:

"59. ‘**growing media**’ means materials, including potting soil, other than soil in situ, in which plants are grown and which is used independently from soil in situ."

(2) In Annex III, Chapter III, point (a) is replaced by the following:

"(a) only be used for the disposal of:

(i) dead pet animals referred to in Article 8(a)(iii) of Regulation (EC) No 1069/2009;

(ii) Category 1 materials referred to in Article 8(b), (e) and (f), Category 2 materials referred to in Article 9 or Category 3 materials referred to in Article 10 of that Regulation; and

(iii) dead individually identified equine animals from holdings not subject to health restrictions in accordance with Article 4(5) or 5 of Directive 2009/156/EC, if authorised by the Member State;"

(3) In Annex IV, Chapter IV is amended as follows:

(a) Section 2 is amended as follows:

(i) point H is deleted;

(ii) the following point is added:

"K. Ensilage of fish material

1. Starting materials

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

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

(b) Category 3 materials.

2. Processing method

2.1. The materials to be treated shall be collected at aquaculture farms and food processing establishments on a daily basis and without undue delays, ground or chopped, and thereafter subjected to ensiling at a pH of 4 or below, with formic acid or other organic acid authorised in accordance with the feed

legislation. The resulting fish silage must be a suspension of parts of aquatic animals liquefied by the action of endogenous enzymes in the presence of the added acid. The proteins of aquatic animals must be reduced into smaller soluble units, by the enzymes and the acid, in order to prevent microbial spoilage. The ensiled material is transported to the processing plant.

2.2. At the processing plant the ensiled material of aquatic animals must be piped into closed storage tanks. The incubation time must be at least 24 hours at a pH of 4 or below before heat treatment can be conducted. Before the heat treatment the ensilage of aquatic animals must have a pH of 4 or below and have a particle size of less than 10 mm following a filtration or maceration at the plant. During processing it must be subjected to preheating to a temperature above 85°C, followed by incubation in an insulated container to obtain 85°C throughout the fish material for 25 minutes. The process must take place in a closed production line with tanks and pipelines.

2.3. Before authorisation is given, the operator's permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be assessed by the competent authority."

(b) In Section 3, point 2(d) is replaced by the following:

"(d) the lime treated mixture of pig and poultry manure may be applied to land as processed manure;"

(c) In Section 3, the following point 2(e) is added:

"(e) The final product derived from the ensilaging of fish material may:

(i) for Category 2 materials, be used for purposes referred to in Article 13(a) to (d) and (g) to (i) of Regulation (EC) No 1069/2009 without further processing or as feed for animals referred to in Article 18 or Article 36(a)(ii) of that Regulation; or

(ii) for Category 3 materials, be used for purposes referred to in Article 14 of Regulation (EC) No 1069/2009."

(4) In Annex V, Chapter III, Section 2 is amended as follows:

(a) in point 2(b), point (x) is replaced by the following:

"(x) animal by-products referred to in Article 10(f) of Regulation (EC) No 1069/2009, which have undergone processing as defined in Article 2(1)(m) of Regulation (EC) No 852/2004;"

(b) in point 2(b), the following point (xi) is added:

"(xi) mixture of animal by-products referred to in point 2(b) with non-animal by-product materials."

(c) in point 3, point (b) is replaced by the following:

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

(5) Annex VI is amended as follows:

(a) in Chapter II, Section 2, point 1(a)(i) is replaced by the following:

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

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

		black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
		golden eagle	Aquila chrysaetos
		white-tailed eagle	Haliaeetus albicilla
		black kite	Milvus migrans
		red kite	Milvus milvus
HR	Croatia	bearded vulture	Gypaetus barbatus
		black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
IT	Italy	bearded vulture	Gypaetus barbatus
		black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
		golden eagle	Aquila chrysaetos
		black kite	Milvus migrans
		red kite	Milvus milvus
CY	Cyprus	black vulture	Aegypius monachus
		griffon vulture	Gyps fulvus
PT	Portugal	black vulture	Aegypius monachus
		Egyptian vulture	Neophron percnopterus
		griffon vulture	Gyps fulvus
		golden eagle	Aquila chrysaetos
SK	Slovakia	golden eagle	Aquila chrysaetos
		imperial eagle	Aquila heliaca
		white-tailed eagle	Haliaeetus albicilla
		black kite	Milvus migrans
		red kite	Milvus milvus

"

(b) In Chapter IV, the second paragraph is deleted.

(6) In Annex IX, the following Chapter V is added:

"*CHAPTER V*

CONTAINMENT METHODS

Section 1
General provisions

1. Materials resulting from a containment method may be used or disposed of only within the Member State where that containment method is authorised by the competent authority.

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

Section 2
Methodology

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

1. Member States concerned

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

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

2. Starting materials

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

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

(b) Category 3 materials referred to in Article 10(h) of Regulation (EC) No 1069/2009.

