AUTHENTICATED
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INFORMATION
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COMMUTED TRAVELTIME ALLOWANCES—Continued

[In hours]

Location covered	Served from	Metropolitan Area	
		Within	Outside
Harlingen	Edinburg, McAllen or Mission.		2
Do	Weslaco		1
Hidalgo	Brownsville		3
Do	Edinburg, Mission and McAllen.		1
Do	Harlingen		2
Do	Lyford		2
Do	Rio Grande City		2
Houston (including Houston Intercontinental Airport).			2
Do	Bellville, TX		4
Do	Bryan, TX		4
Do	Georgetown, TX		8
Do	Pleasanton, TX		8
Laredo		1	
Do	Brownsville or San Antonio.		6
Do	Eagle Pass		5
Do	McAllen, Edinburg or Mission.		6
Presidio		1	
Do	El Paso		6
Utah:			
Salt Lake City	Murray and Ogden.	2	
Vermont:			
Burlington International Airport.	Burlington	1	
Do	Milton		1
Do	Calais		3
Derby Line	Milton		4
Do	Calais		4
Highgate		1	
Do	Milton		2
Do	Calais		4
Highgate Springs.	....do		1
Virginia:			
Dulles International Airport.	Annapolis, MD	3	
Do	Richmond		5
Do	Warrenton		3
Port of Richmond.		2	
Washington:			
Blaine		1	
Do	Seattle		6
Lynden	Blaine		2
Do	Seattle		6
Moses Lake	Oroville, WA		6
Do	Spokane		5
Do	Wenatchee		3
Do	Yakima		4
Oroville		1	
Sea-Tac Airport	Olympia		3
Seattle		2	
Sumas	Blaine		2
Do	Olympia		6
Do	Seattle		6
Tacoma	....do		3
Yelm	Olympia		2
Do	Seattle		3

COMMUTED TRAVELTIME ALLOWANCES—Continued

[In hours]

Location covered	Served from	Metropolitan Area	
		Within	Outside
Wisconsin:			
Barron	Ripon		6
Madison		1	
Monroe	Madison		3

[39 FR 41356, Nov. 27, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §97.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

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AUTHORITY: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§98.1 Prohibition.

An embryo shall not be imported or entered into the United States unless in accordance with the provisions of this part.

[50 FR 43563, Oct. 25, 1985. Redesignated at 56 FR 58808, Oct. 30, 1991]

Subpart A—Ruminant and Swine Embryos from Regions Free of Rinderpest and Foot-and-Mouth Disease; and Embryos of Horses and Asses

§98.2 Definitions.

The following terms, when used in this subpart, shall be construed as defined. Those terms used in the singular form in this subpart shall be construed as the plural form and vice versa, as the case may demand.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal. Any cattle, sheep, goats, other ruminants, swine, horses, or asses.

Animal and Plant Health Inspection Service. The Animal and Plant Health Inspection Service of the United States Department of Agriculture (APHIS).

Approved artificial insemination center. A facility approved or licensed by the national government of the region in which the facility is located to collect and process semen under the general supervision of such government.

Approved embryo transfer unit. A facility approved or licensed by the national government of the region in which the facility is located for the artificial insemination of donor dams or for conception as a result of artificial breeding by a donor sire and for collecting and processing embryos for export under the general supervision of such government.

Department. The United States Department of Agriculture.

Embryo. The initial stage of an animal's development after collection from the natural mother, while it is capable of being transferred to a recipient dam, but not including an embryo that has been transferred to a recipient dam.

Enter (entered, entry) into the United States. To introduce into the commerce of the United States after release from governmental detention at the port of entry.

Flock. A herd.

Herd. All animals maintained on any single premises; and all animals under common ownership or supervision on two or more premises which are geographically separated, but among which there is an interchange or movement of animals.

Import (imported, importation) into the United States. To bring into the territorial limits of the United States.

Inspector. An employee of APHIS who is authorized to perform the function involved.

Person. Any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other legal entity.

Region. Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

United States. All of the several States of the United States, the District of Columbia, Guam, the Northern

Mariana Islands, Puerto Rico, the Virgin Islands of the United States and all other territories and possessions of the United States.

