Semen Collection Center (SCC)-

Bovine, Porcine, Ovine, Caprine, and Equine

Section 1: Germinal Product Establishment Information

***Name of Semen Collection Center:**

***Physical Address of Semen Collection Center:**

***Approval Number of the Semen Collection Center (assigned by Riverdale Staff if this is the initial inspection):**

*Note: Above items with (*****) must match **exactly** the information published on the EU's TRACES NT list: Establishment Lists - TRACES NT (europa.eu) [Select "United States (US)" for the Country field at the top; then select "Germinal Products" for the Chapter.]*

ISO Code: US *(no additional answer required)*

Name of Center Veterinarian:

USDA Accreditation Number of Center Veterinarian:

Date of inspection:

Species: ___Bovine ___Porcine ___Ovine ___Caprine ___Equine

Central Competent Authority: USDA APHIS- Veterinary Services; 4700 River Road, Riverdale, MD 20737 *(no additional answer required)*

Section 2: Attestation of Compliance and Acknowledgement of Inspection Scheduling Responsibility:

The above germinal product establishment has been inspected and complies with requirements referred to in Article 82(2) of and Delegated Regulation (EU) 2020/692. (Described in Section 3)

The center veterinarian understands that it is the responsibility of the center, not USDA-APHIS, to schedule the next inspection within the required timeframe (6 months for bovine & porcine; 12 months for ovine, caprine & equine; +/- 30 days). If the center does not request and obtain an inspection within the required timeframe, the center may be removed from the EU's list and any stocks of germinal products stored under this approval will irrevocably lose EU-eligibility.

Name of Center Veterinarian [type or print]: _____

Signature: _____

Name of Inspecting USDA Veterinary Medical Officer [type or print]: _____

Signature: _____

After this inspection document has been completed and signed, APHIS-VS FiOps needs to submit information about the inspection via MS Forms to APHIS-VS in Riverdale:

https://forms.office.com/g/RMU9fw5gZr

This information can be submitted by the inspecting VMO or the VETS office, depending on local policy. The signed documents should also be filed as per local policy.

Section 3: Requirements referred to in Article 82(2) of and Delegated Regulation (EU) 2020/692, attested to above.

Notes:

- Some requirements may not apply to all species as noted within the text.
- *Italicized text* is referenced legislation and is linked within in the document to its reference.
- ~~Lined-out text~~ is part of the quoted legislation, but can be ignored for clarity

Article 82(2) of and Delegated Regulation (EU) 2020/692:

2. Consignments of germinal products shall only be permitted to enter the Union from approved germinal product establishments referred to in paragraph 1 that comply with the following requirements set out in Annex I to Delegated Regulation (EU) 2020/686:

(a) Part 1 of that Annex, in respect of a semen collection centre;

(b) Part 2 of that Annex, in respect of an embryo collection team;

(c) Part 3 of that Annex, in respect of an embryo production team;

(d) Part 4 of that Annex, in respect of a germinal product processing establishment;

(e) Part 5 of that Annex, in respect of a germinal product storage centre.

Part 1 of Annex I to Delegated Regulation (EU) 2020/686

REQUIREMENTS FOR SEMEN COLLECTION CENTRES ~~REFERRED TO IN ARTICLE 4~~

1. The responsibilities of the centre veterinarian, ~~as referred to in Article 4(1)(a)(i),~~ shall be the following:

(a) the centre veterinarian shall ensure that:

(i) at the semen collection centre, only animals which have not been used for natural breeding for a period of at least 30 days prior to the date of the first semen collection and during the collection period are kept;

(ii) at the semen collection centre, records are kept in accordance with the requirements laid down in Article 8(1)(a);

[Article 8(1)(a)…approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals shall keep and maintain records containing at least the following information:

(a) in respect of a semen collection centre:

(i) the species, breed, date of birth and identification of each donor animal present at the semen collection centre;

(ii) the dates of any movement of donor animals to and from the semen collection centre and, where those animals are accompanied by any document, the reference to those documents;

(iii) the health status, the results of clinical and diagnostic tests and the laboratory techniques used, treatments and vaccinations carried out on the donor animals;

(iv) the date of semen collection and, where relevant, the date and the place of processing of semen;

(v) the identification of semen and details of its destination;]

(iii) the entry of unauthorised persons is effectively prevented;

(iv) authorised visitors comply with the animal health and biosecurity requirements referred to in point (c)(i);

(v) each straw or other package in which semen is placed is clearly marked in accordance with the requirements laid down in Article 10;

[Article 10:

1. …shall mark each straw or other package in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, in such a way that the following information can be readily established:

(a) the date of collection or production of those germinal products;

(b) the species and identification of the donor animal(s);

(c) the unique approval number of the germinal product establishment of collection or production, processing and storage of those germinal products;

(d) any other relevant information.

