

## [<sup>F1</sup>ANNEX D

### Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) No 176/2010 of 2 March 2010 amending Annex D to Council Directive 92/65/EEC as regards semen collection and storage centres, embryo collection and production teams, and conditions for donor animals of the equine, ovine and caprine species and for handling semen, ova and embryos of those species \(Text with EEA relevance\).](#)

## CHAPTER II

### Conditions applicable to donor animals

- I. *Conditions applicable to donor stallions*
  1. In order to be used for the collection of semen, the donor stallion shall, to the satisfaction of the centre veterinarian, meet the following requirements:
    - 1.1. it shall not show any clinical sign of an infectious or contagious disease at the time of admission and on the day the semen is collected;
    - 1.2. it shall come from the territory or, in the case of regionalisation, from the part of the territory of a Member State or a third country and from a holding under veterinary supervision each of which satisfy the requirements of Directive 90/426/EEC;
    - 1.3. it shall be kept for 30 days prior to the date of semen collection in holdings where no equine has shown any clinical sign of equine viral arteritis or contagious equine metritis during that period;
    - 1.4. it shall not be used for natural mating during the 30 days prior to the first semen collection and during the collection period;
    - 1.5. [<sup>F2</sup>it shall be subjected to the following tests, carried out and certified in a laboratory which is recognised by the competent authority and has the tests referred to hereinafter included in its accreditation in accordance with Article 12 of Regulation (EC) No 882/2004 of the European Parliament and of the Council<sup>(1)</sup>, according to the programme provided for in point 1.6:
      - (a) an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia with negative result;
      - (b) a test for the isolation of the equine arteritis virus or the detection of its genome by polymerase chain reaction (PCR) or real-time PCR carried out with negative result on an aliquot of the entire semen of the donor stallion, unless the donor stallion has reacted with negative result at a serum dilution of one in four in a serum neutralisation test for equine viral arteritis;
      - (c) an agent identification test for contagious equine metritis, carried out with negative result in each case on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than seven days, and in no case earlier than seven days (systemic treatment) or 21 days (local treatment) after possible antimicrobial treatment of the donor stallion, from at least the following sites:

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- the penile sheath (prepuce),
- the urethra,
- the fossa glandis.

The specimens shall be placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.

The specimens shall be subjected to at least one of the following tests:

- (i) culture under microaerophilic conditions for at least 7 days for the isolation of *Taylorella equigenitalis*, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport; or
- (ii) polymerase chain reaction (PCR) or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within 48 hours after taking the specimens from the donor animal.]

1.6. it shall be subjected to one of the following testing programmes:

- (a) [F<sup>2</sup>:if the donor stallion is continuously resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, and no equidae on the semen collection centre come into direct contact with equidae of lower health status than the donor stallion, the tests required in point 1.5 shall be carried out on samples taken from the donor stallion at least once a year at the beginning of the breeding season or prior to the first collection of semen intended for trade in fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection;
- (b) if the donor stallion is resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, but may leave the centre occasionally under the responsibility of the centre veterinarian for a continuous period of less than 14 days, and/or other equidae on the collection centre come into direct contact with equidae of lower health status, the tests required in point 1.5 shall be carried out as follows:
  - (i) at least once a year on samples taken from the donor stallion at the beginning of the breeding season or prior to the first collection of semen intended for trade in fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection; and
  - (ii) during the period of collection of semen intended for trade in fresh, chilled or frozen semen as follows:
    - the test required in point 1.5(a) on samples taken not more than 90 days prior to the collection of semen for trade,
    - the test required in point 1.5(b) on samples taken not more than 30 days prior to the collection of semen for trade, unless the non-shedder state of a donor stallion is confirmed by virus isolation test, PCR or real-time PCR

- carried out on samples of an aliquot of the entire semen taken not more than 6 months prior to the collection of semen for trade and the donor stallion has reacted with positive result at a serum dilution of at least one in four in a serum neutralisation test for equine viral arteritis,
- the test required in point 1.5(c) on samples taken not more than 60 days prior to the collection of semen for trade, which in the case of PCR or real-time PCR may be carried out on three specimens (swabs) taken on a single occasion;
- (c) if the donor stallion does not meet the conditions in points (a) and (b) and the semen is collected for trade in frozen semen, the tests required in point 1.5 shall be carried out on samples collected from the donor stallion as follows:
- (i) at least once a year at the beginning of the breeding season;
- (ii) during the storage period provided for in point 1.3(b) of Section I of Chapter III and before the semen is removed from the centre or used, on samples taken not earlier than 14 days and not later than 90 days following the date of collection of the semen.

