Council Directive 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 (90/429/EEC)

[F1 ANNEX A

Textual Amendments

F1 Substituted by Commission Decision of 10 September 1999 amending Annexes of Council Directive 90/429/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (notified under document number C(1999) 2836) (Text with EEA relevance) (1999/608/EC).

CHAPTER I

Conditions for the approval of semen collection centres

Semen collection centres must:

1. be placed under the permanent supervision of a centre veterinarian;

2. have at least:

   (a) animal housing including facilities for the isolation of animals which have failed tests described in Annex B, Chapter II, or which show clinical signs of disease,

   (b) semen collection facilities including a separate room for the cleaning and disinfection or sterilisation of equipment,

   (c) a semen processing room which need not necessary be on the same site,

   (d) a semen storage room which need not necessarily be on the same site;

3. be so constructed or isolated that contact with livestock outside is prevented;

4. be so constructed that the animal housing and semen collection, processing and storage facilities can be readily cleaned and disinfected;

5. be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.

CHAPTER II

Conditions relating to the supervision of semen collection centres

The collection centres must:

1. be so supervised that they contain only animals of the species whose semen is to be collected;

2. be so supervised that a record, file or computer record is kept of all porcine animals at the centre, giving details of the breed, date of birth and identification of each of the animals, and also a record, file or computer record of all checks for diseases and all vaccinations carried out, giving also information from the disease/health file of each animal;

3. be regularly inspected by an official veterinarian, at least twice a year, at which time checks on the conditions of approval and supervision shall be carried out;

4. be so supervised that the entry of unauthorised persons is prevented. Furthermore, authorised visitors must be required to comply with the conditions laid down by the centre veterinarian;

5. employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;

6. be so supervised that:

   (a) only semen collected at an approved centre is processed and stored in approved centres, without coming into contact with any other consignment of semen;

   (b) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under conditions of the strictest hygiene;

   (c) all implements which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilised prior to use;

   (d) products of animal origin used in the processing of semen — including additives or a diluent — are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;

   (e) storage flasks and transport flasks are properly disinfected or sterilised before the beginning of each filling operation;

   (f) the cryogenic agent used has not been previously used for other products of animal origin;

   (g) each collection of semen, whether or not it is separated into individual doses, is clearly marked in such a way that the date of collection of the semen and the breed and identification of the donor animal, as well as the name and the registration number of the centre, preceded by the name of the country of origin, where appropriate, in the form of a code, can be readily established; the characteristics and form of this marking will be established under the procedure laid down in Article 19.**]**

[F2ANNEX B

Textual Amendments

F2 Substituted by Commission Implementing Regulation (EU) No 176/2012 of 1 March 2012 amending Annexes B, C and D to Council Directive 90/429/EEC as regards animal health requirements for brucellosis and Aujeszky's disease (Text with EEA relevance).

CHAPTER I

Conditions for the admission of domestic animals of the porcine species to a semen collection centre

1. All domestic animals of the porcine species ('animals') admitted to the semen collection centre must, prior to admission:

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

1.2. prior to entering the quarantine accommodation referred to in point 1.1:

1.2.1. have been chosen from herds or holdings:

(a) which are 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);

(b) in which no animal vaccinated against foot-and-mouth disease has been present in the preceding 12 months;

(c) in which no clinical, serological, virological or pathological evidence of Aujeszky's disease has been detected in the preceding 12 months;

(d) which are not situated in a restricted area defined under the provisions of Union legislation due to the emergence of an infectious or contagious disease in domestic pigs, including foot-and-mouth disease, swine vesicular disease, vesicular stomatitis, classical swine fever and African swine fever;

1.2.2. not have been kept previously in any herd of a lower status than described in point 1.2.1;

1.3. within 30 days prior to entering the quarantine accommodation referred to in point 1.1 have been subjected to the following tests, performed in accordance with standards laid down or referred to in relevant Union legislation, with negative results:

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

(b) as regards Aujeszky's disease:

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

(ii) in the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to Aujeszky's disease virus glycoprotein E (ADV-gE);

(c) as regards classical swine fever, an antibody ELISA or a serum neutralisation test.