2. In case of sex-sorting of semen at a germinal product processing establishment, the operator of the semen collection centre shall supplement the information referred to in paragraph 1 with information which permits the identification of the unique approval number of the germinal product processing establishment where that semen was sex-sorted.

3. Where a single straw or another package contains semen of bovine, porcine, ovine or caprine animals collected from more than one donor animal, the operator shall ensure that the information referred to in paragraph 1 permits the identification of all donor animals that have contributed to the dose of semen used for insemination.

4. By way of derogation from paragraph 1, where the semen of ovine or caprine animals is

(a) frozen in pellets, the operator may mark the goblet containing the semen pellets of a single donor instead of marking each individual pellet in that goblet;

(b) fresh or chilled semen, the operator may mark the goblet containing the semen tubes or straws of a single donor instead of marking each individual tube or straw in that goblet.

~~*5. By way of derogation from paragraph 1(c), the operator shall ensure that the marking of each straw or other package in which semen, oocytes or embryos are placed, stored and transported, is carried out in such a way that it permits the identification of:*~~

~~*(a) in the case of semen of ovine and caprine animals which has been collected at the establishment where the donor animals are kept as referred to in Article 13, the unique registration number of that establishment; or*~~

~~*(b) in the case of germinal products of bovine, porcine, ovine, caprine or equine animals which have been collected or produced at a confined establishment referred to in Article 14, the unique approval number of that confined establishment*~~*. [Note: point (5) is not currently relevant to any U.S. establishments]]*

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

(vii) only semen collected at a semen collection centre is processed and stored at that semen collection centre, and it must not come into contact with any other consignment of germinal products of lesser health status;

(viii) all instruments which come into contact with the semen or the donor animal during the collection and processing of semen are cleaned and either disinfected or sterilised prior to use, except for new single-use instruments;

(ix) where, in the case of equine animals, the semen collection centre is located within the perimeters of a registered establishment which also hosts an artificial insemination or service centre, there is a strict separation between the instruments and equipment coming into contact with donor animals, their semen and other animals kept in the semen collection centre and the semen, instruments and equipment used for artificial insemination or natural service;

(x) any biological product originating from animals used in the processing of semen, including diluents, additives or extenders, is obtained from sources which present no animal health risk or which are treated prior to use so that such risk is prevented;

(xi) before the commencement of each filling operation, the storage containers and transport containers are cleaned and either disinfected or sterilised, except for new single-use containers;

(xii) the cryogenic agents used for the preservation or storage of semen have not previously been used for other products;

(xiii) the staff employed at the semen collection centre have received adequate training on disinfection and hygiene techniques to prevent the spread of diseases;

(b) by way of derogation from point (a)(vii), the centre veterinarian may authorise semen that was not collected at a semen collection centre to be processed at the semen collection centre provided that the following conditions are met:

(i) such semen is collected from animals which fulfil the following requirements set out in Annex II

— in respect of bovine animals, the requirements set out in point 1(b) of Chapter I of Part 1, and as applicable in Chapters I, II and III of Part 5 thereof,

[Point 1(b) of Chapter I of Part 1:
(b) within the period of 30 days ~~prior to the commencement of the quarantine referred to in point (a)~~, the animals must have been subjected to the following tests with a negative result in each case, except for the bovine viral diarrhoea antibody test referred to in point (v):

(i) for infection with Mycobacterium tuberculosis complex (M. bovis, M. caprae and M. tuberculosis), a test referred to in Part 2 of Annex I to Delegated Regulation (EU) 2020/688;

[1. Tuberculin skin tests:

(a) the single intradermal tuberculin test (SITT);

(b) the comparative intradermal tuberculin test (CITT).

