COMMISSION IMPLEMENTING DECISION

of 1 March 2012

on imports into the Union of semen of domestic animals of the porcine species

(notified under document C(2012) 1148)

(Text with EEA relevance)

(2012/137/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species [1], and in particular Article 7(1), Article 9(2) and (3) and Article 10(2) thereof,

Whereas:

(1) Directive 90/429/EEC lays down the animal health conditions applicable to intra-Union trade in and imports from third countries of semen of domestic animals of the porcine species. It provides that Member States may authorise importation of such semen only from those third countries which appear on a list drawn up in accordance with the procedure laid down therein and accompanied by an animal health certificate, the model of which must correspond to a specimen drawn up in accordance with that Directive. The animal health certificate is to certify that the semen comes from approved semen collection centres offering the guarantees provided for in Article 8(1) of that Directive.

(2) Commission Decision 2009/893/EC of 30 November 2009 on importation of semen of domestic animals of the porcine species into the Community as regards lists of third countries and of semen collection centres, and certification requirements [2] sets out a list of third countries from which Member States are to authorise imports of semen. That list is established on the basis of the animal health status of those third countries.

(3) Directive 90/429/EEC, as amended by Commission Implementing Regulation (EU) No 176/2012 [3], provides for revised animal health requirements for donor animals of the porcine species and semen as regards brucellosis and Aujeszky's disease.

(4) Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever [4] deleted Teschen disease (porcine enterovirus encephalomyelitis) from the list of diseases laid down in Annex I to Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease [5] and consequently by Commission Decision 2008/650/EC of 30 July 2008 amending Council Directive 82/894/EEC on the notification of animal diseases within the Community to include certain diseases in the list of notifiable diseases and to delete porcine enterovirus encephalomyelitis from that list [6] that disease was deleted from the list of the compulsorily notifiable diseases within the Union.

(5) In addition, it is necessary to align certain animal health requirements for imports into the Union of semen of domestic animals of the porcine species to the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE) in particular as regards country freedom of swine vesicular disease and semen collection centre freedom of tuberculosis and rabies.

(6) Accordingly, the model animal health certificate set out in Part 1 of Annex II to Decision 2009/893/EC should be amended to take account of those amendments made to Directive 90/429/EEC and to delete all references to Teschen disease (porcine enterovirus encephalomyelitis), country freedom of swine vesicular disease and semen collection centre freedom of tuberculosis and rabies.

(7) There are bilateral agreements concluded between the Union and certain third countries containing specific conditions for the imports into the Union of semen of domestic animals of the porcine species. Therefore, where the bilateral agreements contain specific conditions and model animal health certificates for imports, those conditions and models should apply instead of the conditions and the model set out in this Decision.

(8) Switzerland is a third country with an animal health status equivalent to that of the Member States. It is therefore appropriate that semen of domestic animals of the porcine species imported into the Union from Switzerland is accompanied by an animal health certificate drawn up in accordance with the models

[1] OJ L 224, 18.8.1990, p. 62.
[2] OJ L 320, 5.12.2009, p. 12.
[3] OJ L 61, 2.3.2012, p. 1.
[4] OJ L 192, 20.7.2002, p. 27.
[5] OJ L 62, 15.3.1993, p. 69.
[6] OJ L 213, 8.8.2008, p. 42.

used for intra-Union trade in such semen set out in Annex D to Directive 90/429/EEC, with the adaptations set out in point 3 of Chapter VIII(B) of Appendix 2 of Annex 11 to the Agreement between the European Community and the Swiss Confederation on Trade in Agricultural Products, as approved by Decision 2002/309/EC, Euratom of the Council, and of the Commission as regards the Agreement on Scientific and Technological Cooperation, of 4 April 2002 on the conclusion of seven Agreements with the Swiss Confederation [1].

(9) In the interest of clarity and consistency of Union legislation, Decision 2009/893/EC should be repealed and replaced by this Decision.

(10) To avoid any disruption of trade, the use of animal health certificates issued in accordance with Decision 2009/893/EC should be authorised during a transitional period.

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

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

This Decision lays down a list of third countries or parts thereof from which Member States shall authorise imports into the Union of semen of domestic animals of the porcine species.

It also lays down certification requirements for imports of semen into the Union.

Article 2

Imports of semen

1. Member States shall authorise the import of semen provided that it complies with the following conditions:

(a) it comes from a third country, or part thereof, listed in Annex I;

(b) it comes from a semen collection centre listed in accordance with Article 8(2) of Directive 90/429/EEC;

(c) it is accompanied by an animal health certificate drawn up in accordance with the model animal health certificate set out in Part 1 of Annex II, and completed in accordance with the explanatory notes set out in Part 2 of that Annex;

(d) it complies with the requirements set out in the animal health certificate referred to in point (c).

