USDA APHIS VETERINARY SERVICES STRATEGY & POLICY
PROTOCOL FOR THE IMPORTATION OF
SHEEP AND GOAT SEMEN FROM FMD FREE
MEMBER STATES OF THE EUROPEAN UNION
Updated December 2023

This protocol describes conditions required to import semen from domestic sheep (*Ovis spp.*) and goats (*Capra spp.*) according to regulations found in 9 CFR Part 98. It provides additional clarification as intended in the "Health Certificate for Export of Ovine or Caprine Semen from Member States of the European Union to the United States of America" posted on the USDA APHIS Live Animal Imports website.

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. Additionally, USDA APHIS requires all diagnostic test records be kept for a minimum of five (5) years on the premises of export and be made available for audit by this Agency upon request.

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**

The application, **VS Form 17-129, "Application for Import or in Transit Permit,"** may be filed electronically using the eFile system. Alternatively, the form may be downloaded from the APHIS web site and submitted by emailing the completed application and all required supporting documentation to laipermits@usda.gov for processing.

1.2. Applications for a permit to import sheep and goat semen must include statements:

1.2.1. All first-generation offspring resulting from imported semen will be identified with a permanent official identification consistent with the provisions of the USDA Scrapie Program and

1.2.2. Records of any sale of first-generation offspring, 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.

1.3. An official health certificate is required. The official health certificate must be issued by a veterinarian designated by the Competent Veterinary Authority of the Member State and must be endorsed by a veterinarian employed by Competent Veterinary Authority of the Member State 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.

1.4. The semen must originate from a semen collection center (SCC) or from premises that are under the general supervision of a veterinarian employed by Competent Veterinary Authority of the Member State for the collection of sheep or goat semen for export to the United States.

2. CERTIFICATION STATEMENTS:

2.1. The European Union Member State is free of foot-and-mouth disease (FMD), contagious caprine pleuropneumonia, Rift Valley Fever, and surra.

2.2. The donor and teaser animals must be part of Member State'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 and teaser animals were imported from countries recognized by the USDA to be free of FMD: these animals must have been free of any import restrictions and able to move freely within Member State's national herd for a minimum of 60 days prior to collecting semen for export to the United States.

2.2.2. If the donor and teaser animals were imported from a country not recognized by the USDA to be free of FMD, then the animals must have been free of any import restrictions and have been able to move freely within Member State's national herd for a minimum of 90 days prior to collecting the germplasm for export to the UnitedStates, 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 and teasers were inspected by the veterinarian issuing the health certificate and found to be clinically free of contagious diseases.

2.4. As far as can be determined, during the 60 days prior to the collection of semen for export to the United States, the donors and teasers 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) 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.

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.

2.6. The following statements concerning scrapie can be certified:

2.6.1. 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).

2.6.2. The donor animals are permanently identified, to enable traceback to their herd/flock of origin;

2.6.3. The donor animals have been kept since birth in herds/flocks where no case of scrapie had been confirmed during their residency;

2.6.4. The donor animals neither showed clinical signs of scrapie at the time of semen collection, or prior to the export of semen to the United States;

2.7. In the Member State:

2.7.1. Scrapie is a compulsorily notifiable disease; and an effective surveillance and monitoring system for scrapie is in place.

2.7.2. Scrapie- affected sheep and goats are slaughtered and completely destroyed; and

2.7.3. 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 the 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.

2.8.5. The following certifications are made with respect to bovine tuberculosis[1] and brucellosis:

2.8.5.1. **Either**: The animals have been resident in the SCC for less than one year, and come from a flock/herd of origin that 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;

2.8.5.2. **OR** the animals have been resident in the SCC for less than a year but were isolated for at least 120 days prior to entry into the SCC. All animals in the SCC were tested for tuberculosis and brucellosis on two occasions, at least 60 days

apart. ***See "Additional Guidance" in item 10 below**.

2.8.5.3. **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. Schmallenberg virus (SBV):

2.9.1. **Either** the semen for export to the United States was collected prior to June 1, 2011;

2.9.2. **OR** 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.