[50 FR 43563, Oct. 25, 1985. Redesignated and amended at 56 FR 55808, Oct. 30, 1991; 57 FR 29194, July 1, 1992; 61 FR 17241, Apr. 19, 1996; 62 FR 56025, Oct. 28, 1997]

§ 98.3 General conditions.

Except as provided in subpart B of this part, an animal embryo shall not be imported into the United States unless it is from a region listed in § 94.1(a)(2) of this chapter as being free of rinderpest and foot-and-mouth disease, and:

(a) The embryo is exported to the United States from the region in which it was conceived;

(b) The embryo was conceived as a result of artificial insemination with semen collected from a donor sire at an approved artificial insemination center, or the embryo as conceived as a result of natural breeding by a donor sire at an approved embryo transfer unit;

(c) If artificially inseminated, the donor dam conceived the embryo after being inseminated in an approved embryo transfer unit with semen collected at an approved artificial insemination center;

(d) At the time of collection of the semen used to conceive the embryo or at the time of natural breeding, the donor sire met all requirements the donor sire would have to meet under part 93 of this chapter for a health certificate required as a condition of importation into the United States;

(e) At the time of collection of the embryo from the donor dam, the donor dam met all requirements the donor dam would have to meet under part 92 of this chapter for a health certificate required as a condition of importation into the United States;

(f) There is no basis for denying an import permit for the donor sire or donor dam under § 93.304(a)(2) for horses, § 93.404(a)(2) or (3) for ruminants, and § 93.504(a)(2) or (3) for swine of this chapter;

(g) The embryo is collected and maintained under conditions determined by the Administrator to be adequate to protect against contamination of the embryo with infectious animal disease organisms; and

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

(i) The embryo is contained in a shipping container which at the time of offer for entry is sealed with an official seal which was affixed to the shipping container by a full-time salaried veterinarian of the national animal health service of the region of origin or by a veterinarian authorized to do so by the national animal health service of the region of origin.

[50 FR 43563, Oct. 25, 1985, as amended at 55 FR 31558, Aug. 2, 1990; 56 FR 55809, Oct. 30, 1991; 57 FR 29194, July 1, 1992; 62 FR 56025, Oct. 28, 1997]

§ 98.4 Import permit.

(a) Except as provided in subpart B of this part, an animal embryo shall not be imported into the United States unless accompanied by an import permit issued by APHIS and unless imported into the United States within 14 days after the proposed date of arrival stated in the import permit.

(b) An application for an import permit must be submitted to the Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, Maryland 20737–1231. An application form for an import permit may be obtained from this staff.

(c) The completed application shall include the following information:

(1) The name and address of the person intending to export an embryo from the region of origin,

(2) The name and address of the person intending to import an embryo,

(3) The species, breed, and number of embryos to be imported,

(4) The purpose of the importation,

(5) The region in which the embryo is conceived,

(6) The port of embarkation,

(7) The mode of transportation,

(8) The route of travel,

(9) The port of entry in the United States,

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

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

(12) The measures to be taken to ensure that the embryo is collected and maintained under conditions adequate to protect against contamination of the embryo with infectious animal disease organisms.

(d) After receipt and review of the application by APHIS, an import permit indicating the applicable conditions under this subpart for importation into the United States shall be issued for the importation of embryos described in the application if such embryos appear to be eligible to be imported. Even though an import permit has been issued for the importation of an embryo, the embryo may be imported only if all applicable requirements of this subpart are met.

[50 FR 43563, Oct. 25, 1985, as amended at 56 FR 55809, Oct. 30, 1991; 57 FR 29194, July 1, 1992; 59 FR 67616, Dec. 30, 1994; 62 FR 56025, Oct. 28, 1997]

§98.5 Health certificate.

(a) Except as provided in subpart B of this part, an animal embryo shall not be imported into the United States unless it is 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. The certificate shall state:

(1) The dates, places, types, and results of all examinations and tests performed on the donor sire and donor dam as a condition for importation of the embryo, and the names and addresses of persons or laboratories conducting the examinations or tests, and a statement that any other requirements established by §98.3 have been complied with,

(2) The name and address of the consignor and consignee,

(3) The name and address of the approved artificial insemination center where the semen for the embryo was collected, if applicable,

(4) The name and address of the approved embryo transfer unit where the donor dam was inseminated or bred and the embryo was collected, and

(5) The measures taken to ensure that the embryo was collected and maintained under conditions adequate to protect against contamination of the embryo with infectious animal disease organisms.