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

diseases or have been killed for diseases control purposes, or parts of those animals.

3. Methodology

3.1. General principles

The method is a process authorised by the competent authority.

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

The operator must:

(a) take preventive measures against access of animals and put in place a documented pest control programme;

(b) put in place procedures to prevent the spreading of diseases;

(c) put in place procedures to prevent the spreading of used sawdust outside the closed system.

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

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

3.2. Phases

3.2.1 Filling and storage phase

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

Personnel must not walk on the stored material.

3.2.2 Maturing phase

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

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

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

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

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

(a) where the temperature of 55°C or more is maintained during 3 consecutive days, the pile may be removed after a 3 consecutive months maturing phase, or may remain stored on the premises awaiting a later removal;

(b) where the temperature of 55°C is not reached during 3 consecutive days, measures defined in the permanent written procedure referred to in Article 29(1) to (3) of Regulation (EC) No 1069/2009 must be set by the operator; if needed, the competent authority may stop the processing method and the material must be disposed of in compliance with Article 13 of the aforementioned Regulation.

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

3.2.3 Transport and incineration or co-incineration

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

B. Hydrolysis with subsequent disposal

1. Member States concerned

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

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

2. Starting materials

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

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

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

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

3. Methodology

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

(a) Following their collection on a holding for which the competent authority has authorised the use of the processing method, based on an assessment of the animal density of the holding, the likely mortality rate and the potential risks for public and animal health which may arise, the animal by-products must be placed into a container which has been constructed in accordance with point (b) ('the container') and which has been placed at a dedicated site in accordance with points (c) and (d) ('the dedicated site').

(b) The container must:

(i) have a device to close it;

(ii) be water-proof, leak-proof and hermetically sealed;

(iii) be coated in a way which prevents corrosion;

(iv) be equipped with a device for controlling emissions in accordance with point (e).

(c) The container must be placed in a dedicated site which is physically separate from the holding.

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

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

(e) The container must be linked to a pipe for gaseous emissions, which must be equipped with appropriate filters to prevent the transmission of diseases communicable to humans and animals.

(f) The container must be closed for the process of hydrolysis for a period of at least three months, in such a way that any unauthorised opening is prevented.

(g) The operator must put in place procedures to prevent the transmission of diseases communicable to humans or animals by movements of personnel.

(h) The operator must:

(i) take preventive measures against birds, rodents, insects and other vermin;

(ii) put in place a documented pest control programme.

(i) The operator must keep records of:

(i) any placing of material into the container;

(ii) any collection of hydrolysed material from the container.

(j) The operator must empty the container at regular intervals for a check:

(i) for the absence of corrosion;

(ii) to detect and prevent possible leakage of liquid materials into the ground.

(k) Following hydrolysis, the materials must be collected, used and disposed of in accordance with Article 13(a), (b), (c) or Article 13(e)(i) of Regulation (EC) No 1069/2009 or Article 14 of that Regulation for Category 3 materials.

(l) The process must be carried out in a batch mode.

(m) Any other handling or use of the hydrolysed materials, including their application to land, shall be prohibited."

(7) In Annex X, Chapter II is amended as follows:

(a) in Section 3, point A, point 1 is replaced by the following:

"1. Rendered fats

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

(b) in Section 4, Part III, the following paragraph is added:

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

(8) In Annex XI, Chapter II, a new Section 3 is added:

"Section 3
Requirements for approval of establishments or plants

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

(a) have adequate facilities for storage of incoming ingredients to prevent cross-contamination and avoid contamination during storage;

(b) dispose of unused animal by-products or derived products in accordance with Articles 13 and 14 of Regulation (EC) No 1069/2009."

(9) In Annex XII, point 3(a) is replaced by the following:

"3. The intermediate products imported into the Union shall be checked at the border inspection post in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post either to:

(a) a registered establishment or plant for the production of laboratory reagents, medical devices and in vitro diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Regulation (EC) No 1069/2009, where the intermediate products must be further mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the Union legislation applicable to the derived product;".

(10) Annex XIV is amended as follows:

(a) Chapter I is amended as follows:

(i) In Section 1, in row 2 of Table 1, the text in the fourth column is replaced by the following:

"The blood products must have been produced in accordance with Section 2 of Chapter II of Annex X and Section 5 of Chapter I of Annex XIV."

(ii) the following Section is added:

"Section 5

Imports of blood products for the feeding of farmed animals

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

These derived products must be:

(a) subjected to a heat treatment at a temperature of at least 80°C throughout the substance and the dry blood and blood plasma is of not more than 8% moisture with a water activity (Aw) of less than 0,60;

(b) stored in dry warehouse conditions under room temperature for at least 6 weeks."

(b) in Chapter II, Section 7, point 1(b) is replaced by the following:

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

(11) Annex XV is amended as follows:

(a) Chapter 4(B) is replaced by the following:

"CHAPTER 4(B)

Health certificate

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

COUNTRY: **Veterinary certificate to EU**

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: Animal feedingstuff ☐ 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	Batch number

COUNTRY **Blood products not intended for human consumption that could be used as feed material**

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 certify that the blood products described above:

II.1. consist of blood products that satisfy the health requirements below;

II.2. consist exclusively of blood products not intended for human consumption;

II.3. have been prepared and stored in a plant, approved, validated and supervised by the competent authority in accordance with Article 24 of Regulation (EC) No 1069/2009;

II.4. have been prepared exclusively with the following animal by-products:

[2]*either* [blood of slaughtered animals, which is fit for human consumption in accordance with Union legislation, but is not intended for human consumption for commercial reasons;]

[2]*and/or* [blood of slaughtered animals, which is rejected as unfit for human consumption in accordance with Union legislation, but which did not show any signs of diseases communicable to humans or animals, derived from carcases that have been slaughtered in a slaughterhouse and were considered fit for human consumption following an ante-mortem inspection in accordance with Union legislation;]

II.5. in order to inactivate pathogenic agents, have been submitted

[2]*either* [to processing in accordance with processing method ……..[3] as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011;]

[2]*or* [to a method and parameters which ensure that the product complies with the microbiological standards set in Chapter I of Annex X to Regulation (EU) No 142/2011;]

[2]*or* [in the case of blood products, including spray dried blood and blood plasma, of porcine origin intended for the feeding of porcine animals, to a heat treatment at a temperature of at least 80°C throughout the substance and the dry blood and blood plasma is of not more than 8% moisture with a water activity (Aw) of less than 0,60.]

II.6. have been examined under the responsibility of the competent authority taking a random sample immediately prior to dispatch and found it to comply with the following standards[4]:

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

Enterobacteriaceae: n = 5, c = 2, m = 10, M = 300 in 1 gram;

II.7. the end product was:

[2]*either* [packed in new or sterilised bags;]

[2]*or* [transported in bulk in containers or other means of transport that were thoroughly cleaned and disinfected with a disinfectant approved by the competent authority before use,]

and which bear labels indicating 'NOT FOR HUMAN CONSUMPTION';

II.8. the end product was stored in enclosed storage;

II.9. the product has undergone all precautions to avoid contamination with pathogenic agents after treatment;

[2]*and* [in the case of blood products, including spray dried blood and blood plasma of porcine origin intended for the feeding of porcine animals, has been stored in dry warehouse conditions under room temperature for at least 6 weeks.]

II.10. does not contain and is not derived from:

[2]*either* [specified risk material or mechanically separated meat obtained from bones

COUNTRY **Blood products not intended for human consumption that could be used as feed material**

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

of bovine, ovine or caprine animals and, except for animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001 of the European Parliament and of the Council[5], the animals from which this animal by-product or derived product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod- shaped instrument introduced into the cranial cavity.]

[2]*or* [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 by a decision in accordance with Article 5(2) of Regulation (EC) No 999/2001.]

Notes

Part I:

- Box reference I.6: Person responsible for the consignment in the European Union: this box is to be filled in only if it is a certificate for transit commodity; it may be filled in if the certificate is for import commodity.
- Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity. The products in transit can only be stored in free zones, free warehouses and custom warehouses.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship); information is to be provided in case of unloading and reloading.
- Box reference I.19: use the appropriate HS code: 05.11.91 or 05.11.99.
- Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.
- Box reference I.25: technical use: any use other than for animal consumption.
- Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.
- Box reference I.28: Species: select from the following: Aves, Ruminantia, Suidae, Mammalia other than Ruminantia, Pesca, Reptilia.

Part II:

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

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

(2) Delete as appropriate.

(3) Insert method 1 to 5 or 7 as applicable.

(4) Where:

n = number of samples to be tested;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all samples does not exceed m;

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial 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.

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

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

COUNTRY

Blood products not intended for human consumption that could be used as feed material

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

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

Official veterinarian/Official inspector

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

"

(b) Chapter 20 is replaced by the following:

"CHAPTER 20

Model declaration

Declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents and cosmetic products

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) / Approval number of establishments Manufacturing plant / Net weight / Batch number		

COUNTRY

Intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostics medical devices for medical and veterinary purposes, laboratory reagents, and cosmetic products

Part II: Certification

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

DECLARATION

I, the undersigned, declare that the intermediate product referred to above is intended to be imported by me into the Union and satisfies the definition provided for in point 35 of Annex I of Commission Regulation (EU) No 142/2011[1a], and in particular that:

(1) it is intended for the manufacture of:

[2]*either* [- medicinal products,]

