This protocol describes the conditions required to import semen from domestic sheep (*Ovis spp.*) and goats (*Capra spp.*) according to regulations found in 9 CFR Part 98.

Note: In accordance with this protocol, USDA APHIS reserves the right to inspect the germplasm collection, processing and export facilities as needed in order to ensure USDA APHIS imports standards are met.

1. GENERAL REQUIREMENTS

1.1. The importer must obtain an import permit from:

U.S. Department of Agriculture (USDA)
Animal and Plant Health Inspection Service (APHIS)
Veterinary Services (VS)
Strategy & Policy (S&P)
4700 River Road, Unit 39
Riverdale, Maryland
20737- 1231

Telephone: (301) 851-3300, Option 2

Fax: (301) 734-4704

Web Site: **APHIS Imports**

The application, VS Form 17-129, "Application for Import or in Transit Permit," may be obtained by writing or telephoning S&P, or by downloading it from the APHIS web site: Animal Health Permits

- 1.2. The semen must originate from a semen collection center (SCC) or from premises that are under the general supervision of a veterinarian employed by Icelandic Food and Veterinary Authority (MAST) for the collection of sheep or goat semen for export to the United States.
- 1.3. An official health certificate is required. The official health certificate must be issued by a veterinarian designated by the Icelandic Food and Veterinary Authority (MAST) and must be endorsed by a veterinarian employed by MAST attesting to the certifications and tests required in this protocol. The health certificate must accompany the semen to the port of entry designated on the USDA import permit.

2. CERTIFICATION STATEMENTS:

- 2.1. Iceland is free of foot-and-mouth disease (FMD), contagious caprine pleuropneumonia, Rift Valley Fever and epizootic hemorrhagic disease (EHD).
- 2.2. The donor animals must be part of Iceland's national herd for a minimum period of

time. Paragraph 2.2.1 and 2.2.2 describe how the United States defines "part of the national herd" and for what time frame it must be part of the national herd:

- 2.2.1. If the donor animals were imported from countries recognized by the USDA to be free of FMD, then these animals must have been free of any import restrictions and able to move freely within Iceland's national herd for a minimum of 60 days prior to collecting the semen for export to the United States.
- 2.2.2. If the donor animals were imported from a country not recognized by the USDA to be free of FMD, then the donor animals must have been free of any import restrictions and have been able to move freely within Iceland's national herd for a minimum of 90 days prior to collecting the germplasm for export to the United States, and are not otherwise subject to any movement restrictions or quarantines due to disease.
- 2.3. Prior to the collection of semen for export to the United States, the donors were inspected by the veterinarian issuing the health certificate and found to be clinically free of contagious diseases.
- 2.4. 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 in which there was any evidence of scrapie, Maedi- visna, enzootic abortion of ewes, brucellosis or tuberculosis (TB) which would make them ineligible as donors of semen for export to the United States.
- 2.5. 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.
- 2.6. The premises where the semen is collected, and the herds of origin of the donor 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.
- 2.7. The following statements concerning scrapie can be certified:
 - 2.7.1. 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.
 - 2.7.2. The semen donor showed no evidence of any condition resembling scrapie at the time of semen collection.
 - 2.7.3. Insofar as can be determined after due inquiry, the parents of the semen

donor were not affected with any spongiform encephalopathy disease.

- 2.7.4. The donor animals are permanently identified, to enable traceback to their herd/flock of origin;
- 2.7.5. The donor animals have been kept since birth in herds/flocks in which no case of scrapie had been confirmed during their residency;
- 2.7.6. 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;
- 2.7.7. In Iceland:
 - 2.7.7.1. Scrapie is a compulsorily notifiable disease; and an effective surveillance and monitoring system for scrapie is in place.
 - 2.7.7.2. Affected sheep and goats are slaughtered and completely destroyed;
 - 2.7.7.3. The feeding of sheep and goats with meat-and-bone meal or greaves derived from ruminants has been banned and the ban has been effectively enforced in the whole region since_____(the date of the effective enforcement of a ruminant-to-ruminant feed ban). The donors have not been in any other regions prior to the collection of semen for export.
- 2.8. The following certifications are made with respect to any sheep or goats resident in the SCC:
 - 2.8.1. The animals are permanently identified to enable traceback to their flock/herd of origin.
 - 2.8.2. 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.
 - 2.8.3. 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.
 - 2.8.4. 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.
- 2.9. The following certifications are made with respect to bovine tuberculosis and brucellosis:

- 2.9.1. **EITHER**¹ 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 and brucellosis 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;
- 2.9.2. **OR** the animals have been resident in the SCC for more than one year, and were tested negative for bovine tuberculosis and brucellosis during annual herd tests at the SCC.
- 2.9.3. **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.
- 2.10. Schmallenberg virus (SBV):
 - 2.10.1. **EITHER**¹ no cases of SBV have been diagnosed in Iceland;
 - 2.10.2. **OR** the semen for export to the United States was collected prior to June 1, 2011;
 - 2.10.3. **OR** the semen 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.
 - 2.10.4. Tests were performed in a laboratory approved by the National Competent Authority.

