1. GENERAL REQUIREMENTS

1.1. The importer must obtain an import permit from the:

U.S. Department of Agriculture (USDA)
Animal and Plant Health Inspection Service (APHIS)
Veterinary Services (VS)
National Import and Export Services (NIES),
Unit 39 4700 River Road
Riverdale, MD 20737-1231

Telephone: (301) 851-3300, Menu option 2.
Fax: (301) 734-4704

The application (VS Form 17-129, Application for Import or In-Transit Permit,), with accompanying instructions, may be obtained by writing or telephoning NIES, or by downloading it from the APHIS web site:  http://www.aphis.usda.gov/animal_health/permits/

1.2. An official health certificate is required. The official health certificate must be issued by a veterinarian designated by the Ministry for Primary Industries (MPI), New Zealand and must be endorsed by a MPI veterinarian. The health certificate must accompany the embryos to the port of entry designated on the USDA import permit.

1.3. The embryos must be collected by an embryo collection (EC) team that is approved by MPI, and collected at an embryo collection unit meeting the criteria in Section 2.

1.3.1. The embryo collection team is a group of competent technicians, including at least one veterinarian, to perform the collection, processing and storage of embryos. The following conditions apply:

1.3.1.1. The team is supervised by a team veterinarian.

1.3.1.2. The team veterinarian is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors, and disinfection and hygienic procedures.

1.3.1.3. Team personnel are adequately trained in the techniques and principles of disease control. High standards of hygiene are practiced to preclude the introduction of infection.

1.3.1.4. The collection team have adequate facilities and equipment for: collecting embryos;
1.3.1.4.1. Processing and treatment of embryos at a permanent site or mobile laboratory;

1.3.1.4.2. Storing embryos.

1.3.1.4.3. [Note: These processes in points a through c above need not necessarily be performed at the same location.]

1.3.1.5. Tests of all donors must be conducted in laboratories designated and approved by the MPI to conduct the tests.

2. THE EMBRYO COLLECTION UNIT: Goat and sheep embryos are eligible for exportation to the United States if they were conceived, collected, processed, and stored prior to exportation at an EC unit or facility approved by MPI. The embryo collection may be carried out on the premises where the donor dam’s herd of origin is kept, or at any other location, provided that the following requirements are met:

2.1. Animal holding and breeding area(s). The EC facility has an area or areas for holding the donor dams and for breeding them (either by natural breeding or artificial insemination).

2.2. Embryo collection area. The EC facility has a room or outdoor area for collection of embryos that contains a device or devices for restraining goats and sheep during embryo collection. If the EC area is a room, then the floor, walls, and ceiling are impervious to moisture and disinfection. If the EC area is an outdoor area, then the area has a floor that is impervious to moisture and is constructed of materials that can withstand repeated cleaning and disinfection. If the outdoor area also has walls or a roof, the walls or roof also are impervious to moisture and constructed of materials that can withstand repeated cleaning and disinfection.

2.3. Embryo processing area. The EC team utilizes an enclosed room (which may be a separate mobile facility) that is used only for processing embryos. The walls, floor, and ceiling of the room are impervious to moisture and constructed of materials that can withstand repeated cleaning and disinfection. The room contains a work surface for handling the embryos, such as table or countertop that is impervious to moisture. The room also contains a microscope with a minimum of 50x magnification and equipment for freezing the embryos.

2.4. Embryo storage area. The EC area has a lockable storage tank that is used only for storing frozen embryos intended for exportation to the United States.

2.5. Area for cleaning and disinfection or sterilizing equipment. The EC team utilizes an enclosed room for cleaning and disinfecting or sterilizing equipment used for the artificial insemination or for the collection, processing, or storage of embryos. The walls, floor, and ceiling of the room are impervious to moisture and constructed of materials that can withstand...
3. **THE HEALTH CERTIFICATE MUST INCLUDE THE FOLLOWING INFORMATION:**

3.1. The name and address of the place where the embryos were collected;

3.2. The name and address of the team veterinarian who monitored the collection of embryos;

3.3. The date of embryo collection(s);

3.4. The identifying information for of the donor dam and donor sire, including breed, age and identification numbers for each animal;

3.5. The number of ampules or straws covered by the health certificate and the identification number or code on each ampule or straw;

3.6. The dates, types, and results of all examinations and tests performed on the donor dam and donor sire in accordance with Section 4 below;

3.7. The name and address of the consignor and consignee;

4. **CERTIFICATIONS:**

4.1. New Zealand is free of Foot-and-Mouth Disease (FMD), Rinderpest, and Scrapie. There have been no reported cases of FMD, Rinderpest, Scrapie, goat pox, Contagious Caprine Pleuropneumonia, Caprine Arthritis Encephalitis, Bluetongue, Akabane, Aino, Epizootic Hemorrhagic Disease (EHD);

4.2. No cases of disease caused by Schmallenberg virus have been detected or reported in New Zealand.

4.3. The donor animals have been part of New Zealand’s national flock and have been free of any movement restrictions for the 60 days prior to collection of embryos for export to the U.S. (or for the 90 days prior to collection of embryos for export to the U.S., if donors were imported to NZ from any region not considered by APHIS as free from FMD).

4.4. During the 60 days prior to collection of embryos for export to the United States, the donor dams were not corralled, pastured, or held with animals of a lesser health status or under any restrictions which would have made them ineligible for export to the United States.

4.5. During the 30 days prior to the collection of embryos for export to the United States, the donor...
dam was inspected by the team veterinarian and found to be clinically free of contagious diseases; and the team veterinarian has provided a declaration certifying this.