(b) The certificate accompanying sheep or goat embryos intended for importation from any part of the world shall, in addition to the statements required by paragraph (a) 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.

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

[50 FR 43563, Oct. 25, 1985, as amended at 56 FR 55809, Oct. 30, 1991; 61 FR 15183, Apr. 5, 1996; 61 FR 17241, Apr. 19, 1996; 62 FR 56025, Oct. 28, 1997]

§98.6 Ports of entry.

An embryo shall not be imported into the United States unless at a port of entry listed in §93.303 for horses, §93.403 for ruminants, or §93.503 for swine of this chapter.

[50 FR 43563, Oct. 25, 1985, as amended at 55 FR 31558, Aug. 2, 1990; 62 FR 56025, Oct. 28, 1997]

§98.7 Declaration upon arrival.

Upon arrival of an embryo at a port of entry, the importer or the importer's agent shall notify APHIS of the arrival by giving an inspector a document stating:

(a) The port of entry,

(b) The date of arrival,

(c) Import permit number,

(d) Carrier, and identification of the means of conveyance,

(e) The name and address of the importer,

(f) The name and address of the broker,

(g) The region of origin of the embryo,

(h) The number, species, and purpose of importation of the embryo, and

(i) The name and address of the person to whom the embryo will be delivered.

[50 FR 43563, Oct. 25, 1985, as amended at 57 FR 29194, July 1, 1992; 62 FR 56025, Oct. 28, 1997]

§ 98.8 Inspection.

Any embryo offered for entry into the United States in accordance with this subpart and documents accompanying the embryo shall be subject to inspection by an inspector at the time the embryo is offered for entry in order to determine whether the embryo is eligible for entry. The import permit and the health certificate shall be given to the inspector.

[50 FR 43563, Oct. 25, 1985, as amended at 56 FR 55809, Oct. 30, 1991]

§ 98.9 Embryos refused entry.

Any embryo refused entry into the United States for noncompliance with the requirements of this subpart shall be removed from the United States within a time period specified by the Administrator or abandoned by the importer for destruction, and pending such action shall be subject to such safeguards as the inspector determines necessary to prevent the possible introduction into the United States of infectious animal diseases. If such embryo is not removed from the United States within such time period, or abandoned for destruction, it may be seized, destroyed, or otherwise disposed of as the inspector determines necessary to prevent the possible introduction into the United States of infectious animal diseases.

[50 FR 43563, Oct. 25, 1985, as amended at 56 FR 55809, Oct. 30, 1991; 57 FR 29194, July 1, 1992]

§ 98.10 Other importations.

Notwithstanding other provisions in this part, the Administrator may in specific cases allow the importation and entry into the United States of embryos other than as provided for in this part under such conditions as the Administrator may prescribe to prevent the introduction into the United States of infectious animal diseases.

[50 FR 43563, Oct. 25, 1985, as amended at 57 FR 29194, July 1, 1992]

§ 98.10a Embryos from sheep in regions other than Australia, Canada, and New Zealand.

(a) Except for embryos from sheep in Australia, Canada, or New Zealand, embryos from sheep may only be imported into the United States if they comply with all applicable provisions of this subpart and one of the following conditions:

(1) The embryos are transferred to females in a flock in the United States that participates in the Voluntary Scrapie Flock Certification Program (see 9 CFR part 54, subpart B) and qualifies as a ''Certified'' flock; or

(2) The embryos are transferred to females in a flock in the United States that participates in the Voluntary Scrapie Flock Certification Program (see 9 CFR part 54, subpart B) and the flock owner has agreed, in writing, to maintain the flock, and all first generation progeny resulting from embryos imported in accordance with this section, in compliance with all requirements of the Voluntary Scrapie Flock Certification Program until the flock, including all first generation progeny resulting from embryos imported in accordance with this section, qualifies as a ''Certified'' flock.

(b) Sheep embryos may be imported under paragraph (a) of this section only if the importer provides the Voluntary Scrapie Flock Certification Program identification number of the receiving flock as part of the application for an import permit.

(c) Sheep embryos may be imported under paragraph (a)(1) of this section only if they are the progeny of a dam and sire that are part of flocks in the region of origin that participate in a

program determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, and the flocks have been determined by the Administrator to be at a level equivalent to ''Certified'' in the Voluntary Scrapie Flock Certification Program.

