COMMISSION

COMMISSION DECISION

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

(notified under document C(2009) 9354)

(Text with EEA relevance)

(2009/893/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 8(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-Community 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. Directive 90/429/EEC also provides that, under the same procedure, a list is to be drawn up of approved semen collection centres from which Member States may authorise the importation of semen originating in those third countries.

(2) In addition, Directive 90/429/EEC provides that consignments of semen are to be accompanied by an animal health certificate, the model of which must correspond to a specimen drawn up in accordance with that Directive.

(3) Commission Decision 2002/613/EC of 19 July 2002 laying down the importation conditions of semen of domestic animals of the porcine species [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.

(4) Decision 2002/613/EC also sets out a list of semen collection centres from which Member States are to authorise the importation of semen.

(5) A number of semen collection centres in Canada and the United States are currently included in that list. Those third countries have requested that numerous amendments be made to the entries for their semen collection centres included in the list. Some of those amendments concern administrative details or deletion of already approved centres, while some concern the addition of new centres.

[1] OJ L 224, 18.8.1990, p. 62.

[2] OJ L 196, 25.7.2002, p. 45.

(6) Canada and the United States have provided appropriate guarantees regarding the compliance of the new semen collection centres with the appropriate conditions laid down in Directive 90/429/EEC and the semen collection centres concerned have been officially approved for exports to the Community by the veterinary services of those third countries. The list of approved semen collection centres set out in Decision 2002/613/EC should therefore be amended accordingly.

(7) The model veterinary certificate in Annex III to Decision 2002/613/EC includes the animal health conditions for the importation of semen into the Community. Those conditions are not entirely consistent with those set out in the Terrestrial Animal Health Code of the World Organisation for Animal Health, (Terrestrial Animal Health Code) and hence they need to be updated.

(8) In addition, Commission Decision 2007/240/EC [1] provides that the various veterinary, public and animal health certificates required for the import of live animals, semen, embryo, ova and products of animal origin into the Community are to be based on the standard models for veterinary certificates set out in Annex I thereto.

(9) Accordingly, the model health certificate set out in Annex III to Decision 2002/613/EC should be amended to take account of the relevant parts of the Terrestrial Animal Health Code and of the relevant standard model set out in Annex I to Decision 2007/240/EC.

(10) Annex IV to Decision 2002/613/EC sets out a model veterinary certificate which is to be used when consignments of semen are imported into the Community from Switzerland. However, specific certification requirements are provided for in point 3(b) 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 [2]. That Agreement was 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 [3].

(11) In view of those specific requirements, it is appropriate that consignments of semen from Switzerland imported into the Community be accompanied by a health certificate drawn up in accordance with the model used for intra-Community trade in semen and 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. Annex IV to Decision 2002/613/EC should therefore be deleted.

(12) In the application of this Decision, account should be taken of the specific certification requirements and model health attestations which may be laid down in accordance with the Agreement between the European Community and the Government of Canada on sanitary measures to protect public and animal health in respect of trade in live animals and animal products [4], as approved by Council Decision 1999/201/EC [5].

(13) In the application of this Decision, account should also be taken of the specific certification requirements and model health attestations which may be laid down in accordance with the Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products [6], as approved by Council Decision 97/132/EC [7].

(14) In the interest of clarity and consistency of Community legislation, Decision 2002/613/EC should be repealed and replaced by this Decision.

(15) To avoid any disruption of trade, the use of health certificates issued in accordance with Decision 2002/613/EC should be authorised during a transitional period.

(16) Council Directive 2008/73/EC [8] amended Directive 90/429/EEC and introduced a simplified procedure of listing and publishing the list of semen collection centres in third countries approved for imports of semen into the Community.

(17) Under that new procedure, which is to apply from 1 January 2010, the competence to establish the list will no longer lie with the Commission. The list of semen collection centres that the competent authority of the third country has approved in accordance with the conditions laid down in Directive 90/429/EEC and from which semen may be dispatched to the Community will only have to be communicated to the Commission, which is to make it available to the public for information purposes.

