

## ANNEX

## 'ANNEX B

## 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 <sup>(1)</sup>;

(1) OJ L 59, 4.3.2008, p. 19.

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

<sup>(1)</sup>either [a semen collection centre complying with Directive 90/429/EEC.]

<sup>(1)</sup>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.]

<sup>(1)</sup>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 12 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 leptospire, 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), (c) 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.

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