

HEALTH CERTIFICATE FOR EXPORT OF OVINE OR CAPRINE SEMEN FROM MEMBER STATES OF THE EUROPEAN UNION TO THE UNITED STATES OF AMERICA						
1. EU Member State of provenance and competent authority:				2. Health certificate No.		
<b>A. ORIGIN OF SEMEN</b>						
3. Approval number of the semen collection center (hereinafter 'SCC').....						
4. Name and address of the SCC:				5. Name and address of the consignor:		
6. Country and place of loading:				7. Means of transport:		
<b>B. DESTINATION OF SEMEN</b>						
8. Name and address of the consignee:						
<b>C. IDENTIFICATION OF SEMEN</b>						
9.1 Name of donor ram/buck	9.2 Species/Breed	9.3 Age	9.4 Identification Number	9.5 Number of straws	9.6 Date of collection	9.7 Collection code(s) on straws
9.8. Seal number(s) of container(s):.....						

**D. HEALTH INFORMATION****10. Section A (to be signed in Sections 12-14 by the Semen Collection Center Veterinarian):**

I, the undersigned Center Veterinarian of the described semen collection center, hereinafter 'SCC,' certify that:

- 10.1 The SCC where the donor(s) represented in this consignment was (were) collected are currently approved in accordance with Part 1 of Annex I to Delegated Regulation (EU) 2020/686.
- 10.2 The ovine or caprine semen donors, and any teaser animals, were established as residents of the SCC in accordance with Part 3, Chapter I of Annex II to Delegated Regulation (EU) 2020/686; and in accordance with any additional U.S. import requirements as specified in this certificate.
- 10.3 During the period of semen collection involved, the SCC has continuously been under my supervision, or that of another veterinarian designated by the national government of the EU Member State of origin; and whose information has been verified by me.
- 10.4 The premises where the semen is collected, and the flocks/herds of origin of the donors and all contact animals, are located in an area at least 50 kilometers from any known occurrence of FMD, and have remained within the area for at least 90 days prior to and 30 days following collection of the semen for export to the United States.
- 10.5 The donor and teaser animals have been part of the national flock/herd of \_\_\_\_\_ (the EU Member State) for at least 60 days prior to collection of semen for export to the United States, and are not otherwise subject to movement restrictions or quarantines due to disease. If imported from any country considered by APHIS as affected with foot-and-mouth disease, the donor animals have been part of the national flock/herd for at least 90 days prior to collection of semen for export to the United States, and are not otherwise subject to any movement restrictions or quarantines due to disease.

10.6 The following certifications are made with respect to any sheep or goats resident in the SCC:

- a. The animals are permanently identified to enable traceback to their flock/herd of origin.
- b. The animals have been isolated as a group, without further additions, for a period of at least 30 days prior to the first collection of semen for export to the United States (hereafter 30-day pre-entry quarantine). During this time, there were no clinical signs of communicable diseases.
- c. Immediately prior to the first collection of semen for export to the United States, the donors were inspected by the SCC veterinarian and found to be clinically free of contagious diseases.
- d. There was no clinical evidence of infection of the animals by bluetongue virus during the 60 days prior to and during the period of collection of semen for export to the United States.

10.7 Scrapie:

- a. The animals have been kept since birth in flocks/herds in which no case of scrapie had been confirmed during their residency.
- b. The animals showed no clinical signs of scrapie at the time of semen collection, or prior to the export of semen to the United States.
- c. The donor animal is not, nor was not, restricted in the country of origin, or destroyed, due to exposure to a Transmissible Spongiform Encephalopathy (TSE).

10.8 The following certifications are made with respect to bovine tuberculosis and brucellosis [*Note: strike out sections that are not applicable where a choice is given*]:

Either<sup>1</sup>:

The animals have been resident in the SCC for less than one year, and come from a flock/herd of origin that was tested negative for bovine tuberculosis<sup>2</sup> and brucellosis<sup>3</sup> on two occasions, at least 60 days

apart. The first test was within one year prior to entry into the SCC; with the second test occurring during the 30-day pre-entry quarantine period before their admission into the SCC; and no clinical, microbiological, or serological evidence of these diseases was found during the 24 months prior to export of the semen to the United States;

OR

The animals have been resident in the SCC for more than one year, and were tested negative for bovine tuberculosis<sup>2</sup> and brucellosis<sup>3</sup> during annual herd tests at the SCC.