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 brucellosis, the following tests are acceptable:

3.1.1.1. *Brucella abortus/melitensis*:

3.1.1.1.1. The FPA (a negative result is considered anything less than 20 millipolar above the negative control value);

3.1.1.1.2. **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);

3.1.1.1.3. **OR** 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);

3.1.1.1.4. **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).

3.1.1.2. *Brucella ovis* (in the case of sheep): acceptable tests include either:

3.1.1.2.1. The enzyme- linked immunosorbent assay (ELISA), (using the International Standard standards for anti-*Brucella ovis* serum referenced in the World Organization of Animal Health (WOAH) Terrestrial Manual);

3.1.1.2.2. **OR** the complement fixation test, (sera with no fixation reaction for a titer less than 50 ICFTU/ml are considered to be negative).

3.2. TB tests specified in 2.8.5 must consist of negative intradermal TB tests using purified protein derivative *Mycobacterium bovis* tuberculin. 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.

3.2.1. 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.

3.2.2. 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): the donor animal was:

3.3.1.1. **EITHER** 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;

3.3.1.2. **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;

3.3.1.3. **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;

3.3.1.4. **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** 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;

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.

3.5. 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 Carpine Arthritis Encephalitis virus (in the case of goats) has been clinically detected in the three (3) years prior to the collection of semen to be exported.

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[2]

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 collection center is authorized by the Competent Veterinary Authority of the Member State. The center has proper areas for semen collection, processing, freezing, and storage, for residence of donor(s) and teasers, and proper record keeping. The center has a control program for vectors and pests, and good cleaning and disinfection. In the semen collection center, the equipment used for collection, processing, and storage is new or properly cleaned and disinfected.

5.3. Semen collection equipment coming into contact with rams or bucks, or their secretions and excretions, was thoroughly disinfected after each use. Good laboratory practices were followed during collection and processing of semen in order to minimize the possible introduction of microbial contamination.

5.4. 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.

5.5. 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.

5.6. 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.

5.7. The veterinarian issuing the health certificate must certify, 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 Competent Veterinary Authority of the Member State and were maintained under Competent Veterinary Authority of the Member State 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.

5.8. The veterinarian issuing the health certificate must certify the shipping tank is new or has been cleaned and sanitized; only fresh liquid nitrogen has been used to charge the tank.

5.9. 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.

5.10. It is acceptable for semen collected at different locations within a Member State under the Competent Veterinary Authority of the Member State supervision, and qualified for exportation to the United States, to be included in a single shipment, provided that Competent Veterinary Authority of the Member State can certify the integrity of the total shipment, and none of the germplasm was transported in a container with germplasm collected under less than equivalent health standards.

5.11. 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. POST-ENTRY RESTRICTIONS AFTER IMPORTATION INTO THE UNITED STATES

6.1. Post-entry requirements pertaining to imported ovine and/or caprine semen from the EU can be found on the APHIS website.

6.2. Sheep and goat semen may only be imported for transfer to recipient females in the United States if the flock or herd in which recipients reside is listed in the National Scrapie Database; except that APHIS may permit importation of sheep and goat semen to an APHIS-approved storage facility where they may be kept until later transferred to recipient females in a flock or herd in the United States listed in the APHIS National Scrapie Database, and under such conditions as the Administrator deems necessary to trace the movement of the imported semen. Imported sheep or goat semen not otherwise restricted by the conditions of an import permit may be transferred from a listed flock or herd to any other listed flock or herd or from an approved semen storage facility to a listed flock or herd or another approved semen storage facility with written notification to the responsible APHIS Veterinary Services Service Center.

6.3. The importer, the owner of a recipient flock or herd to which delivery of the semen is made, or the owner of an APHIS-approved semen storage facility must maintain records of the disposition (including destruction) of imported or stored semen for 5 years after the semen is transferred or destroyed. These records must be made available during normal business hours to APHIS representatives on request for review and copying.

6.4. The owner of all sheep or goats resulting from semen imported under this section shall:

6.4.1. Identify them at birth with a permanent official identification number consistent with the provisions of 9 CFR 79.2; such identification may not be removed except at slaughter and must be replaced if lost;

6.4.2. Maintain a record linking the official identification number to the imported semen, including a record of the replacement of lost tags;

6.4.3. Maintain records of any sale or disposition of such animals, including the date of sale or disposition, the name and address of the buyer, and the animal's official identification number; and

6.4.4. Keep the required records for a period of 5 years after the sale or death of the animal. APHIS may view and copy these records during normal business hours.