(d) Sheep embryos may be imported under paragraph (a)(2) of this section only if they are transferred to animals in a Certifiable Class C flock participating in the Voluntary Scrapie Flock Certification Program; *except*, that if the embryos are the progeny of a dam and sire whose flock in the region of origin participates in a program determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, then the embryos may be placed in a flock in the United States which would be classified at a level equivalent to or lower (*i.e.*, at a greater risk) than the certification level, as determined by the Administrator, of either the flock of the dam or the flock of the sire, whichever one presents the greater risk.

(e) The flock to which the sheep embryos are transferred pursuant to paragraph (a)(2) of this section must be monitored for scrapie disease until the flock, and all first generation progeny resulting from the embryos imported in accordance with this section, qualifies as a ''Certified'' flock.

(f) Except for sheep embryos being placed in Certifiable Class C flocks, the certificate accompanying sheep embryos imported under paragraph (a) of this section must contain the following statement: ''The embryos identified on this certificate are the progeny of a dam and sire that have been monitored by a salaried veterinary officer of [*name of region of origin*], for [*number of months*], in the same source flock which had been determined by the Administrator, APHIS, prior to the exportation of these embryos to the United States, to be equivalent to [*certification level (of dam or sire) presenting greater risk*] of the Voluntary Scrapie Flock Certification Program authorized under 9 CFR part 54, subpart B.''

(1) The Administrator will determine, based upon information supplied by the importer, whether the flock of the embryos' dam and sire participates in a program in the region of origin that is equivalent to the Voluntary Scrapie Flock Certification Program, and if so, at what level the source flock would be classified.

(2) In order for the Administrator to make a determination, the importer must supply the following information with the application for an import permit, no less than 1 month prior to the anticipated date of importation:

(i) The name, title, and address of a knowledgeable official in the veterinary services of the region of origin;

(ii) The details of scrapie control programs in the region of origin, including information on disease surveillance and border control activities and the length of time such activities have been in effect;

(iii) Any available information concerning additions, within the 5 years immediately preceding collection of the embryos, to the flock of the embryos' sire and dam;

(iv) Any available data concerning disease incidence, within the 5 years immediately preceding collection of the embryos, in the flock of the embryos' sire and dam, including, but not limited to, the results of diagnostic tests, especially histopathology tests, conducted on any animals in the flock;

(v) Information concerning the health, within the 5 years immediately preceding collection of the embryos, of other ruminants, flocks, and herds with which the embryos' sire and dam and the flock of the embryos' sire and dam might have had physical contact, and a description of the type and frequency of the physical contact; and

(vi) Any other information requested by the Administrator in specific cases as needed to make a determination.

(g) All first generation progeny resulting from embryos imported under this section are subject to the requirements of 9 CFR part 54 and all other applicable regulations.

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0101)

[61 FR 17241, Apr. 19, 1996, as amended at 62 FR 56025, Oct. 28, 1997]

Subpart B—Ruminant and Swine Embryos From Regions Where Rinderpest or Foot-and-Mouth Disease Exists

SOURCE: 56 FR 55809, Oct. 30, 1991, unless otherwise noted.

§ 98.11 Definitions.

Animal and Plant Health Inspection Service. The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Collection of embryos. Embryos removed from a single donor dam in one operation.

Embryo. The initial stages of development of an animal, after collection from the natural mother and while it is capable of being transferred to a recipient dam, but not after it has been transferred to a recipient dam.

Embryo collection unit. 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.

Foreign Animal Disease Diagnostic Laboratory. The Foreign Animal Disease Diagnostic Laboratory of the Animal and Plant Health Inspection Service.

Herd of origin. The herd in which the donor dam is kept during the 60 days before the donor dam is required to be housed in an embryo collection unit, in accordance with § 98.17(a) of this subpart.

Import. To bring into the territorial limits of the United States.

Inspector. An employee of the Animal and Plant Health Inspection Service who is authorized to perform the function involved.

Official veterinarian. A full-time salaried veterinarian of the national government of the country of origin or a veterinarian employed by the Animal and Plant Health Inspection Service (APHIS), and designated by APHIS to supervise or conduct procedures required by this subpart, and to certify that requirements of this subpart have been met.

