COMMISSION IMPLEMENTING REGULATION (EU) No 102/2013

of 4 February 2013

amending Regulation (EU) No 206/2010 as regards the entry for the United States in the list of third countries, territories or parts thereof authorised for the introduction of live ungulates into the Union, the model veterinary certificate 'POR-X' and the protocols for testing for vesicular stomatitis

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC [1], and in particular the first and second subparagraphs of Article 3(1), the first subparagraph of Article 6(1), Article 7(e), Article 9 and Article 13(1)(e) thereof,

Whereas:

(1) Directive 2004/68/EC lays down the animal health requirements for the importation into and transit through the Union of certain live ungulates. It provides that specific provisions, including model veterinary certificates, may be laid down for the import into the Union of live ungulates of the species listed in Annex I thereto from authorised third countries.

(2) Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements [2] lays down amongst others the veterinary certification requirements for the introduction into the Union of certain consignments of live cloven-hoofed animals of the species listed in Annex I to Directive 2004/68/EC. Annex I to Regulation (EU) No 206/2010 sets out a list of third countries, territories or parts thereof from which such consignments may be introduced into the Union. It also provides models of veterinary certificates to accompany those consignments.

(3) Currently, ungulates can only be imported into the Union from third countries, or in case of regionalisation parts of third countries, that are free of vesicular stomatitis for at least six months prior to dispatch of the animals.

(4) The United States requested to be authorised for imports into the Union of live pigs for breeding and production.

(5) Outbreaks of vesicular stomatitis have been notified by the United States. However those outbreaks are sporadic and limited to certain areas. The risk of introduction into the Union of vesicular stomatitis via imports of live pigs from that third country is negligible, if the biosecurity measures which are described in Chapter 8.15.6 of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE) are applied including confinement of the pigs during the pre-export residence period in premises free of the disease, vector protection during pre-export quarantine and transport to the place of loading and testing of all animals to be exported.

(6) Part 1 of Annex I to Regulation (EU) No 206/2010 should therefore be amended to add the United States to the list of third countries, territories or parts thereof from which consignments of live ungulates may be introduced into the Union indicating the appropriate guarantees as regards testing for vesicular stomatitis. The implementation of those guarantees should be confirmed in the veterinary certificate for live pigs for breeding and production accompanying the animals at the time of introduction into the Union.

(7) The model veterinary certificate for the import of live domestic porcine animals, 'POR-X', set out in Part 2 of Annex I to Regulation (EU) No 206/2010, should therefore be amended accordingly to introduce the conditions for pre-export residence and quarantine as well as the laboratory test requirements.

(8) In addition, Article 5 of Regulation (EU) No 206/2010 provides that where sampling and testing is required by the veterinary certificates set out in Annex I to that Regulation, they are to be carried out in conformity with the protocols for the standardisation of materials and testing procedures set out in Part 6 of that Annex. It is therefore necessary to amend Part 6 of Annex I to Regulation (EU) No 206/2010 in order to add the relevant protocol and testing procedure for vesicular stomatitis. The test should be carried out and interpreted in accordance with the protocols for serological tests for vesicular stomatitis prescribed for international trade in Chapter 2.1.19 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

(9) Regulation (EU) No 206/2010 should therefore be amended accordingly.

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

[1] OJ L 139, 30.4.2004, p. 321.
[2] OJ L 73, 20.3.2010, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 206/2010 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, 4 February 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

Annex I to Regulation (EU) No 206/2010 is amended as follows:

(1) in Part 1, the following entry for the United States is added:

'US – United States	US-0	Whole country	POR-X	D'	

(2) Part 2 is amended as follows:

(a) the text concerning 'POR-X' is replaced by the following:

' "POR-X": Model of veterinary certificate for domestic porcine animals (Sus scrofa) intended for breeding and/or production after importation or intended for transit through the Union from one third country to another third country.'

(b) in the list of SG (Supplementary guarantees), the following text is added:

' "D": guarantees regarding vesicular stomatitis test on animals certified according to the model of veterinary certificate POR-X (point II.2.1(b)).'

