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)

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)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the European Parliament[(2)],

Having regard to the opinion of the Economic and Social Committee[(3)],

Whereas provisions relating to animal health problems in intra-Community trade in bovine animals and swine appear in Directive 64/432/EEC[(4)], as last amended by Directive 89/360/EEC[(5)]; whereas in addition, Directive 72/462/EEC[(6)], as last amended by Directive 89/227/EEC[(7)] contains provisions relating to veterinary inspection problems encountered upon importation of bovine animals and swine from third countries;

Whereas the abovementioned provisions have ensured, with regard to intra-Community trade and imports into the Community of bovine animals and swine from third countries, that the country of provenance guarantees that animal health criteria have been fulfilled so that the risk of animal disease spreading has been virtually eliminated; whereas there is nevertheless a certain risk of the spread of such disease in the case of trade in semen;

Whereas in the context of the Community policy of harmonizing national animal health provisions governing intra-Community trade in animals and animal products, it is now necessary to create a harmonized system for intra-Community trade and imports into the Community of semen of porcine animals;

Whereas, in the context of intra-Community trade in semen, the Member State where the semen is collected should be under an obligation to ensure that such semen has been collected and processed at approved and supervised collection centres, has been obtained from animals whose health status is such as to ensure that the risk of spread of animal disease is eliminated, has been collected, processed, stored and transported in accordance with rules which preserve its health status and is accompanied during transport to the country of destination by an animal health certificate in order to ensure that this obligation has been fulfilled;

Whereas the difference in the policies pursued within the Community with regard to vaccination against certain diseases justifies the maintenance of derogations, limited in time, authorizing the requirement by the Member States, in respect of certain diseases, of additional protection against those diseases;

Whereas for imports of semen into the Community from third countries a list of third countries should be drawn up taking into account animal health criteria; whereas independently of such a list the Member States should authorize importation of semen only from semen collection centres which reach certain standards and which are officially supervised; whereas, in addition, in respect of countries on that list, specific animal health conditions should be laid down according to circumstances; whereas, in order to verify compliance with these standards, it must be possible to carry out on-the-spot checks;

Whereas the rules and procedures for checks laid down in Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market[8] should be extended to cover this Directive;

Whereas in order to prevent the transmission of certain contagious diseases, import controls should be carried out when a consignment of semen arrives on the territory of the Community, except in the case of external transit;

Whereas a Member State should be permitted to take emergency measures in the event of an outbreak of a contagious disease in another Member State or in a third country; whereas the dangers associated with such diseases and the protective measures they necessitate should be assessed in the same way throughout the Community; whereas to that end, an emergency Community procedure under which the necessary measures must be taken should be instituted within the Standing Veterinary Committee;

Whereas the Commission should be entrusted with taking certain measures for implementing this Directive; whereas to that end, a procedure should be established for close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas this Directive does not affect trade in semen produced before the date on which the Member States must comply with it,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive 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.

Article 2

For the purposes of this Directive, the definitions contained in Article 2 of Directives 64/432/EEC, 72/462/EEC, 80/407/EEC[(9)] and 90/425/EEC[(10)] shall apply as necessary.

Moreover, 'semen' means the ejaculate of a domestic animal of the porcine species, in the unaltered state or prepared or diluted.

CHAPTER II

Intra-Community trade

Article 3

Each Member State shall ensure that only semen, meeting the following general conditions, is intended for trade:

(a) it must have been collected and processed, for the purpose of artifical insemination, in a collection centre approved from the point of view of animal health for the purposes of intra-Community trade in accordance with Article 5 (1);

(b) it must have been collected from domestic animals of the porcine species whose health status complies with Annex B;

(c) it must have been collected, processed, stored and transported in accordance with Annexes A and C.