By way of derogation from point (ii) of the first subparagraph, post-collection sampling and testing for equine viral arteritis as described in 1.5(b) is not required in case the non-shedder state of a seropositive donor stallion is confirmed by virus isolation test, PCR or real-time PCR carried out with negative result on samples of an aliquot of the entire semen of the donor stallion taken twice a year at an interval of at least four months and the donor stallion has reacted with positive result at a serum dilution of at least one in four in a serum neutralisation test for equine viral arteritis.]

- 1.7. if any of the tests provided for in point 1.5 is positive, the donor stallion shall be isolated, and the semen collected from it since the date of the last negative test shall not be subject for trade with the exception, for equine viral arteritis, of semen from every ejaculate which has undergone the equine arteritis virus isolation test with negative result.

Semen collected from all other stallions at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests provided for in point 1.5. shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 1.5;

- 1.8. semen collected from stallions at a semen collection centre subject to a prohibition order in accordance with Article 4 or 5 of Directive 90/426/EEC shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored by the official veterinarian in accordance with Directive 90/426/EEC and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex A to Directive 90/426/EEC.

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### Textual Amendments

- F2** Substituted by [Commission Implementing Regulation \(EU\) No 846/2014 of 4 August 2014 amending Annex D to Council Directive 92/65/EEC as regards the conditions for donor animals of the equine species \(Text with EEA relevance\).](#)

- II. *Conditions applicable to male ovine and caprine donor animals*
1. For all ovine and caprine animals admitted to a semen collection centre the following requirements shall apply:
    - 1.1. they have been kept in quarantine for a period of at least 28 days in accommodation specifically approved for the purpose by the competent authority, and where only animals having at least the same health status are present (quarantine accommodation);
    - 1.2. prior to their stay in the quarantine accommodation, they have belonged to an officially brucellosis-free ovine or caprine holding pursuant to Article 2 of Directive 91/68/EEC and they shall not be previously kept in a holding of a lower health status as regards brucellosis;
    - 1.3. they come from a holding where during the 60 days prior to their stay in the quarantine accommodation they have undergone a serological test for contagious epididymitis (*B. ovis*) carried out in accordance with Annex D to Directive 91/68/EEC or any other test with an equivalent documented sensitivity and specificity;
    - 1.4. they have undergone the following tests carried out on a blood sample collected within the 28 days preceding the commencement of the period of quarantine specified in point 1.1, with negative results in each case, except for the test for Border disease referred to in point (c)(ii):
      - (a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;
      - (b) for contagious epididymitis (*B. ovis*), a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;
      - (c) for Border disease:
        - (i) a virus isolation test or a test for virus antigen; and
        - (ii) a serological test to determine the presence or absence of antibodies (antibody test).

The competent authority may authorise that the tests referred to in this point are carried out on samples collected in the quarantine accommodation. If such authorisation is granted, the period of quarantine referred to in point 1.1 shall not commence before the date of sampling. However, if any of the tests referred to in this point prove positive, the animal concerned shall be immediately removed from the quarantine accommodation. In the event of group isolation, the quarantine period referred to in point 1.1 shall not commence for the remaining animals until the animal which tested positive has been removed;
    - 1.5. they have undergone the following tests carried out on samples taken during the period of quarantine specified in point 1.1, and at least 21 days after being admitted to the quarantine accommodation, with negative results:

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- (a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;
  - (b) for contagious epididymitis (*B. ovis*), a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;
- 1.6. they have undergone the tests for Border disease referred in points 1.4(c)(i) and (ii) carried out on the blood samples taken during the period of quarantine specified in point 1.1, and at least 21 days after being admitted to the quarantine accommodation.

Any animal (seronegative or seropositive) shall only be allowed entry to the semen collection centre if no sero-conversion occurs in animals which tested seronegative before the day of entry into the quarantine accommodation.

If sero-conversion occurs, all animals that remain seronegative shall be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three weeks from the day the sero-conversion occurred.