Person. Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

Region. Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.);

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

Region of origin. The region in which the embryo is conceived and collected and from which the embryo is imported into the United States.

Ruminant. All animals which chew the cud, including cattle, buffaloes, camelids, cervids (deer, elk, moose, and antelope), sheep, goats, and giraffes.

Swine. The domestic hog and all varieties of wild hogs.

United States. All of the States of the United States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

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

§ 98.12 General prohibitions.

(a) Ruminant and swine embryos may not be imported from regions where rinderpest or foot-and-mouth disease exists except in accordance with this subpart.

(b) Ruminant and swine embryos may not be imported into the United States from any region other than the region in which they were conceived and collected.

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

§ 98.13 Import permit.

(a) Ruminant and swine embryos and all test samples required by this subpart may be imported into the United States from regions where foot-and-mouth disease or rinderpest exists only if accompanied by import permits issued by the Animal and Plant Health Inspection Service (APHIS).

(b) An application for the import permits must be submitted to the Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, Maryland 20737–1231. Application forms also may be obtained at this same address. The application for a permit to import embryos will also serve as the application for a permit to import test samples for those embryos; separate applications are not required. The application must include the following information:

(1) The name and address of the exporter;

(2) The name and address of the importer;

(3) The name and address of the place where the donor dam will be bred and where the embryo(s) will be collected;

(4) The species, breed, and number of embryos to be imported;

(5) The purpose of the importation;

(6) The port of embarkation;

(7) The mode of transportation;

(8) The route of travel;

(9) The port of entry in the United States;

(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 vetrinarian 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 intended 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 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 resterilized.

(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 resterilized.

(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

cleaned with soap and water and disinfected before the room is used for embryos intended for importation to the United States, and the work surface must be cleaned and disinfected at least daily while in use for this purpose.

(6) The area of the embryo collection unit used to store embryos intended for importation 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.

(7) The room used for cleaning and disinfecting 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 prepare equipment for donors of embryos intended for importation into the United States, and at least daily while in use for this purpose.

(e) *Media; cryogenic agent.* (1) All media containing products of animal origin and used for embryo collection and processing must be from sources in the United States or Canada.

(2) The liquid nitrogen used to freeze embryos may not have been used previously for any other products of animal origin.

(f) *Collection and processing of embryos.* (1) If embryos are collected in an outdoor area, they must be collected by using a closed collection system so that the embryos are not exposed to open air until they are inside the embryo processing room.

(2) Embryos from donors that do not meet the requirements of §98.15 of this subpart that are applicable at the time of embryo collection may not be in the processing room at the same time as embryos intended for importation into the United States.

(3) Each embryo must be washed at least 10 times. Each wash must be accomplished by transferring the embryo into an aliquot of fresh medium that is 100 times the volume of the embryo plus any fluid transferred from the previous wash. No more than 10 embryos from the same flush may be washed together. A sterile micropipette must be used for each transfer, and the embryos must be well agitated throughout the entire volume of the wash before the next transfer. Embryos from different donors may not be washed together.

(4) After the last wash, each embryo must be microscopically examined over its entire surface at not less than 50× magnification. An embryo may not be imported into the United States unless its zona pellucida is found to be intact and free from any adherent material.

(5) After washing and examination of the zona pellucida, embryos must be individually packaged in sterile ampules or straws and frozen in liquid nitrogen. The donor dam's and sire's identifications and breed, the date of embryo collection, the name and address of the place where the embryos were collected, and an identification number for the straw or ampule must be recorded with indelible markings on each ampule or straw. If any of this information is provided in code, deciphering information must be attached to the health certificate for the embryos.

(6) 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:

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

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

(g) *Preparation of test samples; tests.* (1) All nontransferrable embryos and unfertilized eggs from each collection of embryos intended for importation into the United States must be pooled, frozen in liquid nitrogen, and sent to the Foreign Animal Disease Diagnostic Laboratory for testing under the personal supervision of an APHIS veterinarian. The collection and last two

wash fluids from the collection of embryos must be frozen and sent to the Foreign Animal Disease Diagnostic Laboratory for testing under the personal supervision of an APHIS veterinarian. Samples from different collections may not be mixed.

(2) All samples collected in accordance with paragraph (g)(1) of this section must be tested and found negative for viral contamination. The wash fluids also must be found negative for bacterial contamination. The only official results for these tests will be those provided by the Foreign Animal Disease Diagnostic Laboratory.