2. Test available for blood samples:

(a) gamma-interferon assay.]

(ii) for infection with Brucella abortus, Brucella melitensis and Brucella suis, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;

[1. Serological tests for bovine, ~~ovine, caprine and camelid animals~~:

(a) buffered Brucella antigen tests;

(b) complement fixation test (CFT);

(c) indirect enzyme-linked immunosorbent assay (I-ELISA);

(d) fluorescence polarisation assay (FPA);]

(iii) for enzootic bovine leukosis, a serological test referred to in point (a) of Part 4 of Annex I to Delegated Regulation (EU) 2020/688, using the derogation provided for in Article 20(2)(a);

[Serological tests:

(a) tests for blood samples:

(i) agar gel immuno-diffusion test (AGID);

(ii) blocking enzyme-linked immunosorbent assay (B-ELISA);

(iii) indirect enzyme-linked immunosorbent assay (I-ELISA).]

[Derogation: [If the animal] is less than 2 years of age [it] has been produced by a dam which was subjected, with negative results, to a serological test for enzootic bovine leukosis after removal of that animal from its dam;]

(iv) for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, a serological test (whole virus) on a blood sample if the animals do not come from an establishment free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis;

(v) for bovine viral diarrhoea:

— a virus isolation test, a test for virus genome or a test for virus antigen, and

— a serological test to determine the presence or absence of antibodies;]

[Part 5

Chapter I-

1. The bovine, ~~porcine, ovine and caprine~~ animals which are semen~~, oocyte or embryo~~ donors must:

(a) come from establishments:

(i) situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the establishment for a period of at least 30 days immediately prior to the date of collection;

(ii) in which foot-and-mouth disease has not been reported during a period of at least 3 months immediately prior to the date of collection;

(b) have not been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection.

2. The centre veterinarian shall ensure that:

(a) the bovine, ~~porcine, ovine and caprine~~ animals which are semen donors are only admitted to the semen collection centre after they have undergone isolation in the quarantine accommodation, which on the day of admission of the animals to the semen collection centre must:

(i) be situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the quarantine accommodation for a period of at least 30 days;

(ii) have had no outbreak of foot-and-mouth disease reported during the period of 3 months preceding the date of admission of the animals into the semen collection centre;

(b) semen is only moved ~~to another Member State~~ subject to compliance with the following conditions:

(i) the semen collection centre is situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the semen collection centre for a period of at least 30 days;

(ii) the semen collection centre has been free from foot-and-mouth disease for a period of at least 3 months prior to the date of collection of the semen and 30 days from the date of collection or, in the case of fresh semen, until the date of dispatch of the consignment of semen ~~to another Member State~~;

(iii) in the case of fresh semen, the donor animal has been kept at the semen collection centre referred to in point (i) for a continuous period of at least 30 days immediately prior to the date of collection of the semen.

3. ~~By way of derogation from point 1(b), the centre veterinarian may authorise the dispatch of semen collected from a kept donor animal which has been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection, provided that:~~

~~(a)the donor animal has not been vaccinated against foot-and-mouth disease within the period of at least 30 days immediately prior to the date of collection;~~

~~*(b)5 % (with a minimum of five straws) of each quantity of semen taken from a donor animal at any time is submitted to a virus isolation test for foot and mouth disease with negative results*~~*[The US is free of, and does not vaccinate for FMD.]…*

Chapter II-

1. The bovine, ~~*ovine and caprine*~~ *animals* ~~*and animals of the families Camelidae and Cervidae*~~ *which are semen donors must fulfil at least one of the following conditions:…[(a) and (b) are not relevant to U.S.]*

(c) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;

(d) they have been subjected to a serological test to detect antibodies to the bluetongue virus serogroup 1-24, with negative results, between 28 and 60 days from the date of each collection of the semen;

(e) they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on blood samples taken at commencement and final collection of the semen and during collection of the semen at intervals of:

(i) at least every 7 days, in the case of the virus isolation test; or

(ii) at least every 28 days, in the case of PCR…[Rest of Chapter II is not relevant to semen donors.]