4.6. During the 12 months prior to the collection of embryos for export to the United States, there has been no evidence to indicate that the donor dams have been affected with or exposed to bovine tuberculosis (TB) or brucellosis.

4.7. There was no clinical evidence of TB, brucellosis or other infectious disease in any flock located on the embryo collection premises on the date(s) of embryo collection.

4.8. After processing, the ampules/straws were stored in dedicated storage tanks containing embryos for export to the US at a storage facility designated by MPI, and under lock and key until such time as they were placed in the shipping tank and sealed with Government of New Zealand seals.

4.9. The embryos were collected, processed and stored in accordance with recommendations provided in Chapters 4.7 and 4.8 of the current OIE Terrestrial Animal Health Code.

4.10. The EC team followed guidelines in the current International Embryo Transfer Society manual for the cleaning disinfection, and sterilization of all equipment that came in contact with embryos or with the media used for the collection and processing of embryos.

5. TESTING [Note: for diseases where more than one testing option is indicated in this section, the applicable test or statement should be included on the health certificate. Any required testing results must be negative or fall within specified ranges.]

5.1. Brucellosis: The donor dam must test negative for brucellosis as described in 5.1.1 or 5.1.2 within 30 days prior to collection and again between 21 and 120 days after collection.

5.1.1. Brucella abortus/melitensis: acceptable tests include:

5.1.1.1. A fluorescent polarization assay (a negative result is considered anything less than 20 millipolar above the negative control value);

OR

5.1.1.2. A 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

5.1.1.3. A 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 at a titer of <30 ICFTU/ml when the animals are tested at an age of 18 months or older);

**OR**

5.1.1.4. A 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).

5.1.1.5. The donor dams must test negative for *Brucella ovis* (applies only to sheep embryo donors) within 30 days prior to the start of collection; acceptable tests include:

5.1.1.5.1. An enzyme-linked immunosorbent assay (ELISA) (*B. ovis* ELISA positive cutoff is Sample OD/Positive OD = greater than 0.75, Indeterminate 0.40-0.75, Negative less than 0.40.),

**OR**

5.1.1.5.2. A complement fixation test, (a negative reaction at the 1:10 dilution is considered to be negative).

5.2. **Tuberculosis:**

5.2.1. Each embryo donor must originate from a herd that tested negative to a whole herd test for bovine tuberculosis. For the purposes of this protocol, APHIS defines a ‘herd’ as any group of sheep or goats held together, without addition and isolated from other animals susceptible to ruminant diseases, for at least 4 months prior to collection. The donors must be tested with negative results during the 4 month isolation period; and tested with negative results a second time at least 120 days after the first test (and after the last collection for export to the United States).

5.2.2. **[Note: TB testing may be performed using a Caudal Fold Tuberculin test (CFT), defined as the intradermal injection of 0.1 mL of bovine purified protein derivative (PPD) tuberculin (2000-5000 IU) into either side of the caudal fold, with reading by visual observation and palpation 72 hours following injection. A negative test result is the total lack of a response that can be seen or palpated. TB testing may be alternatively performed using the cervical test as described in the current OIE Terrestrial Manual of Standards for Diagnostic Tests and Vaccines.]**

5.2.3. Any animal exhibiting a non-negative response to the TB test is ineligible for export to the US.
5.3. Viruses [Note: if testing is elected in lieu of a declaration of freedom, donors must be tested within 30 days prior to collection and again between 21 and 120 days after collection, unless otherwise specified]

5.3.1. Akabane – the donors were negative to an approved serum virus neutralization test at a 1:4 serum dilution; OR were kept in an akabane free region for at least 60 days before commencement of, and during, collection of the embryos.

5.3.2. Bluetongue - the donors were negative agar gel immunodiffusion test or virus isolation test; OR were kept in a bluetongue free region for at least 60 days before commencement of, and during, collection of the embryos.

5.3.3. Aino - the donors were negative virus neutralization test at a 1:10 final serum dilution; OR were kept continuously in an aino free region for at least 60 days before commencement of, and during, collection of the embryos.

5.3.4. EHD: The following serotypes of epizootic hemorrhagic disease (EHD) exist in New Zealand and all donors were tested negative 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 the above-listed serotypes of EHD, using samples or blood taken not more than 12 months apart prior to and not less than 21 days following collection of the embryos; OR the donors were kept in an EHD free region for at least 60 days before commencement of, and during, collection of the embryos.

5.4. If natural breeding or fresh semen was used to fertilize ova to produce embryos for export, then the donor sire met the test requirements of this section.

5.5. Note: if artificial insemination is used, a semen export health certificate for the donor male must accompany the embryo shipment. This certificate must show that the donor male was eligible to export semen to the United States in accordance with the criteria set forth in the USDA "Protocol for the Importation of Goat and Sheep Semen from New Zealand."

6. STORAGE AND SHIPMENT OF EMBRYOS

6.1. Containers carrying embryos to be exported into the United States must be sealed by a MPI veterinarian or authorized designee with official seals. The seal number(s) must be recorded on the health certificate that accompanies the embryos to the United States.

6.2. The shipment must be routed directly to the United States with no stops en route other than those provided for on the USDA import permit.
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 embryos to an APHIS inspector at the port.

7.2. The shipping container and all straws or ampules containing embryos must be made available for inspection at the port of entry and may not be removed until an APHIS inspector determines that the shipment of embryos meet import requirements and releases them.

8. EMBRYOS REFUSED ENTRY: If any embryos are determined to be ineligible for importation into the United States upon arrival at the port of entry, the importer or agent must remove them from the United States within 30 days, or the embryos will be destroyed.