If any of the animals proves positive in the tests for brucellosis referred to in (a), animals with negative results in the same holding must not be admitted in the quarantine accommodation until the brucellosis-free status of the herds or holdings of origin of the positive reactors was confirmed.

The competent authority may give authorisation for the tests referred to in this point to be carried out in the quarantine accommodation, provided that the results are known before the beginning of the period of quarantine set out in point 1.1.

With regard to Aujeszky's disease, the serological tests carried out in accordance with this Directive must meet the standards set out in Annex III to Commission Decision 2008/185/EC of 21 February 2008 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease and criteria to provide information on this disease[(1)];

1.4. have been subjected to the following tests carried out on samples collected during the last 15 days of the period of quarantine set out in point 1.1:

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

(b) as regards Aujeszky's disease:

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

(ii) in the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to Aujeszky's disease virus glycoprotein E (ADV-gE).

If any of the animals proves positive in the tests for brucellosis referred to in (a) and the suspicion of brucellosis has not been ruled out in accordance with point 1.5.2, those animals must be removed immediately from the quarantine accommodation.

If any of the animals proves positive in the tests for Aujeszky's disease referred to in (b), those animals must be removed immediately from the quarantine accommodation.

In case where a group of animals is quarantined, the competent authority must take all necessary measures to ensure that the remaining animals which responded negatively to the tests referred to in (a) and (b) have a satisfactory health status before being admitted to the semen collection centre in accordance with this Annex;

1.5. measures taken in case of a suspicion of brucellosis:

1.5.1. the following protocol must be implemented with regard to animals which tested positive to brucellosis in the test referred to in point 1.4(a):

(a) the positive sera are subjected to at least one of the alternative tests set out in point 1.4(a) which has not been carried out on the samples referred to in point 1.4;

(b) an epidemiological enquiry is carried out on the holding(s) of origin of the reacting animals;

(c) on the animals which have tested positive in the tests referred to in point 1.4(a) and point 1.5.1(a), at least one of the following tests is carried out on samples collected at least 7 days following the date of the collection of the samples referred to in point 1.4:

(i) buffered *Brucella* antigen test (rose Bengal test);

(ii) serum agglutination test;

(iii) complement fixation test;

(iv) cELISA;

(v) iELISA;

1.5.2. the suspicion of brucellosis will be ruled out provided:

(a) either the repeat testing referred to in point 1.5.1(a) produced a negative result, the epidemiological enquiry on the holding(s) of origin did not reveal the presence of porcine brucellosis and the test referred to in point 1.5.1(c) was carried out with negative result; or

(b) the epidemiological enquiry on the holding(s) of origin did not reveal the presence of porcine brucellosis and all of the animals which produced a positive result in the testing referred to in point 1.5.1(a) or (c) have been subjected with negative results in each case to a *post-mortem* examination and an agent identification test for porcine brucellosis;

1.5.3. after the suspicion of brucellosis is ruled out, all of the animals from the quarantine accommodation referred to in the second paragraph of point 1.4 may be admitted into the semen collection centre.

2. All tests must be carried out in an approved laboratory.

3. Animals may only be admitted to the semen collection centre with the express permission of the centre veterinarian. All animal movements, entering and exiting the semen collection centre, must be recorded.

4. No animal admitted to the semen collection centre may show any clinical sign of disease on the date of admission.

5. All animals must, without prejudice to point 6, have come directly from the quarantine accommodation which, on the date of consignment, fulfils the following conditions:

(a) it is not situated in a restricted area defined under the provisions of Union legislation due to the emergence of an infectious or contagious diseases in domestic pigs, including foot-and-mouth disease, swine vesicular disease, vesicular stomatitis, classical swine fever and African swine fever;

(b) no clinical, serological, virological or pathological evidence of Aujeszky's disease has been recorded for the past 30 days prior to the date of consignment.