Chapter III-

The bovine, ~~*ovine and caprine*~~ *animals which are semen donors must fulfil at least one of the following conditions:… [(a) is not relevant to U.S.]*

(b) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;

(c) they have been subjected to a serological test to detect antibodies to EHDV 1-7, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days from the date of the final collection of the semen;

(d) they have been subjected to an agent identification test for EHDV 1-7, with negative results, on blood samples taken at the commencement and final collection of the semen and during the collection of the semen at intervals of:

(i) at least every 7 days, in the case of virus isolation test; or

(ii) at least every 28 days, in the case of PCR.]

— in respect of porcine animals, the requirements set out in point 1(b) of Chapter I of Part 2, and as applicable in Chapters I and IV of Part 5 thereof,

[Point 1(b) of Chapter I of Part 2

(b) within a period of 30 days ~~prior to entering the quarantine accommodation referred to in point (a),~~ the animals must have been subjected to the following tests, with negative results:

(i) as regards infection with Brucella abortus, Brucella melitensis and Brucella suis, a buffered Brucella antigen test (rose Bengal test), a competitive ELISA or an indirect ELISA for the detection of antibodies to smooth Brucella species.

If any of the animals prove positive in the serological tests detecting antibodies to smooth Brucella species (including Brucella abortus, Brucella melitensis and Brucella suis), animals with negative results in the same establishment shall not be admitted into the quarantine accommodation until a disease-free status of the infection with Brucella abortus, Brucella melitensis and Brucella suis of the establishments of origin of the animals that proved positive has been confirmed;

(ii) as regards infection with Aujeszky's disease virus:

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

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

The serological tests for infection with Aujeszky's disease virus must meet the standards set out in Part 7 of Annex I to Delegated Regulation (EU) 2020/688;

Infection with Aujeszky's disease virus

	Methods:
Porcine animals	Aujeszky's disease virus (ADV) ELISA (a)
Porcine animals less than 4 months old born to dams vaccinated with a gE-deleted vaccine	gE ELISA (b)

(a) ELISA for the detection of antibodies against whole ADV, ADV-gB protein or ADV-gD protein. For batch control of ADV-gB kits and ADV-gD kits or whole ADV kits, Community reference serum ADV 1, or sub-standards, must be scored positive at a dilution of 1:2.

(b) ELISA for the detection of antibodies against ADV-gE protein. For batch control, Community reference serum ADV 1, or sub-standards, must be scored positive at a dilution of 1:8.

[ ]

(iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test, in case of animals coming from a Member State or zone thereof where classical swine fever has been reported or vaccination against this disease has been practiced for the period of the preceding 12 months;

(iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (the immunoperoxidase monolayer assay (IPMA), immunofluorescence assay (IFA), or ELISA);]

[Part 5

Chapter I-

1. The ~~bovine,~~ porcine,~~ ovine and caprine~~ animals which are semen~~, oocyte or embryo~~ donors must:

(a) come from establishments:

(i) situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the establishment for a period of at least 30 days immediately prior to the date of collection;

(ii) in which foot-and-mouth disease has not been reported during a period of at least 3 months immediately prior to the date of collection;

(b) have not been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection.

2. The centre veterinarian shall ensure that:

(a) the ~~bovine~~, porcine~~, ovine and caprine~~ animals which are semen donors are only admitted to the semen collection centre after they have undergone isolation in the quarantine accommodation, which on the day of admission of the animals to the semen collection centre must:

(i) be situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the quarantine accommodation for a period of at least 30 days;

(ii) have had no outbreak of foot-and-mouth disease reported during the period of 3 months preceding the date of admission of the animals into the semen collection centre;

(b) semen is only moved ~~to another Member State~~ subject to compliance with the following conditions:

(i) the semen collection centre is situated in an area where foot-and-mouth disease has not been reported within a 10-km radius

centred on the semen collection centre for a period of at least 30 days;

(ii) the semen collection centre has been free from foot-and-mouth disease for a period of at least 3 months prior to the date of collection of the semen and 30 days from the date of collection or, in the case of fresh semen, until the date of dispatch of the consignment of semen ~~to another Member State~~;

(iii) in the case of fresh semen, the donor animal has been kept at the semen collection centre referred to in point (i) for a continuous period of at least 30 days immediately prior to the date of collection of the semen.