[1] OJ L 104, 21.4.2007, p. 37.
[2] OJ L 114, 30.4.2002, p. 132.
[3] OJ L 114, 30.4.2002, p. 1.
[4] OJ L 71, 18.3.1999, p. 3.
[5] OJ L 71, 18.3.1999, p. 1.
[6] OJ L 57, 26.2.1997, p. 5.
[7] OJ L 57, 26.2.1997, p. 4.
[8] OJ L 219, 14.8.2008, p. 40.

(18) As a consequence of the new procedure introduced by Directive 2008/73/EC, the provision concerning the list of approved semen collection centres set out in this Decision should expire on 31 December 2009.

(19) 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

Importation of semen

Consignments of semen shall only be imported into the Community from third countries if they comply with the following conditions:

(a) they come from the third countries listed in Annex I;

(b) they are accompanied by a health certificate drawn up in accordance with the model health certificate set out in Part 1 of Annex II, completed in accordance with the explanatory notes set out in Part 2 of Annex II; however, where specific certification requirements are laid down in bilateral agreements between the Community and third countries, those requirements shall apply;

(c) they comply with the requirements set out in the health certificate referred to in point (b);

(d) they come from a semen collection centre listed in Annex III.

Article 2

General conditions concerning the transport of consignments of semen to the Community

1. Consignments of semen shall not be transported in the same container as other consignments of semen that:

(a) are not intended for introduction into the Community, or

(b) are of a lower health status.

2. During transport to the Community, consignments of semen shall be placed in closed and sealed containers and the seal must not be broken during the transport.

Article 3

Repeal

Decision 2002/613/EC is repealed.

Article 4

Transitional provisions

By way of derogation from Article 1(b), consignments of semen for which health certificates were issued before 31 May 2010 in accordance with the models set out in Annexes III and IV to Decision 2002/613/EC shall be accepted for imports into the Community until 30 June 2010.

Article 5

Applicability

This Decision shall apply from 15 December 2009.

However, Article 1(d) shall only apply from 15 December 2009 to 31 December 2009.

Article 6

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 30 November 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX I

List of third countries from which Member States are to authorise importation 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	

(*) Certificates in accordance with the Agreement between the European Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).

ANNEX II

PART 1

Model health certificate for importation 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. N°		I.2. Certificate reference number	I.2.a
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. N°		I.6. Person responsible for the load in EU Name Address Postal code Tel. N°	
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 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. Identification of container/Seal number		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)	Identification mark	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, African swine fever, swine vesicular disease and porcine enteroviral encephalomyelitis (Teschen disease),

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, African swine fever, swine vesicular disease and porcine enteroviral encephalomyelitis (Teschen disease) in accordance with the rules 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 Community by the veterinary services of .....
(*name of third country* ([2])) and fulfils the requirements of Annex A to Council Directive 90/429/EEC (conditions relating to the approval and supervision of semen collection centres);

II.2.2. was situated in a area not restricted during the period commencing 3 months prior to the date of collection until the date of dispatch due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, porcine enteroviral encephalomyelitis (Teschen disease) and vesicular stomatitis;

II.2.3. was, during the period commencing 30 days prior to the date of collection of the semen to be exported until its date of dispatch, free from tuberculosis, brucellosis, Aujeszky's disease, rabies;

([1]) *either* [II.2.4. contains only animals that have not been vaccinated against Aujeszky's disease and which have reacted negatively to the serum neutralisation or to the ELISA using all the Aujeszky's disease viral antigens;]

([1]) *or* [II.2.4. is a centre in which some or all boars have been vaccinated against Aujeszky's disease using a gE deleted vaccine; such boars had been seronegative with regard to Aujeszky's disease before vaccination and were subjected not sooner than 3 weeks later to a further serological examination which did not reveal the presence of antibodies induced by the disease virus;]

Conditions applying to the admission of animals to approved semen collection centres

II.3. when they were 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;

II.3.2. prior to their entering the quarantine accommodation referred to in point II.3.1, were chosen from herds or holdings:

II.3.2.1. which were free of brucellosis in accordance with the OIE Terrestrial Animal Health Code;

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

II.3.2.4. 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, porcine enteroviral encephalomyelitis (Teschen disease), vesicular stomatitis and Aujeszky's disease;

II.3.3. prior to their entering the quarantine accommodation referred to in point II.3.1, were not previously kept in any herd of a lower health status;

II.4.1. before the period of quarantine referred to in point II.3.1 and within the previous 30 days, were subjected to the following tests, performed in accordance with international standards, with negative results:

II.4.1.1. a buffered brucella antigen test in respect of brucellosis;

(1) either [II.4.1.2. a serum neutralisation or an ELISA using all the Aujeszky's disease viral antigens in the case of non-vaccinated pigs;]

(1) or [II.4.1.2. an ELISA for Aujeszky's disease gE antigens in the case of pigs vaccinated with a gE deleted vaccine;]

II.4.2. during the last 15 days of the period of quarantine of at least 30 days referred to in point II.3.1, were subjected to the following tests with negative results;

II.4.2.1. in respect of brucellosis, a buffered brucella antigen test;

(1) either [II.4.2.2. a serum neutralisation or an ELISA using all the Aujeszky's disease viral antigens in the case of non-vaccinated pigs;]

(1) or [II.4.2.2. an ELISA for Aujeszky's disease gE antigens in the case of pigs vaccinated with a gE deleted vaccine;]

II.5. Without prejudice to the provisions applicable in cases where foot-and-mouth disease or other former OIE list A diseases are diagnosed, if any of the tests referred to in point II.4.2 proved positive, the animal was removed forthwith from the quarantine accommodation. In the case of group quarantine, 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.5.1. However, with regard to brucellosis when animals were positive, the following protocol was implemented:

II.5.1.1. the positive sera were subjected to a sero-agglutination test as well as the test referred to in point II.4.2.1 which has not been carried out;

II.5.1.2. an epidemiological survey was carried out on the holdings of origin of the reacting animals;

II.5.1.3. on the positive animals, a second series of tests (buffered brucella antigen test, sero-agglutination, complement fixation test) was carried out on samples collected more than 7 days after the first collection.

II.5.2. The suspicion of brucellosis is confirmed or ruled out in the light of the results of the survey carried out on the holdings of origin and the comparison of the results of the two series of tests.

II.5.3. When the suspicion of brucellosis is ruled out, the animals negative to the first brucellosis test can be introduced into the centre. Animals positive to one test may be accepted if they answer negatively to two series of tests (buffered brucella antigen test, sero-agglutination, complement fixation test) carried out with an interval of at least 7 days;

II.5.4. All tests were carried out in a laboratory approved by the competent authority;

II.5.5. Animals were only admitted to the semen collection centre with the express permission of the centre veterinarian and all animal movements, both in and out, are recorded;

II.5.6. No animal admitted to the semen collection centre showed any clinical sign of disease on the day of admission; all animals came directly from quarantine accommodation as referred to in point II.3.1. which, on the day of consignment and during the period of residency of the animals, officially fulfilled the following conditions:

II.5.6.1. 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, porcine enteroviral encephalomyelitis (Teschen disease), vesicular stomatitis and Aujeszky's disease;

II.5.6.2. no clinical, pathological or serological evidence of Aujeszky's disease had been recorded for the past 30 days;

Compulsory routine tests for animals kept at an approved semen collection centre

II.6. All animals kept at an approved semen collection centre were subjected to the following tests with negative results:

II.6.1. a serum neutralisation or an ELISA using all the Aujeszky's disease viral antigens in the case of non-vaccinated pigs, or an ELISA for Aujeszky's disease gE antigens in the case of pigs vaccinated with a gE deleted vaccine;

II.6.2. in respect of brucellosis, a buffered brucella antigen test;

II.6.3. The tests referred to in points II.6.1 and II.6.2 were carried out:

([1]) either [II.6.3.1. on all animals when leaving the centre, but not later than 12 months after admission where they have not left the centre before this time. The sampling may be carried out in the abattoir;]

([1]) or [II.6.3.1. on 25 % of the animals in the centre, every 3 months,

and *samples were representative of the whole population, with respect to age group and accommodation, ensuring that all animals are tested at least once during their stay at the centre and at least every 12 months if the stay exceeds 1 year;]*

II.6.4. All tests were carried out in a laboratory approved by the competent authority;

II.6.5. If any of the tests referred to in points II.6.1 – II.6.3 proved positive, the animal was isolated and the semen collected from it since the last negative test was not allowed to be the subject of imports,

and semen collected from each animal at the centre since the date of that animal's last negative test was held in separate storage and not allowed to be the subject of imports until the health status of the centre has been re-established.