(c) the model veterinary certificate 'POR-X' is replaced by the following:

'**Model POR-X**

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.		
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 Address		Approval number	I.12.		
I.13. Place of loading Address		Approval number	I.14. Date of departure		
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references			I.16. Entry BIP in EU I.17.		
I.18. Description of commodity			I.19. Commodity code (HS code) **01.03**		
			I.20. Quantity		
I.21.			I.22. Number of packages		
I.23. Identification of container/seal number			I.24.		
I.25. Commodities certified for: Breeding ☐					
I.26.			I.27. For import or admission into EU ☐		

I.28. Identification of the commodities

Species (scientific name)	Identification system	Identification number	Age	Sex

COUNTRY **Model POR-X**

II.	Health information	II.a. Certificate reference number	II.b.

Part II: Certification

II.1. **Public Health Attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described in this certificate:

II.1.1. come from holdings which have been free from any official prohibition on health grounds, for the last 42 days in the case of brucellosis, for the last 30 days in the case of anthrax and for the past six months in the case of rabies and, the animals have not been in contact with animals from holdings which did not satisfy these conditions;

II.1.2. have not received:

— any stilbene or thyrostatic substances,

— oestrogenic, androgenic, gestagenic or **β**-agonist substances for purposes other than therapeutic or zootechnic treatment (as defined in Directive 96/22/EC).

II.2. **Animal Health attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described above meet the following requirements:

II.2.1. they come from the territory with code: ..... (1) which, at the date of issuing this certificate:

(2) *either* [(a) has been free for 24 months from foot-and-mouth disease, for 12 months from rinderpest, African swine fever, classical swine fever, swine vesicular disease and vesicular exanthema, and]

(2) *or* [(a) (i) has been free [for 24 months from foot-and-mouth disease] (2), for 12 months from rinderpest, African swine fever, vesicular exanthema, [classical swine fever] (2) and [swine vesicular disease] (2), and

(ii) has been considered free from [foot-and-mouth disease] (2), [classical swine fever] (2) and [swine vesicular disease] (2), since ..... (dd/mm/yyyy), without having had cases/outbreaks from that date, and authorised to export these animals by Commission Regulation (EU) No …/… of ..... (dd/mm/yyyy), and]

(2) *either* [(b) for 6 months from vesicular stomatitis, and]

(2) (9) *or* [(b) the animals have been kept for the 21 days, or since birth if younger than 21 days of age, prior to entering the pre-export quarantine in a holding in which no case of vesicular stomatitis was officially reported during that period and during the pre-export quarantine of not less than 30 days prior to shipment in a quarantine station protected from vector insects where they were subjected with negative results at a serum dilution of 1 in 32 to a virus neutralisation test for vesicular stomatitis carried out as referred to in Part 6 of Annex I to Regulation (EU) No 206/2010 on samples taken at least 21 days after commencement of the quarantine; and]

(c) where during the last 12 months, no vaccination against these diseases has been carried out and imports of domestic cloven-hoofed animals vaccinated against these diseases are not permitted;

II.2.2. they have remained in the territory described under point II.2.1 since birth, or for at least the last six months before dispatch to the Union and without contact with imported cloven-hoofed animals for the last 30 days;

II.2.3. they have remained in the holding(s) described under box reference I.11 since birth, or for at least 40 days prior to dispatch, and, during this period, in the holding(s) and in an area with a 10 km radius around the holding(s) of origin, there has been no case/outbreak of the diseases referred to in point II.2.1;

II.2.4. A they are not animals to be killed under a national programme for the eradication of diseases, nor have they been vaccinated against the diseases referred to in point II.2.1;

(2) (3) [II.2.4. B they have been subjected within the past 30 days to a test for swine vesicular disease antibodies and a test for classical swine fever antibodies with negative results in both cases;]

(2) (4) [II.2.4. C they have been subjected within the past 30 days to a buffered Brucella antigen test for porcine brucellosis with negative results;]

II.2.5 they come from herds which are not restricted under the national brucellosis eradication programme;

II.2.6 they are/were (2) dispatched from their holding(s) of origin, without passing through any market,

(2) *either* [directly to the Union,]

(2) *or* [to the officially authorised assembly centre described under box reference I.13 situated within the territory described under point II.2.1,]

COUNTRY **Model POR-X**

II.	Health information	II.a. Certificate reference number	II.b.

and, until dispatched to the Union:

(a) they did not come in contact with other cloven-hoofed animals not complying with the health requirements as described in this certificate, and

(b) they were not at any place where, or around which within a 10 km radius, during the previous 40 days there has been a case/outbreak of any of the diseases referred to in point II.2.1, and

(c) in the case the country has not been free for 6 months of vesicular stomatitis, they were transported to the place of loading protected from vector insects;

II.2.7. any transport vehicles or containers in which they were loaded were cleaned and disinfected before loading with an officially authorised disinfectant;

II.2.8. they were examined by an official veterinarian within 24 hours of loading and showed no clinical sign of disease;

II.2.9. they have been loaded for dispatch to the Union on ..... (dd/mm/yyyy) ([5]) in the means of transport described under box reference I.15 that were cleaned and disinfected before loading with an officially authorised disinfectant and so constructed that faeces, urine, litter or fodder could not flow or fall out of the vehicle or container during transportation.