6. Animals may be transferred directly from one semen collection centre to another of equal health status without quarantine or testing, provided that the conditions set out in point 5 are satisfied and the compulsory routine tests referred to in Chapter II have been carried out during the 12 months prior to the date of transfer.

Such animals must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used must have been cleansed and disinfected before use.

7. For the purpose of point 6 and in case of trade between Member States, animals must be accompanied by an animal health certificate for animals of the porcine species for breeding in conformity with the Model 2 in Annex F to Directive 64/432/EEC, with one of the following additional guarantees, corresponding to their status, being certified by adding the following to Section C of that certificate:

7. The animals come directly from

[1]*either* [a semen collection centre complying with Directive 90/429/EEC.]

[1]*or* [a quarantine accommodation and comply with the conditions for the admission to semen collection centres provided for in Chapter I of Annex B to Directive 90/429/EEC.]

[1]*or* [a holding where they had undergone the pre-quarantine admission protocol and comply with the conditions for admission to the quarantine provided for in points 1.2 and 1.3 and point 2 of Chapter I of Annex B to Directive 90/429/EEC.]

CHAPTER II

Compulsory routine tests for animals kept at a semen collection centre

1. Compulsory routine testing must be carried out as follows:

1.1. all animals kept at a semen collection centre must be subjected to the following tests with negative results:

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

(b) as regards Aujeszky's disease:

(i) in the case of non-vaccinated animals, an ELISA detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) or a serum neutralisation test;

(ii) in the case of animals vaccinated with a gE deleted vaccine, an ELISA detecting antibodies to Aujeszky's disease virus glycoprotein E (ADV-gE);

(c) as regards classical swine fever, an antibody ELISA or a serum neutralisation test;

1.2. the tests set out in point 1.1 must be carried out on samples taken:

(a) from all animals immediately prior to leaving the semen collection centre, or upon arrival at the slaughterhouse, and in no case later than l2 months after the date of admission to the semen collection centre; or

(b) from at least 25 % of the animals in the semen collection centre every 3 months and the centre veterinarian must ensure that the sampled animals are

representative of the total population of that centre, in particular with respect to age groups and housing;

1.3. where the testing is carried out in accordance with 1.2(b), the centre veterinarian must ensure that all animals are tested in accordance with point 1.1 at least once during their stay at the semen collection centre and at least every 12 months from the date of admission, if their stay exceeds 12 months.

2. All tests must be carried out in an approved laboratory.

3. If any of the tests set out in point 1.1 proves positive, the animals must be isolated and the semen collected from them since the last negative test may not be the subject of intra-Union trade.

Semen collected from each animal at the semen collection centre since the date of that animal's last negative test must be held in separate storage and may not be the subject of intra-Union trade until the health status of that centre has been re-established under responsibility of the competent authority of the Member State.

ANNEX C

Conditions for semen collected at a semen collection centre and intended for intra-Union trade

1. Semen must be obtained from animals which:

(a) show no clinical signs of disease on the date the semen is collected;

(b) have not been vaccinated against foot-and-mouth disease;

(c) satisfy the requirements of Chapter I of Annex B;

(d) are not allowed to serve naturally;

(e) are kept in semen collection centres which must not be situated in a restricted area defined under the provisions of Union legislation due to the emergence of an infectious or contagious disease in domestic pigs, including foot-and-mouth disease, swine vesicular disease, vesicular stomatitis, classical swine fever and African swine fever;

(f) are kept in semen collection centres in which no clinical, serological, virological or pathological evidence of Aujeszky's disease has been detected in the 30-day period immediately prior to the date of collection.

2. An effective combination of antibiotics, in particular against leptospires, must be added to the semen after final dilution or to the diluent.

In the case of frozen semen, antibiotics must be added before the semen is frozen.

2.1. The combination of antibiotics referred to in point 2 must produce 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.

2.2. Immediately after the addition of the antibiotics, the diluted semen must be kept at a temperature of at least 15 °C for a period of not less than 45 minutes.