3. TESTS

- 3.1. Serologic tests should be conducted within 30 days of first collection of semen and again not less than 30 nor more than 120 days after semen collection.
 - 3.1.1. For *Brucella abortus/melitensis* evaluation, the following tests are acceptable:
 - 3.1.1.2. **EITHER** the FPA (a negative result is considered anything less than 20 millipolar above the negative control value);
 - 3.1.1.3. **OR** 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);
 - 3.1.1.4. **OR** the complement fixation test is a negative result (Note: ewes

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);

- 3.1.1.5. **OR** 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).
- 3.1.2. Brucella ovis (in the case of sheep): acceptable tests include
 - 3.1.2.1. **EITHER** the enzyme-linked immunosorbent assay (ELISA), (using the International Standard standards for anti-*Brucella ovis* S serum referenced in the OIE Terrestrial Manual);
 - 3.1.2.2. **OR** the complement fixation test, (sera with no fixation reaction for a titer less than 50 ICFTU/ml are considered to be negative)
- 3.1.3. Maedi-Visna disease using an immunodiffusion test with negative results.
- 3.2. TB tests specified in 2.9 must consist of negative intradermal TB tests using purified protein derivative *Mycobacterium bovis* tuberculin.
 - 3.2.1. The first test should be within 30 days prior to the first collection of semen.
 - 3.2.2. A second test is required not less than 30 days, 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.
 - 3.2.3. 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.
 - 3.2.4. If the responder is negative on the CCT test for *M. bovis*, the remainder of the flock/herd will be eligible for export. Responders are not eligible for collection and export to the United States.
- 3.3. The animals are certified as stipulated below, or were tested using the following technical criteria for other specific tests:
 - 3.3.1. Bluetongue virus (BTV):
 - 3.3.1.1. The donor animal was **EITHER**¹ 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;

- 3.3.1.2. **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;
- 3.3.1.3. **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;
- 3.3.2. Epizootic hemorrhagic disease (EHD):
 - 3.3.2.1. **EITHER**¹The animals originate where no cases of EHD have been reported within the previous 12 months, and where no serological evidence of EHD infection exists:
 - 3.3.2.2. **OR** the following serotypes of EHD exist: and animals were tested on two occasions by an agar gel immunodiffusion test (AGID);
 - 3.3.2.3. **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 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).
- 3.4 The tests of the donor animals must be conducted at laboratories and by veterinarians approved by the Chief Veterinary Officer of the Competent Veterinary Authority.

4. THE HEALTH CERTIFICATE MUST CONTAIN:

- 4.1. The identification of the donors by breed and registry number.
- 4.2. The dates on which semen was collected.
- 4.3. The dates and methods of testing and results of the tests on the donors.
- 4.4. The name and address of the semen collection unit or premise where the semen was collected and processed for this shipment.
- 4.5. The name and address of the consignor and consignee.
- 4.6. The name and address of the laboratory conducting the tests.

5. PROCESSING CERTIFICATION

5.1. The veterinarian issuing the health certificate must supervise the collection and

processing of the semen for shipment to the United States.

- 5.2. The semen must be packaged in ampules or straws permanently marked with the name, breed, and individual identification number of the donor and the date of collection.
- 5.3. The veterinarian issuing the health certificate must certify that the shipping tank is new or that it has been cleaned and sanitized and only fresh liquid nitrogen has been used to charge the tank.
- 5.4. The veterinarian issuing the health certificate must certify that after processing, the ampules/straws were segregated in a storage area separate from other embryos and semen not intended for export to the United States at the storage facility designated by MAST and were maintained under MAST supervision until such time as the ampules/straws were placed in the shipping tank and sealed with Government seals. The seal numbers must be recorded on the health certificate.
- 5.5. It is acceptable that semen collected at different locations in Iceland under MAST supervision and qualified for exportation to the United States may be included in a single shipment, provided that MAST can certify the integrity of the total shipment, and that none of the germplasm was transported in a container with germplasm which was collected under less than equivalent health standards.
- 5.6. The shipment must be routed direct to the United States with no stops en route other than those provided for on the USDA import permit.

6. SCRAPIE SURVEILLANCE FOLLOWING IMPORTATION INTO THE UNITED STATES: Applications for a permit to import sheep and goat semen must include statements that:

- 6.1. All first generation (F1) progeny resulting from imported semen will be identified with a permanent official identification consistent with the provisions of the USDA Scrapie Program and
- 6.2. Records of any sale of F1 progeny, including the name and address of the buyer, will be kept for a period of 5 years. APHIS may view and copy these records during normal business hours.

7. ADDITIONAL REQUIREMENTS:

Importers are advised that individual states may additional import regulations. It is the importer's responsibility to verify these conditions and to meet them. The importer should contact the U.S. State veterinarian (<u>State Regulations and Import Requirements</u>) of the destination state to determine the requirements.

8. ARRIVAL AND INSPECTION AT THE PORT OF ENTRY

- 8.1. The shipment must be routed directly to the United States from Iceland with no stops en route other than those provided on the USDA import permit. This shipment may not transit a region considered by USDA APHIS to have foot and mouth disease (FMD) as noted on the USDA APHIS webpage: Animal Health Status
- 8.2. On arrival at the port of entry, the importer or the importer's agent must present the original health certificate and the original import permit for the semen to an inspector at the port.
- 8.3. The shipping container and all straws or ampules containing semen must be made available for inspection at the port of entry and may not be removed from such port of entry until an inspector determines that the semen are eligible for importation in accordance with this protocol and releases them.

9. SEMEN REFUSED ENTRY

If any semen is determined to be ineligible for importation into the United States on arrival at the port of entry, the importer must remove such semen from the United States within 30 days, or the semen will be destroyed.