II.3. **Animal transport attestation**

I, the undersigned official veterinarian, hereby certify, that the animals described above have been treated before and at the time of loading in accordance with the relevant provisions of Regulation (EC) No 1/2005, in particular as regards watering and feeding, and they are fit for the intended transport.

([2]) ([6]) [II.4. **Specific requirements**

II.4.1. Aujeszky's disease is notifiable in the country referred to in box reference I.7;

II.4.2. according to official information, no clinical, pathological or serological evidence of Aujeszky's disease has been recorded for the last 12 months in the holding(s) of origin referred to in box reference I.11., and in those holdings situated in its vicinity within 5 km;

II.4.3. the animals referred to in box reference I.28:

(a) prior to dispatch for exportation, have remained since birth in the holding(s) of origin referred to in box reference I.11. or they have remained in this(ese) holdings(s) for the last 3 months and in others of equivalent status since birth,

(b) have been isolated in accommodation approved by the competent authority for the last 30 days immediately prior to dispatch for export, without direct or indirect contact with other Suidae animals,

(c) have been subjected to an ELISA test for the presence of Ig ([7]) on sera taken at least 21 days after entry into isolation, with negative results; and, all animals in isolation have also given negative results to this test, and

(d) have not been vaccinated against Aujeszky's disease and have not been in contact with vaccinated animals and the herd of origin has not been vaccinated during the previous 12 months.]

([2]) ([8]) [II.4.4. ..... (further requirements and/or tests)
.....]

Notes

This certificate is meant for live domestic porcine animals (*Sus scrofa*) intended for breeding or production.

After importation the animals must be conveyed without delay to the holding of destination where they shall remain for a minimum period of 30 days before further movement outside the holding, except in the case of animals dispatched directly to a slaughterhouse or of animals transiting the Union from one third country to another third country.

Part I:

— Box reference I.8: Provide the code of territory as appearing in Part 1 of Annex I to Regulation (EU) No 206/2010.

— Box reference I.13: The assembly centre, if any, must fulfil the conditions for its approval, as laid down in Part 5 of Annex I to Regulation (EU) No 206/2010.

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II. Health information	II.a. Certificate reference number	II.b.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the BIP of entry into the Union.

— Box reference I.23: For containers or boxes, the container number and the seal number (if applicable) should be included.

— Box reference I.28.: *Identification system*: the animals must bear:

  — An individual number which permits tracing of their premises of origin. Specify the identification system (such as tag, tattoos, brand, chip, transponder).

  — An ear tag that includes the ISO code of the exporting country. The individual number must permit tracing of their premises of origin.

— Box reference I.28: *Age*: months.

— Box reference I.28.: *Sex* (M = male, F = female, C = castrated).

Part II:

([1]) Code of the territory as it appears in Part 1 of Annex I to Regulation (EU) No 206/2010.

([2]) Keep as appropriate.

([3]) Supplementary guarantees to be provided when required in column 5 'SG' of Part 1 of Annex I to Regulation (EU) No 206/2010, with the entry **'B'**.

([4]) Supplementary guarantees to be provided when required in column 5 'SG' of Part 1 of Annex I to Regulation (EU) No 206/2010, with the entry **'C'**.

([5]) Date of loading. Imports of these animals shall not be allowed when the animals were loaded either prior to the date of authorisation for exportation to the Union of the third country, territory or part thereof referred to in boxes I.7. and I.8., or during a period where restrictive measures have been adopted by the Union against imports of these animals from this third country, territory or part thereof.

([6]) When required by the EU Member State of destination or Switzerland, in accordance with Decision 2008/185/EC and the Agreement between the Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132) except for those countries with **'IX'** in column 6 'Specific conditions' of Part 1 of Annex I to Regulation (EU) No 206/2010.

([7]) To be carried out according to the standards laid down in Annex III to Decision 2008/185/EC. In the case of pigs aged over 4 months, the test used shall be the whole virus ELISA.

([8]) Further requirements requested by Finland in respect of transmissible gastro-enteritis.

([9]) Supplementary guarantees to be provided when required in column 5 'SG' of Part 1 of Annex I to Regulation (EU) No 206/2010, with the entry **'D'**.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:'

Stamp:

(3) in Part 6, the following text is added:

'Vesicular stomatitis (VS)

The virus neutralisation (VN) test shall be carried out in accordance with the testing protocols for vesicular stomatitis set out in Chapter 2.1.19 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

Sera that prevent cytopathic effect (CPE) at dilutions of 1 in 32 or greater shall be considered to contain antibodies to the vesicular stomatitis virus.'