2. Where specific animal health and certification conditions are laid down in bilateral agreements between the Union and third countries, those conditions shall apply instead of the conditions laid down in paragraph 1.

Article 3

Conditions concerning the transport of semen to the Union

1. The semen referred to in Article 2 shall not be transported in the same container as other consignments of semen that:

(a) are not intended for introduction into the Union; or

(b) are of a lower health status.

2. During transport to the Union, semen shall be placed in closed and sealed flasks and the seal shall not be broken during transport.

Article 4

Repeal

Decision 2009/893/EC is repealed.

Article 5

Transitional provision

For a transitional period until 30 November 2012, Member States shall authorise imports of semen from third countries which are accompanied by an animal health certificate issued not later than 31 October 2012 in accordance with the model set out in Part 1 of Annex II to Decision 2009/893/EC.

Article 6

Applicability

This Decision shall apply from 1 June 2012.

Article 7

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 1 March 2012.

For the Commission
John DALLI
Member of the Commission

[1] OJ L 114, 30.4.2002, p. 1.

ANNEX I

List of third countries or part thereof from which Member States are to authorise imports of semen of domestic animals of the porcine species

ISO code	Name of the third country	Remarks
CA	Canada	
CH	Switzerland (*)	
NZ	New Zealand	
US	United States	

(*) The certificate to be used for imports from Switzerland is set out in Annex D to Directive 90/429/EEC, with the adaptations set out in point 3 of Chapter VIII(B) of Appendix 2 of Annex 11 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products as approved by Decision 2002/309/EC, Euratom.

ANNEX II

PART 1

Model animal health certificate for imports of semen of domestic animals of the porcine species

COUNTRY: **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel.		I.2. Certificate reference No	I.2.a.
		I.3. Central competent authority	
		I.4. Local competent authority	
I.5. Consignee Name Address Postal code Tel.		I.6. Person responsible for the load in EU Name Address Postal code Tel.	
I.7. Country of origin / ISO code	I.8. Region of origin / Code	I.9. Country of destination / ISO code	I.10 Region of destination / Code
I.11. Place of origin Name Address Postal code		I.12. Place of origin Name Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code) **05 11 99 85**	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Seal/Container No		I.24.	
I.25. Commodities certified for: Artificial reproduction ☐			
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)	Breed	Donor identity	Date of collection	Approval number of the centre	Quantity

COUNTRY **Porcine semen**

Part II: Certification

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

I, the undersigned, official veterinarian, hereby certify that:

II.1. the exporting country .....
(name of exporting country) ([2])

([1]) *either* [II.1.1. has during the past 12 months been free of foot-and-mouth disease, classical swine fever and African swine fever,

and that no vaccinations have been carried out against any of these diseases during the past 12 months;]

([1]) *or* [II.1.1. is recognised as free of foot-and-mouth disease without vaccination by the World Organisation for Animal Health (OIE) and free of classical swine fever and African swine fever, in accordance with the recommendations laid down in the OIE Terrestrial Animal Health Code;]

II.2. the semen collection centre in which the semen in this consignment was collected:

II.2.1. is approved for export to the Union by the veterinary services of ..... (*name of third country* ([2])) and complies with the conditions for approval and supervision set out in Chapter I and Chapter II of Annex A to Directive 90/429/EEC;

II.2.2. was, during the period commencing three months prior to the date of collection of the semen in this consignment until the date of its dispatch, situated in an area not restricted due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, and vesicular stomatitis;

II.2.3. was, during the period commencing 30 days prior to the date of collection of the semen in this consignment until the date of its dispatch, free from brucellosis and Aujeszky's disease;

([1]) *either* [II.2.4. contains only animals that have not been vaccinated against Aujeszky's disease and meet the requirements of Annex B to Directive 90/429/EEC.]

([1])([3]) *and/or* [II.2.4. is a centre in which some or all of the animals have been vaccinated against Aujeszky's disease using a gE deleted vaccine and meet the requirements of Annex B to Directive 90/429/EEC.]

Conditions for the admission of animals to the semen collection centre

II.3. Prior to be admitted to the semen collection centre, all animals:

II.3.1. were subjected to a period of quarantine of at least 30 days in accommodation specifically approved for the purpose by the competent authority, and where only animals having at least the same health status were present (quarantine accommodation);

II.3.2. prior to entering the quarantine accommodation, were chosen from herds or holdings:

II.3.2.1. which were free of brucellosis in accordance with the Chapter on porcine brucellosis of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE);

II.3.2.2. in which no animal vaccinated against foot-and-mouth disease was present in the preceding 12 months;

II.3.2.3. which were not situated in a restricted area defined under the provisions of the national legislation due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;

II.3.2.4. in which no clinical, serological, virological or pathological evidence of Aujeszky's disease was detected in the preceding 12 months;