3. Semen intended for intra-Union trade must:

(a) be 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 prior to dispatch;

(b) be transported to the Member State of destination in flasks which have been cleaned and disinfected or sterilised before use and which have been sealed prior to dispatch from the semen collection centre.

4. Member States may refuse admission of semen from semen collection centres where animals vaccinated against Aujeszky's disease are admitted, to their territory or to a region of their territory, when it has been recognised as free of Aujeszky's disease in accordance with Article 10 of Directive 64/432/EEC.

Member States intending to avail of the provisions in the first paragraph shall inform the Commission and the other Member States prior to their application.

ANNEX D

Model animal health certificate for intra-Union trade in semen of domestic animals of the porcine species]

EUROPEAN UNION **Porcine semen**

Part II: Certification

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

I, the undersigned official veterinarian, hereby certify that the semen described above was:

II.1. collected, processed and stored in a semen collection centre (2) approved and supervised by the competent authority in accordance with Chapters I and II of Annex A to Directive 90/429/EEC;

(1) *either* [II.2. collected in a semen collection centre which only contains 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. collected in a semen collection 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;]

II.3. collected, processed, stored and transported under conditions which comply with the standards laid down in Annex C to Directive 90/429/EEC.

Notes

Part I:

Box I.12: *Place of origin* shall correspond to the semen collection centre [as defined in Article 2 of Directive 90/429/EEC] of the semen dispatch.

Box I.13: *Place of destination* shall correspond to the semen collection centre [as defined in Article 2 of Directive 90/429/EEC], or to the holding of semen destination.

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

Box I.31: *Donor identity* shall include the official identification mark of the animal in accordance with Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (OJ L 213, 8.8.2008, p. 31).
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 centre where the semen was collected.

Part II:

(1) Delete as necessary.

(2) Only approved semen collection centres listed in accordance with Article 5(2) of Council Directive 90/429/EEC on the Commission website: http://ec.europa.eu/food/animal/approved_establishments/establishments_vet_field_en.htm

(3) This option must 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 colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian

Name (in capital letters): Qualification and title:

Local veterinary unit: LVU No:

Date: Signature:

Stamp:'

EUROPEAN UNION **Porcine semen**

Part II: Certification

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

I, the undersigned official veterinarian, hereby certify that the semen described above was:

II.1. collected, processed and stored in a semen collection centre (2) approved and supervised by the competent authority in accordance with Chapters I and II of Annex A to Directive 90/429/EEC;

(1) *either* [II.2. collected in a semen collection centre which only contains 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. collected in a semen collection 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;]

II.3. collected, processed, stored and transported under conditions which comply with the standards laid down in Annex C to Directive 90/429/EEC.

Notes

Part I:

Box I.12: *Place of origin* shall correspond to the semen collection centre [as defined in Article 2 of Directive 90/429/EEC] of the semen dispatch.

Box I.13: *Place of destination* shall correspond to the semen collection centre [as defined in Article 2 of Directive 90/429/EEC], or to the holding of semen destination.

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

Box I.31: *Donor identity* shall include the official identification mark of the animal in accordance with Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (OJ L 213, 8.8.2008, p. 31).
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 centre where the semen was collected.

Part II:

(1) Delete as necessary.

(2) Only approved semen collection centres listed in accordance with Article 5(2) of Council Directive 90/429/EEC on the Commission website: http://ec.europa.eu/food/animal/approved_establishments/establishments_vet_field_en.htm

(3) This option must 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 colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian

Name (in capital letters): Qualification and title:

Local veterinary unit: LVU No:

Date: Signature:

Stamp:'

(1) **[**[F2]OJ L 59, 4.3.2008, p. 19.**]**

Textual Amendments

F2 Substituted by Commission Implementing Regulation (EU) No 176/2012 of 1 March 2012 amending Annexes B, C and D to Council Directive 90/429/EEC as regards animal health requirements for brucellosis and Aujeszky's disease (Text with EEA relevance).