

HEALTH CERTIFICATE FOR EXPORT OF OVINE OR CAPRINE SEMEN FROM ICELAND TO THE UNITED STATES OF AMERICA

1. Iceland competent authority:	2. Health certificate No.
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A. ORIGIN OF SEMEN

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. DESTINATION OF SEMEN

8. Name and address of the consignee:

C. IDENTIFICATION OF SEMEN

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, is currently approved in accordance with Chapters I and II of Annex D of Council Directive 92/65/EEC.
- 10.2 The ovine or caprine semen donors, and any teaser or mounting animals, were established as residents of the SCC in accordance with Chapter II of Annex D, Council Directive 92/65/EEC, as amended (including any related applicable requirements under Council Directive 91/68/EEC); and in accordance with any additional U.S. import requirements as specified in this certificate. 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.
- 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 Iceland; 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 or rinderpest, 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 Iceland 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 or rinderpest, 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.

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.

Scrapie:

- a. Insofar as can be determined after due inquiry, the semen donor has not been in a herd nor had direct contact with other animals that had been a herd where scrapie has occurred within 5 years of the date of collection of semen for export to the United States.
- b. The semen donor showed no evidence of any condition resembling scrapie at the time of semen collection.
- c. Insofar as can be determined after due inquiry, the parents of the semen donor were not affected with any spongiform encephalopathy disease.
- d. The donor animals are permanently identified, to enable traceback to their herd/flock of origin;
- e. The donor animals have been kept since birth in herds/flocks in which no case of scrapie had been confirmed during their residency;
- f. The donor animals neither showed clinical signs of scrapie at the time of semen collection nor developed scrapie between the time of semen collection and the export of semen to the United States;

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*]:

Either¹:

The animals have been resident in the SCC for less than one year, and come from a flock/herd of origin tested negative for bovine tuberculosis² and brucellosis³ 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 tuberculosis² and brucellosis³ during annual herd tests at the SCC.

OR The animals have been resident in the SCC for at least 120 days. All animals in the SCC were tested for tuberculosis and brucellosis on two occasions, at least 60 days apart.

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. **EITHER**¹ Schmallenberg virus (SBV) No cases of SBV have been diagnosed or reported in Iceland

OR the semen for export to the United States was 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 (BTV): the donor animal was either¹:

- 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): Either¹:

The animals originate from Iceland 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 Tested by competitive enzyme-linked immunosorbent assay (C-ELISA) AND by either a whole-blood PCR test or a virus neutralization test (VNT) for all 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).

d. Maedi- Visna disease: using an immunodiffusions test with negative results.

11. Collection and processing certifications⁴

11.1 The SCC veterinarian supervised the collection and processing of the semen for shipment to the United States.

- 11.2 Semen collection equipment coming 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.
- 11.3 The semen was packaged in ampules or straws permanently marked with the name, breed, and individual identification number of the donor and the date of collection.
- 11.4 Any antibiotics 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.
- 11.5 Ruminant products used in commercial semen extenders in the Iceland, where the semen was collected, were sourced from countries considered by USDA to be free from foot-and mouth disease and rinderpest as listed in 9 CFR Part 94 and other official publications.
- 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.
- 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.
- 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 Iceland; and were maintained under supervision until such time as the ampules/straws were placed in the shipping tank and sealed under official veterinary supervision.

12. Date and place	13. Name and qualification of the SCC Veterinarian	14. Signature of the SCC Veterinarian
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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 ofIceland, 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 Council Directive 92/65/EEC.
- 15.2 The Center Veterinarian completing 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 Council Directive 96/93/EEC 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 Iceland, 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 Office International des Epizooties (OIE) 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 Iceland is free of foot-and-mouth disease (FMD), rinderpest, contagious caprine pleuropneumonia, Rift Valley Fever and Epizootic Hemorrhagic Disease (EHD).
- 15.8 In Iceland:
- 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 preventing 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 Insofar as can be determined, during the 60 days prior to the collection of semen for export to the United States, the donors were not corralled, pastured, or held with other animals where there was any evidence of scrapie, Maedi-visna, enzootic abortion of ewes, brucellosis or tuberculosis (TB), making them ineligible as donors of semen for export to the United States.
- 15.10 During the 24 months prior to the collection of semen for export to the United States, there has been no clinical or test evidence of TB or brucellosis found in the donor or the donors' herd of origin or in the place where semen is collected.
- 15.11 The premises where the semen is collected, and the herds of origin of the donor(s) and all contact animals are in an area at least 50 kilometers from any known occurrence of FMD or rinderpest within the three months prior to and the month following the collection of semen for the United States. The herds of origin of the semen donors are qualified for exporting semen to the United States regarding Maedi-Visna.
- 15.12 Ruminant products used in commercial semen extenders in Iceland, where the semen was collected, were sourced from countries considered by USDA to be free from foot-and mouth disease and rinderpest as listed in 9 CFR Part 94 and other official publications.
- 15.13 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 Iceland, where the semen was collected;
- 15.14 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.
- 15.15 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 maintained under continuous oversight of the Official Veterinarian until the conveyance is scheduled to depart for the United States.
- 15.16 The shipping containers were sealed with an approved seal from the competent authority of the exporting Iceland, and the seal number(s) is (are) recorded in Box 9.8
- 15.17 The semen is routed directly to the United States from Iceland where it was collected with no stops en route other than those provided on the USDA import permit.

16. Date and place	17. Name and title of Official Veterinarian	18. Signature and stamp ⁵ of the Official Veterinarian
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Notes:

1. Delete as appropriate
2. Animals must be individually tested negative for bovine TB by an intradermal TB test using purified protein derivative *Mycobacterium bovis* tuberculin. A negative test means no detectable response using both visual and manual palpation read 72 hours following injection with intradermal tuberculin
 - a. The first test should be within 30 days prior to the first collection of semen. A second test is required not less than 30 and not more than 120 days after the date of the last semen collection. Consecutive TB tests must be conducted at least 60 days apart.
 - b. If an animal vaccinated against *Mycobacterium avium ssp paratuberculosis* (Johne's disease) responds to the *M. bovis* PPD in the initial skin test (hereafter referred to as a "responder"), a comparative cervical tuberculin test can be applied to determine eligibility of the remainder of the flock/herd for semen collection and export. If the responder is negative on the CCT test for *M. bovis*, the semen of the remainder of the flock/herd will be eligible for export. Responders are not eligible for collection and export to the United States.
3. For brucellosis, the following tests are acceptable: *Brucella abortus/melitensis*:
 - a. The FPA (a negative result is considered anything less than 20 millipolar above the negative control value.
OR
 - b. The rose-bengal test/card test, (utilizing 8% *Brucella abortus*/ 3% *Brucella melitensis* lipopolysaccharide antigen; a negative result is the absence of any visible reaction);
OR
 - c. The complement fixation test (Note: ewes that have been vaccinated with *Brucella abortus* 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);
OR
 - d. 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).
4. *Brucella ovis* (in the case of sheep): acceptable tests include either:
 - a. The enzyme- linked immunosorbent assay (ELISA), (using the International Standard standards for anti-*Brucella ovis* S serum referenced in the OIE Terrestrial Manual);
OR
 - b. The complement fixation test, (Sera with no fixation reaction for a titer less than 50 ICFTU/ml are considered to be negative)
5. Semen collected in Iceland at different approved locations under the supervision of the same SCC veterinarian may be qualified for exportation to the United States and included in a single shipment, provided 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 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.
6. The signature and the stamp must be in a different color from that of the printed text.