II.3.3. prior to entering the quarantine accommodation, were not previously kept in any herd of a lower health status than described in II.3.2;

II.3.4. within 30 days prior to entering the quarantine accommodation referred to in point II.3.1, were subjected to the following tests, performed in accordance with international standards, with negative results:

II.3.4.1. as regards brucellosis, a buffered *Brucella* antigen test (rose Bengal test), or a cELISA or an iELISA;

COUNTRY **Porcine semen**

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

II.3.4.2. as regards Aujeszky's disease,

([1]) *either* [II.3.4.2.1. in the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);]

([1]) *or* [II.3.4.2.1. in the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);]

([1]) *either* [II.3.5. were admitted to the centre after all of the animals had reacted with negative result to a buffered *Brucella* antigen test (rose Bengal test), or a cELISA or an iELISA carried out on samples collected during the last 15 days of the period of quarantine specified in point II.3.1;]

([1]) *or* [II.3.5. were admitted to the centre after not all of the animals had reacted with negative result to a buffered *Brucella* antigen test (rose Bengal test), or a cELISA or an iELISA carried out on samples collected during the last 15 days of the period of quarantine specified in point II.3.1 and the suspicion of brucellosis was ruled out in accordance with point 1.5 of Chapter I of Annex B to Directive 90/429/EEC;]

II.3.6. were subjected to the following tests for Aujeszky's disease carried out on samples collected during the last 15 days of the period of quarantine specified in point II.3.1:

([1]) *either* [II.3.6.1. in the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);]

([1]) *or* [II.3.6.1. in the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);]

([1]) *either* [II.3.6.2. the tests referred to in point II.3.6.1 were carried out with negative result in each case;]

([1]) *or* [II.3.6.2. the animals that proved positive in a test referred to in point II.3.6.1 were removed immediately from the quarantine accommodation and the competent authority took all necessary measures to ensure that the remaining animals had a satisfactory health status before being admitted to the collection centre in accordance with point II.3;]

II.3.7. All tests were carried out in a laboratory approved by the competent authority;

II.3.8. Animals were only admitted to the semen collection centre with the express permission of the centre veterinarian and all animal movements, entering and exiting the semen collection centre, are recorded;

II.3.9. No animal admitted to the semen collection centre showed any clinical sign of disease on the day of admission; all animals came directly from the quarantine accommodation which, on the day of consignment and during the period of residency of the animals, officially fulfilled the following conditions:

II.3.9.1. it was not situated in a restricted area defined under the provisions of national legislation due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;

II.3.9.2. no clinical, serological, virological or pathological evidence of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease had been recorded for the past 30 days.

Compulsory routine tests for animals kept at the semen collection centre

II.4. All animals kept at the semen collection centre are subjected to the following routine tests carried out in a laboratory approved by the competent authority:

II.4.1. as regards brucellosis, a buffered *Brucella* antigen test (rose Bengal test), or a cELISA or an iELISA;

II.4.2. as regards Aujeszky's disease,

([1]) *either* [II.4.2.1. in the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);]

COUNTRY **Porcine semen**

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

([1]) *or* [II.4.2.1. in the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);]

II.4.3. The routine tests referred to in points II.4.1 and II.4.2. are carried out on samples taken in accordance with point 1.2 of Chapter II of Annex B to Directive 90/429/EEC in order to ensure that all animals in the centre have been tested at least once during their stay at that centre and at least every 12 months from the date of admission, if their stay exceeds 12 months;

([1]) *either* [II.4.4. All of the animals have reacted with negative results in the routine tests referred to in points II.4.1 and II.4.2 carried out on samples referred to in point II.4.3.]

([1]) *or* [II.4.4. Not all of the animals have reacted with negative results in the tests referred to in points II.4.1 and II.4.2 carried out on samples referred to in point II.4.3:

(a) the animals which proved positive were isolated,

(b) the semen collected from each animal at the centre since the date of that animal's last negative test was held in separate storage from semen eligible for export to the European Union which was collected before the animal's last negative test or after the health status of the centre had been re-established under responsibility of the competent authority of the exporting country.]

Conditions for semen collected at a semen collection centre and intended for export to the Union

II.5. The semen in this consignment was obtained from animals which:

II.5.1. have been resident in ..... (*name of third country* ([2])) for a minimum period of three months immediately prior to collection;

II.5.2. showed no clinical signs of disease on the day the semen was collected;

II.5.3. had not been vaccinated against foot-and-mouth disease;

II.5.4. satisfy the requirements referred to in point II.3;

II.5.5. have not been allowed to serve naturally;

II.5.6. were kept in semen collection centres which were not situated in a restricted area designated under the provisions of the national legislation relating to foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;

II.5.7. were kept in semen collection centres in which no clinical, serological, virological or pathological evidence of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease has been detected in the 30-day period immediately prior to collection.

