USDA APHIS VETERINARY SERVICES, STRATEGY & POLICY
PROTOCOL FOR THE IMPORTATION OF *In Vivo* SHEEP AND GOAT EMBRYOS FROM AUSTRALIA

Updated December 2025

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

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).

1.2. The application, **VS Form 17-129, "Application for Import or in Transit Permit,"** may be filed electronically using the eFile system.

1.3. An official health certificate is required. This official health certificate must be issued by an Official Veterinarian from the Australian Government Department responsible for Agriculture (Australia's Competent Authority), attesting to the certification and tests as required in this protocol. The health certificate must accompany the embryos to the port of entry designated on the USDA import permit.

1.4. The embryos must originate from an embryo collection (EC) unit that is approved by the Government of Australia; the approval number must be listed. [Note: An embryo collection unit is defined as: Area or areas where the donor dam will be bred to produce embryos for importation into the United States, and where the embryos will be collected, processed, and stored pending shipment to the United States.]

2. HEALTH CERTIFICATE:

2.1. The health certificate must include the following information:

2.1.1. The name, address and approval number of the place where the embryos were collected;

2.1.2. The name and address of the EC unit veterinarian/team who collected the embryos;

2.1.3. The date(s) of embryo collection;

2.1.4. The official identification and breed of the donor dam and donor sire;

2.1.5. The number of ampules or straws covered by the health certificate and the identification number or code on each ampule or straw. If any of this information is provided in code, deciphering information is attached to the health certificate for the embryos;

2.1.6. The dates, types, and results of all examinations and tests performed on the donor dam and donor sire as a condition for importing the embryo;

2.1.7. The name and address of the consignor and consignee.

2.1.8. The name and address of the laboratory(ies) conducting the tests.

2.2. HEALTH STATUS

2.2.1. Australia is free of foot-and-mouth disease (FMD), surra, scrapie, contagious caprine pleuropneumonia, sheep and goat pox, and *Brucella melitensis*.

2.2.2. Bovine tuberculosis and bovine brucellosis (*Brucella abortus*) are notifiable diseases in Australia.

2.2.3. No cases of disease caused by Schmallenberg virus have been detected or reported in Australia.

2.2.4. The (donor) animals were born, raised, and continuously resident in Australia or were part

of Australia's national flock/herd for a minimum period of time. [Note: Paragraphs 2.2.4.1 and 2.2.4.2 describe how the United States defines "part of the national flock/herd" and the length of time the animals must be part of the national flock/herd.]

2.2.4.1. If the donor animals were legally imported from countries recognized by USDA as free of FMD, then these animals must have been free of any import quarantine restrictions and able to move freely within Australia's national flock/herd for a minimum of 60 days prior to beginning the qualifications necessary for the collection of germplasm for export to the United States.

2.2.4.2. If the donor animals were legally imported from a country not recognized by USDA as free of FMD, then the animals for export must have been free of any import quarantine restrictions and able to move freely within Australia's national flock/herd for a minimum of 90 days prior to beginning the qualifications necessary for the collection of germplasm for export to the United States.

2.2.5. During the 60 days prior to collection of embryos (and semen, where natural breeding or fresh semen is used) for export to the United States, no donor dam (and no donor sire where natural breeding or fresh semen is used) has been corralled, pastured, held, or otherwise had contact with other animals of lesser health status or under restrictions which would make it ineligible for importation to the United States under APHIS' regulations.

2.2.6. The donor dams (and donor sires, where natural breeding or fresh semen is used) have resided in flocks/herds considered by the Australian Competent Authority as free of bovine tuberculosis and bovine brucellosis (*B. abortus*) and showed no signs of bovine tuberculosis or bovine brucellosis on the day of collection of the embryos (or semen, where natural breeding or fresh semen is used), **AND** were kept in an EC facility free from bovine tuberculosis and bovine brucellosis that only accepts animals from flocks/herds considered by the Australian Competent Authority as free of these diseases.

2.2.7. During the 12 months prior to the collection of embryos (and semen, where natural breeding or fresh semen is used) for export to the United States, there has been no reported or confirmed cases of bovine tuberculosis, bovine brucellosis (*B. abortus*), ovine brucellosis (*B. ovis*), bluetongue, Akabane, Aino, paratuberculosis, or contagious agalactia in the donor dam (or sire where natural breeding or fresh semen is used) or on any premises the donors were located during that time.