Article 4

1 Until 31 December 1992, Member States in which all collection centres contain only animals which have not been vaccinated against Aujeszky's disease giving a negative reaction to the serum neutralization test, or to the ELISA test for Aujeszky's disease, in accordance with the provisions of this Directive:

— may refuse admission to their territory of semen from collection centres which do not have that status,

— may not prohibit the admission of semen from boars which have been vaccinated in the collection centre with the GI deleted vaccine, provided that:

  — such vaccination has only been carried out on boars that were serum-negative with regard to the virus of Anjeszky's disease,

  — serological examinations carried out at the earliest three weeks after vaccination of such boars do not reveal the presence of antibodies induced by the disease virus.

  In this event a sample of semen from each daily collection intended for trade may be subjected to a virus isolation test in an approved laboratory in the Member State of destination.

  The provisions of this paragraph shall not come into effect until such time as the Commission, acting in accordance with Article 18, not later than 1 July 1991, has laid down the protocols for the tests to be used for these examinations following the opinion of the Scientific Veterinary Committee, in particular in connection with the frequency of the tests to be carried out in the centre, the virus isolation tests and the effectiveness and safety of the GI deleted vaccine.

2 In accordance with the procedure referred to in Article 18, it may be decided to extend the provisions of paragraph 1 to part of the territory of a Member State if all the collection centres in that part of the territory contain only animals giving a negative reaction to the serum neutralization test or the ELISA test for Aujeszky's disease.

3 The Council shall, before 31 December 1992, review this Article on the basis of a report from the Commission, accompanied by any proposals.

Article 5

1 The Member State on whose territory the semen collection centre is situated shall ensure that the approval provided for in Article 3 (a) is granted only if it meets the conditions of Annex A and satisfies the other provisions of this Directive.

The Member State shall also ensure that the official veterinarian supervises the observance of those provisions. The official veterinarian shall propose that approval be withdrawn when one or more of the provisions is no longer observed.

[F1 2 All semen collection centres shall be registered, each centre being given a veterinary registration number.

Each Member State shall draw up and keep up to date a list of semen collection centres and their veterinary registration numbers and make it available to the other Member States and to the public.**]**

3 The general rules for applying this Article shall be adopted in accordance with the procedure laid down in Article 18.

Textual Amendments

F1 Substituted by Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC (Text with EEA relevance).

Article 6

1 Member States shall ensure that each consignment of semen is accompanied by an animal health certificate drawn up in accordance with the specimen in Annex D by an official veterinarian of the Member State of collection.

This certificate must:

a be drawn up in at least one of the official languages of the Member State of collection and one of those of the Member State of destination;

b accompany the consignment to its destination in its original form;

c be drawn up on a single sheet of paper;

d be made out to a single consignee.

2 The Member State of destination may, in addition to measures provided for in Article 8 of Directive 90/425/EEC, take the necessary measures, including storage in quarantine, provided this does not affect the viability of the semen, in order to obtain definite proof in cases where semen is suspected of being infected or contamined by pathogenic organisms.

CHAPTER III

Imports from third countries

Article 7

1 A Member State may authorize importation of semen only from those third countries which appear on a list drawn up in accordance with the procedure laid down in Article 19. That list may be supplemented or amended in accordance with the procedure laid down in Article 18.

2 In deciding whether a third country may appear on the list referred to in paragraph 1, particular account shall be taken of:

a the state of health of the livestock, other domestic animals and wildlife in that country, with particular reference to exotic animal diseases, and of the environmental health situation in that country, which might endanger animal health in the Member States;

b the regularity and rapidity of the information supplied by that country concerning the existence of contagious animal diseases in its territory transmissible by semen, in particular those diseases mentioned in lists A and B of the International Office of Epizootic Diseases;

c that country's rules on animal disease prevention and control;

d the structure of the veterinary services in that country and their powers;

e the organization and implementation of measures to prevent and control contagious animal diseases; and

f the guarantees which that country can give with regard to compliance with this Directive.

3 The list referred to in paragraph 1 and all amendments thereto shall be published in the *Official Journal of the European Communities*.