Serologically positive animals shall be allowed entry into the semen collection centre subject to a negative result in a test referred in point 1.4(c)(i).

2. Animals shall only be admitted to the semen collection centre with the express permission of the centre veterinarian. All movements into and out of the semen collection centre shall be recorded.
3. No animals admitted to the semen collection centre shall show any clinical sign of disease on the date of admission.

All animals shall, without prejudice to point 4, have come from quarantine accommodation, which on the day of dispatch of the animals to the semen collection centre complies with the following conditions:

- (a) it is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius;
  - (b) it has for the past three months been free from foot-and-mouth disease and brucellosis;
  - (c) it has for the past 30 days been free from compulsory notifiable diseases as defined in Article 2(b)(6) of Directive 91/68/EEC.
4. Provided, that the conditions set out in point 3 are complied with and the routine tests referred to in point 5 have been carried out during 12 months prior to the movement of the animals, animals may be moved from one approved semen collection centre to another of equal health status, without isolation or testing if the transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used shall be disinfected before use. If an animal is moved from one semen collection centre to a semen collection centre in another Member State that movement shall be carried out in accordance with Directive 91/68/EEC.
5. All ovine and caprine animals kept at an approved semen collection centre shall be subjected at least once every calendar year to the following tests, with negative results:
  - (a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

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- (b) for contagious epididymitis (*B. ovis*) a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;
  - (c) for Border disease, the antibody test referred to in point 1.4(c)(ii) which is applied only to seronegative animals.
6. All tests referred to in this section shall be carried out by an approved laboratory.
7. If any of the tests described in point 5 is positive, the animal shall be isolated and the semen collected from it since the date of the last negative test shall not be subject for trade.

The animal referred to in the first paragraph shall be removed from the centre, except in the case of Border disease, in which case the animal shall be subjected with negative result to a test referred in point 1.4(c)(i).

Semen collected from all other animals at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests described in point 5 shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 5.

8. Semen shall be obtained from animals which:
- (a) show no clinical signs of disease on the date the semen was collected;
  - (b) during the 12 months prior to the date of the collection of the semen:
    - (i) either have not been vaccinated against foot-and-mouth disease; or
    - (ii) have been vaccinated against foot-and-mouth disease at least 30 days prior to the collection, in which case 5 % (with a minimum of five straws) of each semen collection shall be submitted to a virus isolation test for foot-and-mouth disease with negative results;
  - (c) have been kept at an approved semen collection centre for a continuous period of at least 30 days prior to the date of collection of the semen, in the case of collection of fresh semen;
  - (d) meet the requirements laid down in Articles 4, 5 and 6 of Directive 91/68/EEC;
  - (e) if kept on holdings referred to in the first indent of Article 11(2), had undergone with negative results during the 30 days prior to the date of collection of the semen:
    - (i) a serological test for brucellosis (*B. melitensis*) carried out in accordance with Annex C to Directive 91/68/EEC;
    - (ii) a serological test for contagious epididymitis (*B. ovis*) carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;
    - (iii) a test for the Border disease virus;
  - (f) shall not be used for natural breeding during at least 30 days prior to the date of first semen collection and between the date of the first sample referred to in points 1.5 and 1.6 or in point (e) and until the end of the collection period.

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9. Semen collected from male ovine and caprine donor animals at a semen collection centre or holding referred to in first indent of Article 11(2) subject to a prohibition on animal health grounds in accordance with Article 4 of Directive 91/68/EEC shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre or the holding has been restored by the official veterinarian in accordance with Directive 91/68/EEC and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex B(I) to Directive 91/68/EEC.]

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- (1) [<sup>F1</sup> [<sup>F2</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).]]

**Textual Amendments**

- F1** Substituted by Commission Regulation (EU) No 176/2010 of 2 March 2010 amending Annex D to Council Directive 92/65/EEC as regards semen collection and storage centres, embryo collection and production teams, and conditions for donor animals of the equine, ovine and caprine species and for handling semen, ova and embryos of those species (Text with EEA relevance).
- F2** Substituted by Commission Implementing Regulation (EU) No 846/2014 of 4 August 2014 amending Annex D to Council Directive 92/65/EEC as regards the conditions for donor animals of the equine species (Text with EEA relevance).