2.2.8. In the two years prior to collection of the embryos (and semen, where natural breeding or fresh semen is used) for export to the United States, there was no reported cases of enzootic abortion of ewes (*Chlamydia abortus*) in the donor animals or on any premises the donors were located during that time.

2.2.9. In the three years prior to collection of embryos (and semen, where natural breeding or fresh semen is used) for export to the United States, there was no reported or confirmed cases of maedi-visna (in the case of **sheep only**) or caprine arthritis/encephalitis (CAE) (in the case of **goats only**) in the donor animals or on any premises the donors were located during that time.

2.2.10. There was no clinical evidence of any infectious disease in the embryo collection unit flock/herd on the date(s) of embryo collection.

2.2.11. If artificial insemination is used, the donor male(s) was/ were eligible to export semen to the United States at the time of collection, in accordance with the criteria set forth in the USDA APHIS "Protocol for the Importation of Goat and Sheep Semen from Australia" located on the APHIS website.

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2.3. **TESTING**

2.3.1. Tests of all donors was conducted at laboratories accredited by Australia's National Association of Testing Authorities to ISO/IEC 17025. The name and address of the laboratory(ies) are as follows: _____.

2.3.2. **Arboviruses** –

2.3.2.1. **Bluetongue:** The donor dams (and donor sires, where natural breeding or fresh semen is used):

2.3.2.1.1. **EITHER**: were kept in an EC facility approved by Australia's Competent Authority, located in Australia's Bluetongue Virus Transmission-Free Zone for a minimum of 60 consecutive days before commencement of, and during, collection of the embryos for export; [Note: The dates of residence in the EC facility must be included on the export health certificate.]

2.3.2.1.2. **OR** were tested negative on two occasions for bluetongue virus antibodies, the first test at or near the time of collection (within 30 days prior to collection), and the second test between 30 and 180 days after collection of the embryos, to an agar gel immunodiffusion test or the competitive ELISA (cELISA) test.

2.3.2.1.3. **OR** were tested negative for bluetongue virus on blood samples collected at the start and conclusion of, and at least every 7 days for virus isolation or every 28 days for PCR, during embryo collection for this consignment.

2.3.2.2. **Akabane/Aino:** The donor dams (and donor sires, where natural breeding or fresh semen is used):

2.3.2.2.1. **EITHER**: were tested on two occasions, the first test at or near the time of collection (within 30 days prior to collection), and the second test between 30 and 180 days after collection of the embryos, using the following tests:

2.3.2.2.1.1. Akabane - Negative to a serum neutralization test at 1:4 serum dilution.

2.3.2.2.1.2. Aino - Negative to a serum neutralization test at a 1:10 serum dilution

2.3.2.2.2. **OR** were tested negative for Akabane and Aino on blood samples collected at the start and conclusion of, at least every 7 days for virus isolation or every 28 days for PCR, during embryo collection for this consignment.

2.4. **EMBRYO COLLECTION, PROCESSING AND STORAGE**

2.4.1. The embryos were collected, processed and stored in accordance with the guidelines and standards of the current *International Embryo Transfer Society (IETS) Manual* and the *World Organisation for Animal Health (WOAH) Terrestrial Animal Health Code, Chapter 4.8, Collection and Processing of in Vivo Derived Embryos from Livestock and Equids.*

2.4.2. The embryos for export were determined, based on microscopic examination, to have an intact zona pellucida at the time the embryos were placed into its immediate container (straw or ampule) for shipping.

2.4.3. All media and additives of ruminant origin, such as fetal bovine serum and bovine serum albumin, were sourced from countries free of foot-and-mouth disease. Trypsin of porcine origin was sourced from countries free of foot-and-mouth disease, classical swine fever and African swine fever.

2.4.4. The liquid nitrogen used to freeze embryos is new.

2.4.5. The embryo(s) were stored under the supervision of an Official Veterinarian in containers, in which no biological material other than semen or embryo(s) of equivalent health status was held.

2.4.6. Prior to export the embryos were stored in a locked area or in the custody of the official veterinarian until shipped to the United States. The final audit of embryos in the consignment was performed under the supervision of the official veterinarian, and the embryos have been placed in a new/disinfected shipping container and sealed with Government of Australia seals. The seal number(s) are recorded on the export health certificate.