I[F1]Article 8

1 Member States shall only authorise imports of semen dispatched from a semen collection centre situated in one of the third countries appearing on the list referred to in Article 7 and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions are met:

a it meets the conditions:

(i) for the approval of semen collection centres set out in Chapter I of Annex A;

(ii) relating to the supervision of such centres set out in Chapter II thereof;

b it has been officially approved by the competent authority of the third country for exports to the Community;

c it is placed under the supervision of a centre veterinarian;

d it is subject to inspections by an official veterinarian of the third country concerned at least twice a year.

2 The list of semen collection centres that the competent authority of the third country appearing on the list referred to in Article 7 has approved in accordance with the conditions set out in paragraph 1 of this Article and from which semen may be dispatched to the Community shall be communicated to the Commission.

The approval of a semen collection centre must be immediately suspended or withdrawn by the competent authority of the third country where it no longer complies with the

conditions set out in paragraph 1 and the Commission must be immediately informed thereof.

The Commission shall provide the Member States with any new and updated lists that it receives from the competent authority of the third country concerned in accordance with this paragraph and shall make them available to the public for information purposes.

3 Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 18(2).**]**

Textual Amendments

F1 Substituted by Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC (Text with EEA relevance).

Article 9

1 Semen must come from animals which, immediately prior to collection of their semen, have remained for at least three months in the territory of a third country on the list referred to in Article 7 (1).

2 Without prejudice to Article 7 (1) and paragraph 1 of this Article, Member States shall not authorize the importation of semen from a third country on the list unless the semen complies with the animal health requirements adopted under the procedure laid down in Article 18, for imports of semen from that country.

In adopting the requirements referred to in the first subparagraph, consideration shall be given to:

a the health situation in the area surrounding the semen collection centre, with particular reference to the diseases appearing on list A of the International Office of Epizootic Diseases;

b the state of health of the herd in the semen collection centre and testing requirements;

c the state of health of the donor animal and testing requirements;

d testing requirements in relation to semen.

3 The reference basis for fixing animal health conditions shall be the standards laid down in Chapter II and the corresponding Annexes. It may be decided, in accordance with the procedure laid down in Article 18, on a case-by-case basis, to waive these conditions where the third country concerned provides similar animal health guarantees, that are at least equivalent.

4 Article 4 shall apply.

Article 10

1 Member States shall authorize the importation of semen only on submission of an animal health certificate drawn up and signed by an official veterinarian of the third country of collection.

This certificate must:

a be drawn up in at least one of the official languages of the Member State of destination and one of those of the Member State where the import control provided for in Article 11 is carried out;

b accompany the semen to its destination in its original form;

c be drawn up on a single sheet of paper;

d be made out to a single consignee.

2 The animal health certificate must correspond to a specimen drawn up under the procedure laid down in Article 19.

Article 11

1 Member States shall ensure that each consignment of semen entering the customs territory of the Community is subjected to control before being released for free circulation or placed under a customs procedure and shall prohibit the introduction of the semen into the Community if the import control made on arrival reveals that:

— the semen does not come from the territory of a third country on the list drawn up in accordance with Article 7 (1),

— the semen does not come from a semen collection centre on the list provided for in Article 8 (1),

— the semen comes from the territory of a third country from which imports are prohibited in accordance with Article 15 (2),

— the animal health certificate which accompanies the semen is not in conformity with the conditions laid down in Article 10 and fixed pursuant thereto.

This paragraph shall not apply to consignments of semen which arrive in the customs territory of the Community and are placed under a customs transit procedure for consignment to a destination situated outside the said territory.

However, it shall be applicable where customs transit is waived during transport through the territory of the Community.

2 The Member State of destination may take the necessary measures, including storage in quarantine provided that this does not affect the viability of the semen, in order to obtain definite proof in cases where semen is suspected of being infected or contamined by pathogenic organisms.