3. ~~By way of derogation from point 1(b), the centre veterinarian may authorise the dispatch of semen collected from a kept donor animal which has been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection, provided that:~~

~~(a)the donor animal has not been vaccinated against foot-and-mouth disease within the period of at least 30 days immediately prior to the date of collection;~~

~~(b)5 % (with a minimum of five straws) of each quantity of semen taken from a donor animal at any time is submitted to a virus isolation test for foot and mouth disease with negative results~~[The U.S. is free of, and does not vaccinate for FMD.]…

Chapter IV-

To qualify as free from infection with Brucella abortus, Brucella melitensis and Brucella suis, an establishment of porcine animals must satisfy the following requirements:

(a) infection with Brucella abortus, Brucella melitensis and Brucella suis must be a notifiable disease in porcine animals in the Member State;

(b) infection with Brucella abortus, Brucella melitensis and Brucella suis has not been confirmed in the establishment for a period of at least the preceding 3 years;

(c) animals showing clinical signs consistent with infection with Brucella abortus, Brucella melitensis and Brucella suis such as abortions or orchitis are subjected to the necessary diagnostic tests with negative results;

(d) no porcine animals belonging to the establishment have been vaccinated against infection with Brucella abortus, Brucella melitensis and Brucella suis for at least the preceding 3 years;

(e) porcine animals which have been introduced to the establishment:

(i) either come from establishments free from infection with Brucella abortus, Brucella melitensis and Brucella suis for a period of at least the preceding 3 years, or were tested on a sample taken within a period of 30 days prior to the date of dispatch with negative results; and

(ii) have not been vaccinated against infection with Brucella abortus, Brucella melitensis and Brucella suis for a period of at least the preceding 3 years;

(f) for a period of at least the preceding 3 years, there has been no evidence of infection with Brucella abortus, Brucella melitensis and Brucella suis in other epidemiological units of the same establishment, or measures have been implemented to prevent any transmission of infection with Brucella abortus, Brucella melitensis and Brucella suis from those other epidemiological units]

— in respect of ovine and caprine animals, the requirements set out in point 1(c) of Chapter I of Part 3, and as applicable in Chapters I, II and III of Part 5 thereof,

[Point 1(c) of Chapter I of Part 3

(c) the animals have been subjected to the following tests carried out on a blood sample taken within a period of 30 days ~~preceding the commencement of the period of quarantine referred to in point (a)~~, with a negative result in each case:

(i) for infection with Brucella abortus, Brucella melitensis and Brucella suis, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;

[1. Serological tests for ~~bovine~~, ovine, caprine ~~and camelid animals~~:

(a) buffered Brucella antigen tests;

(b) complement fixation test (CFT);

(c) indirect enzyme-linked immunosorbent assay (I-ELISA);

(d) fluorescence polarisation assay (FPA);]

(ii) in the case of ovine animals, for ovine epidydimitis (Brucella ovis), a serological test or any other test with an equivalent documented sensitivity and specificity.

In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (Brucella ovis) with negative results;]

[Part 5

Chapter I-

1. The ~~bovine, porcine,~~ ovine and caprine animals which are semen~~, oocyte or embryo~~ donors must:

(a) come from establishments:

(i) situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the establishment for a period of at least 30 days immediately prior to the date of collection;

(ii) in which foot-and-mouth disease has not been reported during a period of at least 3 months immediately prior to the date of collection;

(b) have not been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection.

2. The centre veterinarian shall ensure that:

(a) the ~~bovine, porcine~~, ovine and caprine animals which are semen donors are only admitted to the semen collection centre after they have undergone isolation in the quarantine accommodation, which on the day of admission of the animals to the semen collection centre must:

(i) be situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the quarantine accommodation for a period of at least 30 days;

(ii) have had no outbreak of foot-and-mouth disease reported during the period of 3 months preceding the date of admission of the animals into the semen collection centre;

(b) semen is only moved ~~to another Member State~~ subject to compliance with the following conditions:

(i) the semen collection centre is situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the semen collection centre for a period of at least 30 days;

(ii) the semen collection centre has been free from foot-and-mouth disease for a period of at least 3 months prior to the date of collection of the semen and 30 days from the date of collection or, in the case of fresh semen, until the date of dispatch of the consignment of semen ~~to another Member State~~;

(iii) in the case of fresh semen, the donor animal has been kept at the semen collection centre referred to in point (i) for a continuous period of at least 30 days immediately prior to the date of collection of the semen.