7. ARRIVAL AND INSPECTION AT THE PORT OF ENTRY

7.1. Upon 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.

7.2. 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 the semen are eligible for importation in accordance with this protocol and releases them.

8. ADDITIONAL STATE REQUIREMENTS: Importers are advised that individual states may have additional import requirements. It is the importer's responsibility to verify and meet these conditions. The importer should contact the U.S. State veterinarian (State Regulations and Import Requirements) of the destination state to determine the state regulations.

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 this semen from the United States within 30 days, or the semen will be destroyed.

10. ADDITIONAL GUIDANCE:

For animals that are not part of a SCC or will not remain in a SCC permanently, there is an option to form a flock/herd subgroup of sheep/goat semen donors and teasers. This guidance outlines the minimum isolation requirements and the proper TB & Brucellosis testing prior to semen collection, all of which must be sanctioned by the Competent Veterinary Authority of the Member State. Health status of animals must be maintained throughout the pre-collection isolation period, transport to the semen collection center (if isolation performed elsewhere), during the semen collection period, transport from the semen collection center (if isolation performed elsewhere) and during the post-collection testing period.

10.1. Definition of a herd/flock

10.1.1. For testing purposes, the herd/flock is defined as all goats/sheep that are 12 months of age or older, and all goats/sheep in the herd that are less than 12 months of age and

were not born into the herd.

10.1.2. A herd/flock of donor and teaser animals can be designated as a separate "herd sub-group or sub-herd", if the animals are assembled as a separate group for 4 months (120 days) from the time of the last addition to the group, to be eligible for recognition as a herd/flock. The isolation area must be separated from other animal areas by a minimum 30 feet. This minimum spacing should also prevent nose- to- nose contact with other ruminants outside the isolation area.

10.1.3. The entire facility must be double-fenced with heavy gauge woven wire fencing at least 1.8 meters high in order to keep out all domestic and wild animals capable of transmitting ruminant diseases of concern.

10.1.4. The space between the fences must be at least 3 meters wide (approximately 10 feet) and kept free of all vegetation.

10.1.5. No pets will be allowed inside the quarantine area.

10.1.6. Personnel must follow proper biosecurity practices in the isolation/quarantine area, for example (but not limited to those listed below):

10.1.6.1. Separate feed and equipment must be used for the animals in isolation.

10.1.6.2. Personnel need to disinfect prior to entering the isolation area.

10.1.6.3. Personnel should change to clean attire and scrub/disinfect boots accordingly when entering the isolation area.

10.1.6.4. Only approved personnel following proper biosecurity practices should be allowed within the isolation area.

10.2. **Testing requirements for a flock subgroup**

10.2.1. TB and brucellosis testing will follow guidelines stated in the Model Health Certificate for Export of Ovine or Caprine Semen from Member States of the EU to USA.

10.2.2. If a sub-group of donor and teaser animals is formed as per above guidance (10.1.2 above), there should be at least two TB and brucellosis tests performed on the donor animals during quarantine period, prior to the collection of semen.

10.2.2.1. The first tests must be performed at the beginning of the 120-day isolation/quarantine period.

10.2.2.2. With the second test occurring at least 60 days after the first test but within 30 days before the first date of semen collection.

10.2.3. Per section 3.3 of the protocol, post-collection TB and brucellosis testing is required not less than 30 and not more than 120 days after the date of the last

semen collection.

10.2.4. The Center veterinarian must also certify that no clinical, microbiological, or serological evidence of these diseases were found during the 24 months prior to export of the semen to the United States.

NOTE: Once donor animals have left the quarantine (including the post-collection testing period) and/or have been exposed to animals of lesser health status, the donors will be required to again undergo the isolation and testing as prescribed in the health certificate and this document.

11. FOOTNOTES:

[1.] 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 when read 72 hours following injection with intradermal tuberculin.

[2.] 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.