3 If the admission of semen has been prohibited on any of the grounds set out in paragraphs 1 and 2 and the exporting third country does not authorize the return of the semen within 30 days in the case of deep-frozen semen, or immediately in the case of fresh semen, the competent veterinary authority of the Member State of destination may order it to be destroyed.

Article 12

Each consignment of semen authorized for admission into the Community by a Member State on the basis of the control referred to in Article 11 (1) must, when sent to the territory of another Member State, be accompanied by the original certificate or an authenticated copy thereof, suitably endorsed, in either case, by the competent authority which was responsible for the control carried out in accordance with Article 11.

Article 13

If it is decided to take destruction measures pursuant to Article 11 (3), any costs incurred shall be chargeable to the consignor, the consignee or their agent, without compensation by the State.

CHAPTER IV

Precautionary and control measures

Article 14

The rules set out in Directive 90/425/EEC shall apply in particular with regard to checks at origin, the organization and the monitoring of the checks to be carried out by the Member State of destination.

Article 15

1 The precautionary measures provided for in Article 10 of Directive 90/425/EEC shall apply to intra-Community trade.

[[F1]2 The rules laid down in Directive 97/78/EC shall apply, in particular to the organisation of, and follow-up to the checks to be carried out by the Member States and the safeguard measures to be applied in accordance with the procedure referred to in Article 22 of that Directive.**]**

Textual Amendments

F1 Substituted by Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC (Text with EEA relevance).

Article 16

1 Veterinary experts from the Commission may, in cooperation with the competent authorities of the Member States and third countries, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of this Directive.

The country of collection within whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the country of collection concerned of the results of the checks.

The country of collection concerned shall take any measures which may prove necessary to take account of the results of this check. If the country of collection does not take those measures, the Commission may, after the situation has been examined by the Standing Veterinary Committee, have recourse to the provisions of the third subparagraph of Article 6 (2) and of Article 5.

2 The general provisions for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph of paragraph 1, shall be laid down under the procedure set out in Article 19.

CHAPTER V

Final provisions

Article 17

The Annexes to this Directive shall be ameneded in accordance with the procedure set out in Article 18 to adapt them to advances in technology.

[F2 Article 18

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002[11].

2 Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC[12] shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 The Committee shall adopt its Rules of Procedure.

Textual Amendments

F2 Substituted by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority).

Article 19

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2 Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.]

Textual Amendments

F2 Substituted by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority).

Article 20

1 This Directive shall not be applicable to semen collected and processed in a Member State before 31 December 1991.

2 Until the date of entry into force of the decisions adopted pursuant to Article 8, 9 and 10, Member States shall not apply to imports of semen from third countries more favourable conditions than those resulting from application of Chapter II.

Article 21

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1991 at the latest. They shall forthwith inform the Commission thereof.

Article 22

This Directive is addressed to the Member States.

[F3ANNEX A

Textual Amendments

F3 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.**]**

[F4ANNEX B

Textual Amendments

F4 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[13];

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**) OJ No C 267, 6. 10. 1983, p. 5.

(**2**) OJ No C 342, 19. 12. 1983, p. 11.

(**3**) OJ No C 140, 28. 5. 1984, p. 6.

(**4**) OJ No 121, 29.07.1964, p. 1977/64.

(**5**) OJ No L 153, 6. 6. 1989, p. 29.

(**6**) OJ No L 302, 31. 12. 1972, p. 28.

(**7**) OJ No L 93, 6. 4. 1989, p. 25.

(**8**) OJ No L 395, 31. 12. 1989, p. 13.

(**9**) OJ No L 194, 22. 7. 1988, p. 10.

(**10**) See page 29 of this Official Journal.

(**11**) **[**[F2]OJ L 31, 1.2.2002, p. 1.**]**

(**12**) **[**[F2]OJ L 184, 17.7.1999, p. 23.**]**

(**13**) **[**[F4]OJ L 59, 4.3.2008, p. 19.**]**

Textual Amendments

F2 Substituted by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority).

F4 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).