

§98.16

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health certificate that accompanies the embryos to the United States.

(8)(i) Between the time the embryos were collected and all examinations and tests required by this subpart were completed, no animals in the embryo collection unit with the donor dam, or in the donor dam's herd of origin, exhibited any clinical evidence of:

(A) Ruminant: Bovine spongiform encephalopathy, brucellosis, contagious bovine pleuropneumonia, foot-and-mouth disease, Rift Valley fever, rinderpest, tuberculosis, and vesicular stomatitis; or

(B) Swine: African swine fever, brucellosis, foot-and-mouth disease, classical swine fever, pseudorabies, rinderpest, swine vesicular disease, tuberculosis, and vesicular stomatitis.

(ii) All signs of any other communicable disease must be listed on the health certificate that accompanies the embryos to the United States.

(b) The donor dam or donor sire is determined to be free of communicable diseases based on other testing or certifications if required by the Administrator. The Administrator may require additional testing or certifications if he or she determines that they are necessary to determine either the donor dam's or the donor sire's freedom from communicable diseases. Circumstances that may result in additional testing or certifications include, but are not limited to:

(1) The existence of communicable diseases of livestock, other than those diseases specifically listed, in the region of origin;

(2) A high prevalence or an increase in the incidence of a communicable disease in the region of origin;

(3) The use of natural breeding, rather than artificial insemination to conceive the embryos;

(4) The use of fresh, rather than frozen semen, for artificial insemination; and

(5) The use of semen collected at a site other than an artificial insemination center approved by the national government of the region of origin.

(c) Embryos produced by any donor dam or sire that dies before being examined and tested as required under

this subpart will not be eligible for importation into the United States.

[56 FR 55809, Oct. 30, 1991, as amended at 61 FR 15183, Apr. 5, 1996; 62 FR 56025, Oct. 28, 1997; 68 FR 16940, Apr. 7, 2003]

§98.16 The embryo collection unit.

Ruminant and swine embryos may be imported into the United States from a region where rinderpest or foot-and-mouth disease exists only if they were conceived, collected, processed, and stored prior to importation at an embryo collection unit. The embryo collection unit may be located on the premises where the donor dam's herd of origin is kept, or at any other location, provided that the embryo collection unit has been inspected and approved by an APHIS veterinarian and that the following requirements are met:

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

(b) *Embryo collection area*. The embryo collection must have a room or outdoor area for collection of embryos that contains a device or devices for restraining embryo donors during embryo collection. If a room, the floor, walls, and ceiling must be impervious to moisture and constructed of materials that can withstand repeated cleaning and disinfection. If an outdoor area, 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.

(c) *Embryo processing area*. The embryo collection 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.

(d) *Embryo storage area.* The embryo collection unit must have one lockable area that is used only for storing frozen embryos intended for importation into the United States.

(e) *Area for cleaning and disinfecting or sterilizing equipment.* The embryo collection unit must have an enclosed room used for cleaning and disinfecting or sterilizing equipment used for artificial insemination or for 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.

[56 FR 55809, Oct. 30, 1991, as amended at 61 FR 15184, Apr. 5, 1996; 62 FR 56025, Oct. 28, 1997]

§ 98.17 Procedures.

(a) *Housing of the donor dam.* (1) Beginning at least 24 hours before a donor dam is bred to produce embryos for importation to the United States, the donor dam must be housed at an embryo collection unit.

(2) The donor dam must remain at the embryo collection unit until the embryos for importation into the United States have been collected.

(3) After collection of embryos, the donor dam must either remain at the embryo collection unit or be returned to the herd of origin and remain there until all examinations and tests required by this subpart have been completed.

(4) During the time the donor dam is in the embryo collection unit, in accordance with paragraphs (a)(1) through (a)(3) of this section, no animals may be in the embryo collection unit with the donor dam unless:

(i) They meet the requirements of § 98.15 of this subpart that are applicable to the donor dam at that time;

(ii) They are part of the donor dam's herd of origin; or

(iii) They are serving as donor sires for the production of embryos to be imported into the United States.

(b) *Oversight and supervision.* (1) All procedures associated with the production of embryos for importation into

the United States, including artificial insemination, natural breeding, and cleaning and disinfection, must be performed under the oversight of an APHIS veterinarian. Collecting test samples, and collecting, processing, and storing embryos, must be supervised in person by an APHIS veterinarian.

(2) Officials from the Animal and Plant Health Inspection Service must be given access to all areas of the embryo collection unit and the donor dam's herd of origin during the time the donor dam is housed there, in accordance with paragraphs (a)(1) through (a)(3) of this section.

(c) *Personnel.* All personnel must put on clean outer garments, including disinfected boots, and must scrub their hands with soap and water each time they enter the embryo collection unit and before entering any room or area listed in § 98.16 of this subpart.

(d) *Cleaning, disinfection, and sterilization.* (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.

(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.

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

(4) The floor, ceiling, and walls of any room or outdoor area used for embryo collection, and the 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 importation to the United States, and at least daily while in use for this purpose.

(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