Select the pertinent brucellosis testing performed<sup>1</sup>:

- ☐ *Brucella abortus/melitensis*:
  - ☐ Fluorescence polarization assay (FPA);
  - ☐ Rose Bengal;
  - ☐ Complement Fixation Test (CFT)
  - ☐ Buffered Plate Antigen Agglutination test
- ☐ *Brucella ovis* (in the case of sheep):
  - ☐ Enzyme linked immunosorbent assay (ELISA)
  - ☐ CFT

10.9 The animals are certified as stipulated below, or were tested using the following technical criteria for other specific tests [*Note: strike out sections that are not applicable where a choice is given*]:

- a. Schmallenberg virus: the semen for export to the United States was either<sup>1</sup>:

Collected prior to June 1, 2011;

OR

The semen in the consignment was collected after June 1, 2011 from donors that were negative to two serum neutralization tests (using a 1:16 cutoff titer) for Schmallenberg virus, with the first performed within 30 days prior to collection, and the second between 28 and 60 days after collection. Tests were performed in a laboratory approved by the National Competent Authority.

- b. Bluetongue virus: the donor animal was either<sup>1</sup>:

kept in a BTV free country or zone, where no cases of BTV have been reported within the previous 12 months, and where no serological evidence of BTV infection exists;

OR

tested negative by an ELISA test for the BTV group on blood serum during the pre-entry quarantine period, and at least every 60 days after, with one test occurring 21-60 days after semen collection;

OR

tested with a whole blood PCR test for BTV group with one negative test at the beginning and conclusion of the collection period, and at least every 28 days during the period of semen collection;

OR

tested with a whole-blood virus isolation test for BTV group with one negative test at the beginning and conclusion of the collection period, and at least every 7 days during the period of semen collection;

- c. Epizootic hemorrhagic disease (EHD): Either<sup>1</sup>:

The animals originate from a Member State where no cases of EHD have been reported within the previous 12 months, and where no serological evidence of EHD infection exists;

OR

The following serotypes of EHD exist: \_\_\_\_\_ and animals were tested on two occasions by an agar gel immunodiffusion test (AGID); OR by competitive enzyme-linked immunosorbent assay (C-ELISA) AND by either a whole-blood PCR test or a virus neutralization test (VNT) for all

<p>the above-listed serotypes of EHD, with negative results using blood samples taken prior to, and not less than 21 days following collection of the semen (the two samples may not be taken more than 12 months apart).</p> <p>10.10 The donor animals do not come from premises and have not been in contact with animals from premises where Maedi-Visna (in the case of sheep) or Caprine Arthritis Encephalitis virus (in the case of goats) has been clinically detected within the 3 years prior to the collection of semen to be exported.</p>		
<p><b>11. Collection and processing certifications<sup>4</sup></b></p> <p>11.1 The SCC veterinarian supervised the collection and processing of the semen for shipment to the United States.</p> <p>11.2 Semen collection equipment which came into contact with rams or bucks or their secretions and excretions was thoroughly disinfected after each use, and good laboratory practices were followed during collection and processing of semen in order to minimize the possible introduction of microbial contamination.</p> <p>11.3 The semen was packaged in ampules or straws which are permanently marked with the name, breed, and individual identification number of the donor and the date of collection.</p> <p>11.4 Any antibiotics that were added to each ml of the semen and semen extender were limited to 100 µg of tylosin, 500 µg of gentamicin, or 300/600 µg of linco-spectin (lincomycin and spectinomycin), as diluted by 0.02 ml of double-distilled sterile water.</p> <p>11.5 Ruminant products used in commercial semen extenders in the Member State where the semen was collected were sourced from countries considered by USDA to be free from foot-and mouth disease as listed in 9 CFR Part 94 and other official publications.</p> <p>11.6 No biological products other than frozen semen or embryos qualified for shipment to the United States were present in the containers prior to use for export of semen to the United States.</p> <p>11.7 The shipping tank is new or has been cleaned and sanitized, and only fresh liquid nitrogen has been used to charge the tank.</p> <p>11.8 After processing, the ampules/straws of ovine or caprine semen to be exported to the United States were segregated in locked containers at a storage facility (or facilities) designated by the national government of the EU Member State; and were maintained under supervision until such time as the ampules/straws were placed in the shipping tank and sealed under official veterinary supervision.</p>		
12. Date and place	13. Name and qualification of the SCC Veterinarian	14. Signature of the SCC Veterinarian

**15. Section B ( to be signed in Sections 16-18 by the Official Veterinarian, after the Center****Veterinarian has signed):**

I, the undersigned Official Veterinarian of ..... (insert name of Member State of the European Union where semen was collected) certify that:

- 15.1 The SCC was last inspected by the Competent Authority on \_\_\_\_\_ and has no outstanding violations under the provisions of Delegated Regulation (EU) 2020/686.
- 15.2 The Center Veterinarian that completed Section A of this certificate is authorized by the National Veterinary Service to perform this service.
- 15.3 The Center Veterinarian is not subject to any past or current disciplinary actions that would result in ineligibility to certify the health of the animals at the SCC, and meets all other applicable requirements of Regulation (EU) 2017/625 or of the Competent Authority, as applicable.
- 15.4 The donor animals for the semen to be exported to the United States have been part of the national flock/herd of the Member State where the semen was collected and are free from any movement or quarantine restrictions, according to Section 10.A above;
- 15.5 Any tests required under Section A. above for ovine or caprine semen exported to the United States were performed by testing methods recognized by the World Organization for Animal Health (WOAH) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, as acceptable for international trade.
- 15.6 The laboratory tests mentioned in 10.8 to 10.9 were carried out with negative results in a laboratory approved by the competent veterinary services;
- 15.7 The EU Member State, \_\_\_\_\_, is free of foot-and-mouth disease (FMD), surra contagious caprine pleuropneumonia, and Rift Valley Fever.
- 15.8 In \_\_\_\_\_ (the EU Member State):
- a. Scrapie is a compulsorily notifiable disease and an effective surveillance and monitoring system for scrapie is in place.
  - b. Sheep and goats affected with scrapie are maintained under quarantine in a manner that will prevent disease spread until the animal is no longer living and the remains have been disposed of in a way that prevents disease spread.
  - c. The feeding of sheep and goats with meat-and-bone meal or greaves derived from ruminants has been banned and the ban is effectively enforced in the whole region for the entire life of the animal; and the donors have not been in any other country/region with a less restrictive feeding policy prior to the collection of semen for export.
- 15.9 Ruminant products used in commercial semen extenders in the Member State where the semen was collected were sourced from countries considered by USDA to be free from foot-and mouth disease as listed in 9 CFR Part 94 and other official publications.
- 15.10 The semen to be exported to the United States was maintained under lock and key or in the custody of the SCC veterinarian, and segregated from other semen of lesser health status, until it was placed in the shipping container and sealed with official seals of the Member State where the semen was collected;
- 15.11 None of the semen for export to the USA has been stored or transported in containers with semen produced under less than equivalent animal health conditions.
- 15.12 The entire shipment exported under this certificate (including semen that might have been collected in more than one approved semen collection center by the same SCC veterinarian) has been

<p style="margin: 0;">maintained under continuous oversight of the Official Veterinarian until the conveyance is scheduled to depart for the United States.</p> <p style="margin: 10px 0 0 0;">15.13 The shipping containers were sealed with an approved seal from the competent authority of the exporting Member State, and the seal number(s) is (are) recorded in Box 9.8</p> <p style="margin: 10px 0 0 0;">15.14 The semen is routed directly to the United States from the Member State in which it was collected with no stops en route other than those provided on the USDA import permit.</p>		
<p>16. Date and place</p>	<p>17. Name and title of Official Veterinarian</p>	<p>18. Signature and stamp<sup>5</sup> of the Official Veterinarian</p>
<p>Notes:</p> <p>1 Delete as appropriate.</p> <p>2 Animals must be individually tested negative for bovine TB by an intradermal TB test using purified protein derivative <i>Mycobacterium bovis</i> tuberculin. A negative test means no detectable response using both visual and manual palpation when read 72 hours following injection with intradermal tuberculin.</p> <p>3 For brucellosis, the following tests are acceptable (line out non-applicable options):</p> <p style="margin-left: 20px;">Brucella abortus/melitensis:</p> <p style="margin-left: 40px;">1) the FPA (a negative result is considered anything less than 20 millipolar above the negative control value);</p> <p style="margin-left: 40px;">OR</p> <p style="margin-left: 40px;">2) the rose-bengal test/card test, (utilizing 8% <i>Brucella abortus</i>/ 3% <i>Brucella melitensis</i> lipopolysaccharide antigen; a negative result is the absence of any visible reaction);</p> <p style="margin-left: 40px;">OR</p> <p style="margin-left: 40px;">3) the complement fixation test (Note: ewes that have been vaccinated with <i>Brucella abortus</i> S19 vaccine between 3 and 6 months of age are considered negative if the sera have no fixation reaction up to a titer of 30 ICFTU/ml when the animals are tested at an age of 18 months or older);</p> <p style="margin-left: 40px;">OR</p> <p style="margin-left: 40px;">4) the buffered plate antigen agglutination test (read for agglutination immediately after the 8-minute period is completed; a negative result is the absence of any visible reaction).</p> <p style="margin-left: 20px;">Brucella ovis (in the case of sheep): acceptable tests include either:</p> <p style="margin-left: 40px;">1) the enzyme- linked immunosorbent assay (ELISA), in accordance with the WOA H Terrestrial Manual;</p> <p style="margin-left: 40px;">OR</p> <p style="margin-left: 40px;">2) the complement fixation test, (Sera with no fixation reaction for a titer less than 50 ICFTU/ml are considered to be negative)</p> <p>4 Semen collected in an EU Member State at different approved locations that are under the supervision of the same SCC veterinarian may be qualified for exportation to the United States and included in a single shipment, provided that the SCC veterinarian can certify the integrity of the total shipment under relevant sections above, and that none of the semen was transported in a container with semen which was collected under less than equivalent health standards. This information must be provided to the Official Veterinarian for semen collected by the same SCC Veterinarian at each different SCC.</p> <p>5 The signature and the stamp must be in a different color from that of the printed text.</p>		