(h) *Storage of embryos.* (1) Frozen embryos to be imported into the United States must be stored in a locked area or must remain in the custody of an official veterinarian until they are sealed in accordance with paragraph (h)(2) of this section and released for shipment to the United States in accordance with § 98.18(a) of this subpart; except that, the embryos may be moved to a U.S. Department of Agriculture-operated animal import center in either New York, Hawaii, or Florida, under seal and in the custody of that individual, and remain in quarantine there until all tests and examinations required by this subpart have been completed and all test results have been provided by the Foreign Animal Disease Diagnostic Laboratory.

(2) Containers in which embryos will be imported into the United States must be sealed by an official veterinarian with the official seal of the region of origin or, if the official veterinarian is an employee of the Animal and Plant Health Inspection Service, with an official seal of the United States Department of Agriculture. The seal number must be recorded on the health certificate that accompanies the embryos to 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 61 FR 15184, Apr. 5, 1996; 62 FR 56026, Oct. 28, 1997]

§ 98.18 Shipment of embryos to the United States.

(a) *Release from the embryo collection unit.* Except as provided in § 98.17(h)(1) of this subpart, embryos may not be moved from the embryo collection unit until all tests and examinations required by this subpart have been completed and the Import-Export Animals Staff, Veterinary Services, APHIS, has received written notification of all test results from the Foreign Animal Disease Diagnostic Laboratory.

(b) *Route.* The sealed shipping containers must be routed directly to the U.S. port of entry designated on the import permit.

(c) *Ports of entry.* The embryos may be imported into the United States only through a port of entry listed in § 93.203(a) of this chapter.

(d) *Date of arrival in the United States.* Embryos that arrive at the port of entry more than 14 days after the proposed date of arrival stated in the import permit will not be eligible for importation into the United States.

[56 FR 55809, Oct. 30, 1991, as amended at 62 FR 56026, Oct. 28, 1997]

§ 98.19 Arrival and inspection at the port of entry.

(a) Upon arrival at the port of entry, the importer or the importer's agent must present an inspector at the port with the original health certificate and the original import permit for the embryos.

(b) The shipping container and all straws or ampules containing embryos must be made available to an inspector at the port of entry for inspection, and may not be removed from the port of entry until an inspector determines that the embryos are eligible for entry in accordance with this subpart and releases them.

§ 98.20 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 must remove the embryos from the United States within 30 days, or the embryos will be destroyed.

§ 98.21 Embryos from sheep in regions other than Australia, Canada, and New Zealand.

Except for embryos from sheep in Australia, Canada, or New Zealand, embryos from sheep may only be imported into the United States if they

comply with all applicable provisions of this subpart and with §98.10a.

(Approved by the Office of Management and Budget under control numbers 0579–0040 and 0579–0101)

[61 FR 17242, Apr. 19, 1996]

Subpart C—Certain Animal Semen

SOURCE: 55 FR 31558, Aug. 2, 1990, unless otherwise noted.

§98.30 Definitions.

Whenever in this subpart of the following terms are used, unless the context otherwise requires, they shall be construed, respectively, to mean:

Administrator. The Administrator of the Animal and Plant Health Inspection Service or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, to whom authority has been or may be delegated to act in the Administrator's stead.

Animal and Plant Health Inspection Service. The Animal and Plant Health Inspection Service of the United States Department of Agriculture (APHIS or Service.)

Animals. Cattle, sheep, goats, other ruminants, swine, horses, asses, zebras, and poultry.

APHIS-defined EU CSF region. The European Union Member States of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Republic of Ireland, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

Cattle. Animals of the bovine species.

Communicable disease. Any contagious, infectious, or communicable disease of domestic livestock, poultry or other animals.

Department. The United States Department of Agriculture (USDA).

Flock. A herd.

Herd. All animals maintained on any single premises; and all animals under common ownership or supervision on two or more premises which are geographically separated, but among which there is an interchange or movement of animals.

Horses. Horses, asses, mules, and zebras.

Inspector. An employee of the Animal and Plant Health Inspection Service authorized to perform duties required under this subpart.

Port veterinarian. A veterinarian employed by the Animal and Plant Health Inspection Service to perform duties required under this part at a port of entry.

Poultry. Chickens, doves, ducks, geese, grouse, guinea fowl, partridges, pea fowl, pheasants, pigeons, quail, swans, and turkeys (including eggs for hatching).

Region. Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

Restricted zone for classical swine fever. An area, delineated by the relevant competent veterinary authorities of the region in which the area is located, that surrounds and includes the location of an outbreak of classical swine fever in domestic swine or detection of the disease in wild boar, and from which the movement of domestic swine is prohibited.

Ruminants. All animals which chew the cud, such as cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes.

Swine. The domestic hog and all varieties of wild hogs.

United States. All of the States of the United States, the District of Columbia, Guam, Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other Territories and Possessions of the United States.

[55 FR 31558, Aug. 2, 1990. Redesignated at 56 FR 55809, Oct. 30, 1991; 61 FR 17242, Apr. 19, 1996; 62 FR 56026, Oct. 28, 1997; 65 FR 56777, Sept. 20, 2000; 71 FR 29071, May 19, 2006; 72 FR 67233, Nov. 28, 2007]

§ 98.31 General prohibitions; exceptions.

(a) No product subject to the provisions of this subpart shall be brought into the United States except in accordance with the regulations in this subpart and part 94 of this subchapter; nor shall any such product be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations; *Provided*, That, except as prohibited by section 306 of the Act of June 17, 1930, as amended (19 U.S.C. 1306), the Administrator may upon request in specific cases permit products to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock or poultry of the United States.

(b) Animal semen may not be imported into the United States from any region other than the region in which it was collected.

[55 FR 31558, Aug. 2, 1990. Redesignated at 56 FR 55809, Oct. 30, 1991, and amended at 58 FR 37643, July 13, 1993; 59 FR 26596, May 23, 1994; 62 FR 56026, Oct. 28, 1997]

§ 98.32 Inspection of certain aircraft and other means of conveyance and shipping containers thereon; unloading, cleaning, and disinfection requirements.

(a) *Inspection:* All aircraft and other means of conveyance (including shipping containers thereon) moving into the United States from any foreign region are subject to inspection without a warrant by properly identified and designated inspectors to determine whether they are carrying any animal, carcass, product or article regulated or subject to disposal under any law or regulation administered by the Secretary of Agriculture for prevention of the introduction or dissemination of any communicable animal disease.

(b) *Unloading requirements:* Whenever in the course of any such inspection at any port in the United States the inspector has reason to believe that the means of conveyance or container is contaminated with material of animal (including poultry) origin, such as, but not limited to, meat, organs, glands, extracts, secretions, fat, bones, blood, lymph, urine, or manure, so as to present a danger of the spread of any communicable animal disease, the inspector may require the unloading of the means of conveyance and the emptying of the container if he or she deems it necessary to enable him or her to determine whether the means of conveyance or container is in fact so contaminated. The principal operator of the means of conveyance and his or her agent in charge of the means of conveyance shall comply with any such requirement under the immediate supervision of, and in the time and manner prescribed by, the inspector.

(c) *Cleaning and disinfection:* Whenever, upon inspection under this section, an inspector determines that a means of conveyance or shipping container is contaminated with material of animal origin so as to present a danger of the spread of any communicable animal disease, he or she shall notify the principal operator of the means of conveyance or his or her agent in charge, of such determination and the requirements under this section. The person so notified shall cause the cleaning and disinfection of such means of conveyance and container under the immediate supervision of, and in the time and manner prescribed by, the inspector.

(d) For purposes of this section, the term ''shipping container'' means any container of a type specially adapted for use in transporting any article on the means of conveyance involved.

[55 FR 31558, Aug. 2, 1990. Redesignated at 56 FR 55809, Oct. 30, 1991; 62 FR 56026, Oct. 28, 1997; 68 FR 6345, Feb. 7, 2003]

§ 98.33 Ports designated for the importation of certain animal semen.

(a) *Air and ocean ports.* The following air and ocean ports are designated as having inspection facilities for the entry of animal semen: Los Angeles, California; Miami, Florida; and Newburgh, New York.

(b) *Canadian border ports.* The following land border ports are designated as having inspection facilities for the entry of animal semen from Canada: Eastport, Idaho; Houlton and Jackman, Maine; Detroit, Port Huron, and Sault

Ste. Marie, