COMMISSION IMPLEMENTING REGULATION (EU) No 483/2014

of 8 May 2014

on protection measures in relation to porcine diarrhoea caused by a deltacoronavirus as regards the animal health requirements for the introduction into the Union of spray dried blood and blood plasma of porcine origin intended for the production of feed for farmed porcine animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries, and in particular Article 22(3) ([1]) thereof,

Whereas:

(1) Article 22(1) of Directive 97/78/EC provides that if in the territory of a third country a disease or any other phenomenon or circumstance liable to present a serious threat to animal health manifests itself or spreads, or if any other serious animal health reason so warrants, the Commission acting on its own initiative or at the request of a Member State, is to adopt measures without delay, including special conditions in respect of products coming from all or part of the third country concerned.

(2) Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([2]) lays down public and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the feed chain. It also categorises those products into specific categories which reflect the level of risk to public and animal health.

(3) Article 41(3) of Regulation (EC) No 1069/2009, lays down requirements for the import of animal by-products and derived products of Category 3 material.

(4) Commission Regulation (EU) No 142/2011 ([3]), lays down implementing rules for Regulation (EC) No 1069/2009, including specific requirements for the treatment or processing of animal by-products and derived products destined for feeding to farmed animals, excluding fur animals.

(5) Blood products intended for the production of feed for farmed animals, including spray dried blood and plasma of porcine animals, must have been produced in accordance with Section 2 of Chapter II of Annex X to Regulation (EU) No 142/2011. With reference to point B of that Section blood products are to be submitted to any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV to that Regulation, or another method which ensures that the blood products comply with the microbiological standards for derived products set out in Chapter I of Annex X to Regulation (EU) No 142/2011. Regulation (EU) No 142/2011 also provides, in particular in column 6 of row 2 in Table 1 of Section 1 of Chapter I of Annex XIV, that blood products not intended for human consumption that could be used as feed intended for dispatch to or for transit through the Union are to be accompanied by health certificate in accordance with the model health certificate set out in Chapter 4(B) of Annex XV.

(6) Porcine diarrhoea caused by a deltacoronavirus occurs in Asia and North America. This virus has never been detected in the Union. Spray dried blood and blood plasma of porcine animals is a traditional ingredient for feed for piglets. Inappropriate heat treatment or contamination after heat treatment may lead to the spread of the virus with such products.

([1]) OJ L 24, 30.1.1998, p. 9.

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

([3]) 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).

(7) Therefore it is necessary to review the requirements for the import of spray dried blood and blood plasma of porcine animals intended for the production of feed for farmed porcine animals.

(8) Scientific observation indicates that porcine coronaviruses are inactivated in swine faeces if heated to and held at a temperature of 71 °C for 10 minutes or left at room temperature of 20 °C for 7 days. The virus did not survive in experimentally infected dry feed stored at a temperature of 24 °C for more than 2 weeks. In third countries the commonly applied temperature for spray drying of blood and blood plasma is 80 °C throughout the substance.

(9) Based on this information available, it appears opportune to require that spray dried blood and blood plasma of porcine origin introduced from third countries and intended for feeding of porcine animals has been subjected to a high temperature treatment followed by subsequent storage for a certain time at room temperature in order to mitigate the risk of contamination after the treatment.

(10) Due to the need to protect animal health in the Union and the serious threat posed by the blood products concerned, the Commission should adopt provisional safeguard measures. Accordingly, the introduction of those products into Union should be accompanied by a health certificate in accordance with the model set out in the Annex to this Regulation.

(11) The provisional safeguard measures should apply from the day following the publication of this Regulation and last for a period of 12 months. They may be amended in the light of a risk assessment based on new scientific information.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

By way of derogation from column 6 of row 2 in Table 1 of Section 1 of Chapter I of Annex XIV and of Chapter 4(B) of Annex XV to Regulation (EU) No 142/2011, blood products not intended for human consumption that could be used as feed material, intended for dispatch to or for transit through the Union, shall be accompanied by a health certificate in accordance with the model set out in the Annex to this Regulation.

Article 2

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

It shall apply for consignments certified as from the day following that of its publication in the *Official Journal of the European Union*.

It shall apply until 31 May 2015.

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

Done at Brussels, 8 May 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

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

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

Part II: Certification

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 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.]

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.

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.

— 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: