

(10) The proposed date of arrival in the United States; and

(11) The name and address of the person to whom the embryos will be delivered in the United States.

(Approved by the Office of Management and Budget under control number 0579-0040)

[56 FR 55809, Oct. 30, 1991, as amended at 59 FR 67616, Dec. 30, 1994; 61 FR 15183, Apr. 5, 1996; 62 FR 56025, Oct. 28, 1997]

§ 98.14 Health certificate.

(a) Ruminant and swine embryos shall not be imported into the United States unless they are accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the region of origin, or issued by a veterinarian designated or accredited by the national government of the region of origin and endorsed by a full-time salaried veterinary officer of the national government of the region of origin, representing that the veterinarian issuing the certificate was authorized to do so.

(b) The health certificate must state:

- (1) The name and address of the place where the embryos were collected;
- (2) The name and address of the veterinarian who collected the embryos;
- (3) The date of embryo collection;
- (4) The identification and breed of the donor dam and donor sire;
- (5) The number of ampules or straws covered by the health certificate and the identification number or code on each ampule or straw;
- (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 embryos;
- (7) The dates and results of all tests performed on unfertilized eggs, nontransferrable embryos, and embryo collection and wash fluids;
- (8) The names and addresses of the consignor and consignee;
- (9) That the embryos are being imported into the United States in accordance with subpart B of 9 CFR part 98.

(c) If any of the information required by paragraph (b) of this section is provided in code, deciphering information must be attached to the health certificate.

(d) The health certificate accompanying sheep or goat embryos in-

tended for importation from any part of the world shall, in addition to the statements required by paragraph (b) of this section, state that:

(1) The embryos' sire and dam have not been in any flock or herd nor had contact with sheep or goats which have been in any flock or herd where scrapie has been diagnosed or suspected during the 5 years prior to the date of collection of the embryos;

(2) The embryos' sire and dam showed no evidence of scrapie at the time the embryos were collected;

(3) Scrapie has not been suspected nor confirmed in any progeny of the embryos' donor dam; and

(4) The parents of the embryos' sire and dam are not, nor were not, affected with scrapie.

(e) There must be a separate health certificate for each collection of embryos.

(Approved by the Office of Management and Budget under control number 0579-0040)

[56 FR 55809, Oct. 30, 1991, as amended at 61 FR 15183, Apr. 5, 1996; 61 FR 17242, Apr. 19, 1996; 62 FR 56025, Oct. 28, 1997]

§ 98.15 Health requirements.

Ruminant and swine embryos may be imported from a region where rinderpest or foot-and-mouth disease exists only if all of the following conditions are met:

(a) The donor dam is determined to be free of communicable diseases based on tests, and examinations, and other requirements, as follows:

(1) During the year before embryo collection, no case of the following diseases occurred in the embryo collection unit or in any herd in which the donor dam was present:

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

(ii) Swine: African swine fever, foot-and-mouth disease, classical swine fever, pseudorabies, rinderpest, swine vesicular disease, or vesicular stomatitis.

(2) During the year before embryo collection, no case of the following diseases occurred within 5 kilometers of the embryo collection unit or in any

herd in which the donor dam was present:

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

(ii) Swine: African swine fever, foot-and-mouth disease, classical swine fever, pseudorabies, rinderpest, swine vesicular disease, or vesicular stomatitis.

(3) During the 60 days before embryo collection, the donor dam did not receive a vaccination for either rinderpest or foot-and-mouth disease.

(4) During the 60 days before the donor dam was required to be in the embryo collection unit, in accordance with § 98.17(a) of this subpart, the donor dam remained in the same herd, and no ruminants or swine were added to that herd.

(5)(i) On the day of embryo collection, and again not less than 30 days nor more than 120 days afterward, one sample of at least 10 ml of serum was collected from the donor dam, frozen, and sent to the Foreign Animal Disease Diagnostic Laboratory for testing.

(ii) The donor dam was determined to be free of foot-and-mouth disease based upon tests of the pair of serum samples. In addition, if any of the following diseases exist in the region of origin, the donor dam was determined to be free of these diseases based upon additional tests of the serum samples:

(A) Ruminant: Contagious bovine pleuropneumonia, Rift Valley fever, rinderpest, or vesicular stomatitis; or

(B) Swine: African swine fever, classical swine fever, pseudorabies, rinderpest, swine vesicular disease, or vesicular stomatitis.

(iii) If the donor dam was in any herd during the year before embryo collection that was not certified free of brucellosis by the national government of the region of origin, the donor dam was determined to be free of brucellosis based on tests of the serum samples.

(iv) The only official test results will be those provided by the Foreign Animal Disease Diagnostic Laboratory.

(6) If the donor dam was in any herd during the year before embryo collection that was not certified free of tuberculosis by the national government

of the region of origin, the donor dam was determined to be free of tuberculosis by an official veterinarian based on an intradermal tuberculin test. The test must have been administered to the donor dam by an official veterinarian not less than 30 days nor more than 120 days after embryo collection, and not less than 60 days after any previously administered intradermal test for tuberculosis.

(7)(i) Not less than 30 days nor more than 120 days after embryo collection, the donor dam was examined by an official veterinarian and found free of clinical evidence of the following diseases:

(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.

(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 re-

straining 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.