3. ~~By way of derogation from point 1(b), the centre veterinarian may authorise the dispatch of semen collected from a kept donor animal which has been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection, provided that:~~

~~(a)the donor animal has not been vaccinated against foot-and-mouth disease within the period of at least 30 days immediately prior to the date of collection;~~

~~(b)5 % (with a minimum of five straws) of each quantity of semen taken from a donor animal at any time is submitted to a virus isolation test for foot and mouth disease with negative results~~[The U.S. is free of, and does not vaccinate for FMD.]…

Chapter II-

The ~~bovine,~~ ovine and caprine animals ~~and animals of the families Camelidae and Cervidae~~ which are semen donors must fulfil at least one of the following conditions:… [(a) and (b) are not relevant to U.S.]

(c) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;

(d) they have been subjected to a serological test to detect antibodies to the bluetongue virus serogroup 1-24, with negative results, between 28 and 60 days from the date of each collection of the semen;

(e) they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on blood samples taken at commencement and final collection of the semen and during collection of the semen at intervals of:

(i) at least every 7 days, in the case of the virus isolation test; or

(ii) at least every 28 days, in the case of PCR…[Rest of Chapter II is not relevant to semen donors.]

Chapter III-

The ~~bovine~~, ovine and caprine animals which are semen donors must fulfil at least one of the following conditions:… [(a) is not relevant to U.S.]

(b) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;

(c) they have been subjected to a serological test to detect antibodies to EHDV 1-7, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days from the date of the final collection of the semen;

(d) they have been subjected to an agent identification test for EHDV 1-7, with negative results, on blood samples taken at the commencement and final collection of the semen and during the collection of the semen at intervals of:

(i) at least every 7 days, in the case of virus isolation test; or

(ii) at least every 28 days, in the case of PCR.]

— in respect of equine animals, in point 1(a) of Chapter I of Part 4 thereof;

[Point 1(a) of Chapter I of Part 4

(a) the animal shall be subjected to the following tests, ~~in accordance with one of the testing programmes provided for in point (b)~~:

(i) an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia with a negative result;

(ii) 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 a negative result on an aliquot of the entire semen of the donor stallion, unless the donor stallion has been subjected to a serum neutralisation test for equine viral arteritis where a negative result was obtained at a serum dilution of one in four;

(iii) an agent identification test for contagious equine metritis (Taylorella equigenitalis), carried out with a negative result in each case on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than 7 days, and in any case no earlier than 7 days (systemic treatment) or 21 days (local treatment) after the possible antimicrobial treatment of the donor stallion, from at least the following sites:

— the penile sheath (prepuce),

— the urethra,

— the fossa glandis.

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

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

— culture under microaerophilic conditions for a period of at least 7 days for the isolation of Taylorella equigenitalis, set up within 24 hours from the time of taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport, or

— PCR or real-time PCR for the detection of genome of Taylorella equigenitalis, carried out within 48 hours from the time of taking the specimens from the donor animal;]

(ii) processing is carried out with separate equipment or at a different time from semen intended to be moved to another Member State, and the equipment in the latter case must be cleaned and sterilised after use;

(iii) such semen is not moved to another Member State and does not at any time come into contact with, or is stored with, semen intended to be moved to another Member State;

(iv) such semen is identifiable by a marking which must be different from that referred to in point (a)(v);

(c) the centre veterinarian shall:

(i) lay down the animal health and biosecurity requirements for the operation of the semen collection centre and the measures to ensure compliance with those requirements;

(ii) only accept into the semen collection centre animals of species whose semen is to be collected;

(d) by way of derogation from point (c)(ii), the centre veterinarian may authorise kept animals other than bovine, porcine, ovine, caprine or equine animals to be admitted to the semen collection centre, provided that they present no risk of infection to those species whose semen is to be collected, and they comply with the animal health and biosecurity requirements referred to in point (c)(i);

(e) the centre veterinarian of a semen collection centre for equine animals, located within the perimeters of a registered establishment which also hosts an artificial insemination or service centre, shall ensure that equine animals entering the establishment meet the requirements of Article 23(1), point (a), and may decide that where direct contact of donor male equine animals with female equine animals or castrated male equine animals for teasing or with uncastrated male equine animals used on the establishment outside the semen collection centre for natural service cannot be excluded, those female and male equine animals must meet all the requirements of Article 23(1).