Conditions which semen collected at approved centres must satisfy

II.7. Semen was obtained from animals which:

II.7.1. have been resident in ..... (*name of third country* ([2])) for a minimum period of 3 months immediately prior to collection;

II.7.2. showed no clinical signs of disease on the day the semen was collected;

II.7.3. had not been vaccinated against foot-and-mouth disease;

II.7.4. satisfy the requirements referred to in point II.3;

II.7.5. have not been allowed to serve naturally;

II.7.6. 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, porcine enteroviral encephalomyelitis (Teschen disease), vesicular stomatitis and Aujeszky's disease;

II.7.7. were kept in semen collection centres which, during the 30-day period immediately prior to collection, were free from Aujeszky's disease;

II.8. An effective combination of antibiotics, in particular against leptospires and mycoplasmas, was added to the semen after final dilution or to the diluent. In the case of frozen semen, antibiotics were added before the semen was frozen;

II.8.1. The combination produced an effect at least equivalent to the following dilutions: not less than:

— 500 µg streptomycin per ml final dilution,

— 500 IU penicillin per ml final dilution,

— 150 µg lincomycin per ml final dilution,

— 300 µg spectinomycin per ml final dilution;

II.8.2. 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;

II.9. the semen in this consignment:

II.9.1. has been stored as laid down in Annex A to Council Directive 90/429/EEC (conditions relating to the approval and supervision of semen collection centres) prior to dispatch;

II.9.2. 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 reference I.8: Provide the code of the third country as appearing in Annex I to Decision 2009/893/EC.

— Box reference I.11: Place of origin shall correspond until 31 December 2009 to the semen collection centre of the semen origin listed in the Annex III to Decision 2009/893/EC and as of 1 January 2010 to the semen collection centre of the semen origin listed in accordance with Article 8(2) of Directive 90/429/EEC: (http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html).

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

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

— Box reference I.28: *Identification mark* shall correspond to the identification of the donor animals and the date of collection.

Approval number of centre: shall correspond until 31 December 2009 to the semen collection centre of the semen origin listed in the Annex III to Decision 2009/893/EC and as of 1 January 2010 to the semen collection centre of the semen origin listed in accordance with Article 8(2) of Directive 90/429/EEC: (http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html).

Part II

(1) Delete as necessary.

(2) Countries listed in Annex I to Decision 2009/893/EC.

— 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 health certificates shall be issued by the competent authority of the exporting third country, in accordance with the model set out in Annex II.

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

(b) The original of the 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 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 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 Community 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 point I.28 of the model health certificate), additional sheets of paper are attached to the health certificate, those sheets of paper shall also be considered as forming part of the original of the health certificate by application of the signature and stamp of the certifying officer, on each of the pages.

(f) When the 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 that has been designated by the competent authority on the top of the pages.

(g) The original of the 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 Community. 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 health certificate. This requirement also applies to stamps other than those embossed or watermarks.

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

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

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

ANNEX III

List of approved semen collection centres from which Member States are to authorise importation of semen of domestic animals of the porcine species

ISO Code	Approval number	Name and address of the centre
CANADA		
CA	7-AI-100	Aurora GTC Box 177 Kipling, Saskatchewan Location SW 15-10-6 W2
CA	8-AI-05	Alberta Swine Genetics Corp. Box 3310 Leduc Alberta T9E 6M3
CA	7-AI-96	Hypor Box 323 Ituna Saskatchewan S0A 1V0
CA	7-AI-105	Topigs Canada Inc 201-1465 Buffalo Place Manitoba R3T 1L8
SWITZERLAND		
CH	CH-LU-AI-01S	Suisag, 6213 Knuttwil, Schaubern A: 041 462 65 50 B: 041 462 65 49 info@suisag.ch
CH	CH-TG-AI-01S	Suisag, 9545 Wängi, Eggetsbühl A: 041 462 65 50 B: 041 462 65 49 kca@suisag.ch
UNITED STATES		
US	09IL002	INET * AI, INC. 2429 N. 1950th Avenue Camp Point, IL 62320