II.6. An effective combination of antibiotics, in particular against leptospires, was added to the semen in this consignment after final dilution or to the diluent. In the case of frozen semen, antibiotics were added before the semen was frozen.

II.6.1. The combination of antibiotics referred to in point II.6. produced an effect at least equivalent to the following concentration in the final diluted semen:

(a) not less than 500 µg streptomycin per ml final dilution,

(b) not less than 500 IU penicillin per ml final dilution,

(c) not less than 150 µg lincomycin per ml final dilution,

(d) not less than 300 µg spectinomycin per ml final dilution;

II.6.2. Immediately after the addition of the antibiotics the diluted semen was kept at a temperature of at least 15 °C for a period of not less than 45 minutes.

COUNTRY **Porcine semen**

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

II.7. The semen in this consignment:

II.7.1. has been stored as laid down in point 2(d) of Chapter I and point 6(a), (b), (e) and (f) of Chapter II of Annex A to Directive 90/429/EEC prior to dispatch;

II.7.2. is being transported to the country of destination in flasks which were cleaned and disinfected or sterilised before use and which have been sealed prior to dispatch from the approved storage facilities.

Notes

Part I:

Box I.6: *Person responsible for the load in EU*: this box is to be filled in only if it is a certificate for transit commodity.

Box I.8: Provide the code of the third country as appearing in Annex I to Commission Implementing Decision 2012/137/EU.

Box I.11: *Place of origin* shall correspond to the semen collection centre of the semen dispatch listed in accordance with Article 8(2) of Directive 90/429/EEC:
http://ec.europa.eu/food/animal/semen_ova/porcine/index_en.htm

Box I.12: *Place of destination*: this box is to be filled in only if it is a certificate for transit commodity.

Box I.22: *Number of packages* shall correspond to the number of containers.

Box I.23: *Identification of container* and *seal number* shall be indicated.

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

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

Box I.28: *Donor identity* shall correspond to the official identification of the animal.
Date of collection shall be indicated in the following format: dd/mm/yyyy.
Approval number of the centre shall correspond to the approval number of the semen collection centre where the semen was collected.

Part II:

(1) Delete as necessary.

(2) Countries listed in Annex I to Commission Implementing Decision 2012/137/EU.

(3) This option shall be deleted in case the Member State, or a region thereof, of destination is free of Aujeszky's disease in accordance with Article 10 of Directive 64/432/EEC, has informed the Commission in accordance with point 4 of Annex C to Directive 90/429/EEC and is listed on the following website: http://ec.europa.eu/food/animal/semen_ova/porcine/index_en.htm

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

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

PART 2

Explanatory notes for the certification

(a) The animal health certificates shall be issued by the competent authority of the exporting third country, in accordance with the model set out in Part 1 of Annex II.

If the Member State of destination requires additional certification requirements, attestations to certify that those requirements are fulfilled shall be also incorporated in the original form of the animal health certificate.

(b) The original of the animal health certificate shall consist of a single sheet of paper, or, where more text is required, it must be in such a form that all sheets of paper required are part of an integrated whole and indivisible.

(c) Where the model animal health certificate states that certain statements shall be kept as appropriate, statements which are not relevant, may be crossed out and initialled and stamped by the certifying officer, or completely deleted from certificate.

(d) The animal health certificate shall be drawn up in at least one of the official languages of the Member State of the border inspection post of introduction of the consignment into the European Union and of the Member State of destination. However, those Member States may authorise the certificate to be drawn up in the official language of another Member State, and accompanied, if necessary, by an official translation.

(e) If for the reasons of identification of the items of the consignment (schedule in Box I.28 of the model animal health certificates), additional sheets of paper are attached to the animal health certificate, those sheets of paper shall also be considered as forming part of the original of the animal health certificate by application of the signature and stamp of the certifying officer, on each of the pages.

(f) When the animal health certificate, including additional schedules referred to in (e), comprises more than one page, each page shall be numbered (page number) of (total number of pages), at the end of the page and shall bear the certificate reference number designated by the competent authority on the top of the pages.

(g) The original of the animal health certificate must be completed and signed by an official veterinarian the last working day prior to loading of the consignment for exportation to the European Union. The competent authorities of the exporting third country shall ensure that certification requirements equivalent to those laid down in Council Directive 96/93/EC [1] are followed.

The colour of the signature and the stamp of the official veterinarian shall be different to that of the printing on the animal health certificate. This requirement also applies to stamps other than those embossed or watermarks.

(h) The original of the animal health certificate must accompany the consignment until it reaches the border inspection post of introduction into the European Union.

(i) The certificate reference number referred to in Box I.2 and Box II.a of the model animal health certificate must be issued by the competent authority of the exporting third country.

[1] OJ L 13, 16.1.1997, p. 28.