2.4.7. **NOTE:** The shipment must be routed directly to the United States with no stops en route other than those provided for on the USDA APHIS import permit. Note: The Administrator may require additional measures to be taken in processing embryos after collection (for example, adding trypsin to the washes) if he or she determines that such measures are necessary to ensure the embryos' freedom from infectious agents that may cause communicable diseases. Circumstances that may result in such additional measures being required include but are not limited to: (1) the existence of other communicable disease of livestock in the country of origin and (2) of an increase in the incidence of a communicable disease in the country of origin.

3. EMBRYO COLLECTION (EC) UNIT: ADDITIONAL INFORMATION

3.1. Goat and sheep embryos may be imported into the United States if they were conceived, collected, processed, and stored prior to importation at an approved EC unit. The embryo collection unit may be located on the premises where the donor dam's flock/herd of origin is kept, or at any other location, provided that the following requirements in this section are met:

3.1.1. **Animal holding and breeding area(s).** The EC unit must have an area or areas for holding the donor dams and for breeding them (either natural breeding or artificial insemination).

3.1.2. **Embryo collection area.** The EC unit must have 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 unit is a room, then the floor, walls, and ceiling must be impervious to moisture and disinfection. If the EC unit is an outdoor area, then the area must have 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 must be impervious to moisture and be constructed of materials that can withstand repeated cleaning and disinfection.

3.1.3. **Embryo processing area.** The EC unit must have an enclosed room which may be mobile that is used only for processing embryos. The walls, floor, and ceiling of the room must be impervious to moisture and constructed of materials that can withstand repeated cleaning and disinfection. The room must contain a work surface for handling the embryos, such as a table or countertop that is impervious to moisture. The room also must contain a microscope with a minimum of 50x magnification and equipment for freezing the embryos.

3.1.4. **Embryo storage area.** The EC unit must have one lockable area that is used only for storing frozen embryos intended for exportation to the United States or is of the same health status.

3.1.5. **Area for cleaning and disinfection or sterilizing equipment.** The EC unit must have 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 must be impervious to moisture and constructed of materials that can withstand repeated cleaning and disinfection.

4. CLEANING, DISINFECTION, AND STERILIZATION: ADDITIONAL INFORMATION

4.1. All equipment that comes in contact with embryos or with media used for their collection or processing must be sterile. Equipment used for embryos from one donor dam, or with associated media, may not be used for embryos or associated media from any other donor dam until it has been re-sterilized.

4.2. All equipment that comes in contact with a donor dam's secretions or excretions must be sterile and may not be used with any other donor dam until it has been re-sterilized.

4.3. Containers used for storing embryos or for shipping embryos to the United States must be free of any organic matter and then disinfected before the ampules or straws are placed inside.

4.4. The floor, ceiling, and walls of any room or outdoor area used for embryo collection, and restraining device(s) used for this procedure, must be cleaned with soap and water, and disinfected before the room or area is used to collect embryos intended for exportation to the United States, and at least daily while in use for this purpose.

4.5. The room and work surface used for processing embryos must be kept free of insects, rodents, trash, manure, and other animal matter and must be cleaned with soap and water and disinfected before the room is used for embryos intended for exportation to the United States, and the work surface must be cleaned and disinfected at least daily while in use for this purpose.

4.6. The area of the embryo collection unit used to store embryos intended for exportation to the United States must be kept free of insects, rodents, trash, manure, and other animal matter and must be cleaned with soap and water and disinfected before being used to store the embryos.

4.7. The room used for cleaning and disinfection, or sterilizing equipment used for artificial insemination or for collection, processing, or storage of embryos must be kept free of insects, rodents, trash, manure, and other animal matter and must be cleaned with soap and water and disinfected before being used to store the embryos.

4.8. The room used for cleaning and disinfecting or sterilizing equipment used for artificial insemination or for the collection, processing, or storage of embryos must be kept free of insects, rodents, trash, manure, and other animal matter and must be cleaned with soap and water and disinfected before being used to prepare equipment for donors of embryos intended for exportation to the United States, and at least daily while in use for this purpose.

5. ADDITIONAL REQUIREMENTS:

5.1. Importers are advised that individual states may require 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 (State Regulations and Import Requirements) of the destination state to determine the requirements.

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6. ARRIVAL AND INSPECTION AT THE PORT OF ENTRY

6.1. The shipment must be routed directly to the United States from Australia 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: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.

6.2. 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 embryos to an inspector at the port.

6.3. 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 from such port of entry until an inspector determines that the embryos are eligible for importation in accordance with this protocol and releases them.

7. EMBRYOS REFUSED ENTRY

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