[2]*and/or* [- veterinary medicinal products,]

[2]*and/or* [- medical devices for medical and veterinary purposes,]

[2]*and/or* [- active implantable medical devices,]

[2]*and/or* [- in vitro diagnostic medical devices for medical and veterinary purposes,]

[2]*and/or* [- laboratory reagents,]

[2]*and/or* [- cosmetic products;]

(2) its design, transformation and manufacturing stages have been sufficiently completed in order to qualify the material directly or as a component of a product intended for that purpose, except for the fact that it requires further manufacturing or transformation such as mixing, coating, assembling or packaging to make it suitable for placing on the market or putting into service as medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes or cosmetic products in accordance with the Union legislation[1b] applicable to those products or as laboratory reagents;

(3) it has been derived from:

[2]*either* [- material which may have originated from animals submitted to illegal treatment as defined in Article 1(2)(d) of Council Directive 96/22/EC or Article 2(b) of Council Directive 96/23/EC;]

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

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

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

(ii) heads of poultry;

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

(iv) pig bristles;

(v) feathers;]

[2]*and/or* [- blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from animals other than ruminants that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human

		consumption following an ante-mortem inspection in accordance with Union legislation;]
[(2)]*and/or*	[-	animal by-products arising from the production of products intended for human consumption, including degreased bone, greaves and centrifuge or separator sludge from milk processing;]
[(2)]*and/or*	[-	products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;]
[(2)]*and/or*	[-	petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;]
[(2)]*and/or*	[-	blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show signs of any disease communicable through that product to humans or animals;]
[(2)]*and/or*	[-	aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of diseases communicable to humans or animals;]
[(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(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]
[(2)]*and/or*	[-	products derived from or generated by: - aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals, - aquatic or terrestrial invertebrates other than species pathogenic to humans or animals, - animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g) of Regulation (EC) No 1069/2009;]
[(2)]and/or	[-	animals and parts of animals, other than those referred to in Article 8 or Article 10 of Regulation (EC) No 1069/2009, (i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes; (ii) foetuses; (iii) oocytes, embryos and semen which are not destined for breeding purposes; and (iv) dead-in-shell poultry;]
[(2)]*and/or*	[-	animal by-products other than Category 1 material or Category 3 material;]
(4)		its outer packaging is labelled 'FOR MEDICINAL PRODUCTS / VETERINARY MEDICINAL PRODUCTS / MEDICAL DEVICES FOR MEDICAL AND VETERINARY

PURPOSES / ACTIVE IMPLANTABLE MEDICAL DEVICES / IN VITRO DIAGNOSTIC MEDICAL DEVICES FOR MEDICAL AND VETERINARY PURPOSES / LABORATORY REAGENTS / COSMETIC PRODUCTS ONLY' and it is not intended to be diverted at any stage within the Union for any other use;

(5) the consignment will be transported directly to the place of destination as indicated under point I.12 of this declaration, that is:

- an establishment or plant for the production of medicinal products, veterinary medicinal products, medical devices for medical and veterinary purposes, active implantable medical devices, in vitro diagnostic medical devices for medical and veterinary purposes, laboratory reagents or cosmetic products, which has been registered in accordance with Article 23 of Regulation (EC) No 1069/2009,
- an establishment or plant which has been approved in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they shall only be dispatched to an establishment or plant referred to in the preceding indent of this point.

Notes

- Box reference I.19: use appropriate Harmonised System (HS) code under the following headings: 02.06; 04.07; 04.08; 05.06; 05.07; 05.11; 12.12; 21.06; 30.01; 30.02; 31.01; 51.01, 51.02 or 15.05.00.
- Box reference I.25: technical use: any use other than for animal consumption.

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

(1b) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1) and Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169), as appropriate.

(2) Delete as appropriate.

The importer

Name (in capital letters): Address:

Date: Signature:

"

(12) In Annex XVI, Chapter III, Section 11 is replaced by the following:

"Section 11

Official controls regarding hydrolysis with subsequent disposal

The competent authority shall carry out controls at sites where hydrolysis with subsequent disposal is carried out in accordance with point B of Section 2 of Chapter V of Annex IX.

Such controls shall, for the purpose of reconciliation of the quantities of hydrolysed materials dispatched and disposed of, include documentary checks:

(a) of the amount of materials which are hydrolysed at the site;

(b) in the establishments or plants where the hydrolysed materials are disposed of.

Controls shall be carried out regularly on the basis of a risk assessment.

During the period of the first twelve months of operation, a control visit to a site, where a container for the hydrolysis is located, shall be carried out every time hydrolysed material is collected from the container.

Following the period of the first twelve months of operation, a control visit to such sites shall be carried out every time the container is emptied and checked for the absence of corrosion and leaking in accordance with point B(3)(j) of Section 2 of Chapter V of Annex IX."