[Article 23(1)

1. The centre veterinarian shall ensure that equine animals admitted to a semen collection centre ~~and the team veterinarian shall ensure that equine animals used for the collection of oocytes and embryos or the production of embryos~~ comply with the following requirements prior to the collection of the germinal products:

(a) they come from an establishment:

(i) where surra (Trypanosoma evansi) has not been reported during the period of the preceding 30 days, or where surra (Trypanosoma evansi) has been reported during the period of the preceding 2 years and following the last outbreak the affected establishment remained under movement restrictions until:

— the infected animals have been removed from the establishment, and

— the remaining animals in the establishment have been subjected to a test for surra (Trypanosoma evansi) with one of the diagnostic methods provided for in Part 3 of Annex I to Delegated Regulation (EU) 2020/688, with negative results carried out on samples taken at least 6 months after the last infected animal has been removed from the establishment;

(ii) where dourine has not been reported during the period of the preceding 6 months, or where dourine has been reported during the period of the preceding 2 years and following the last outbreak the affected establishment remained under movement restrictions until:

— the infected animals have been killed and destroyed or slaughtered, or the infected entire male equine animals have been castrated, and

— the remaining equine animals in the establishment, with the exception of the castrated male equine animals referred to in the first indent kept apart from female equine animals, have been subjected to a test for dourine with one of the diagnostic methods provided for in Part 8 of Annex I to Delegated Regulation (EU) 2020/688, with negative results, carried out on samples taken at least 6 months after the measures described in the first indent have been completed;

(iii) where equine infectious anaemia has not been reported during the period of the preceding 90 days, or where equine infectious anaemia has been reported during the period of the preceding 12 months and following the last outbreak the affected establishment remained under movement restrictions until:

— the infected animals have been killed and destroyed or slaughtered, and

— the remaining equine animals in the establishment have been subjected to a test for equine infectious anaemia with one of the diagnostic methods provided for in Part 9 of Annex I to Delegated Regulation (EU) 2020/688, with negative results, carried out on samples taken on two occasions at least 3 months apart after the measures described in the first indent have been completed and the establishment was cleaned and disinfected;

(b) in the case of semen donors, they were kept for a period of 30 days prior to the date of semen collection in establishments where no equine animal has shown any clinical sign of infection with equine arteritis virus or of contagious equine metritis during that period;

(c) they fulfil the additional animal health requirements laid down in Part 4 of Annex II]

2. The requirements for the facilities, equipment and operational procedures of the semen collection centre, ~~as referred to in Article 4(1)(b)(i)~~, shall be the following:

(a) the semen collection centre must have at least:

(i) lockable animal accommodation and, if required, an exercise area for equine animals which is physically separated from the semen collection facilities, the semen processing room and the storage room;

(ii) isolation facilities for animals which have failed tests referred to in Annex II of this Regulation or which show symptoms or signs of any of the category D diseases relevant for the bovine, porcine, ovine, caprine or equine animals, and which have no direct connection with the regular animal accommodation referred to in point (i);

(iii) semen collection facilities that may be open air provided that they are protected from adverse weather effects and are equipped with slip-proof flooring at and around the place of semen collection;

(iv) a separate room for the cleansing and disinfection or sterilisation of equipment;

(v) a semen processing room, separated from the semen collection facilities and the room for cleansing equipment referred to in point (iv), which need not necessarily be on the same site;

(vi) a semen storage room, which need not necessarily be on the same site; the semen storage room must be furnished with the necessary installation to store germinal products, which must be so constructed that it protects those germinal products and the installation from adverse weather and environment effects;

(b) the semen collection centre must be so constructed or isolated that contact with outside livestock is prevented;

(c) the semen collection centre must be so constructed that, except for the office rooms and, in the case of equine animals, the exercise area, it can be readily cleansed and disinfected;

(d) the semen collection centre must be so constructed that unauthorised access of people is effectively prevented.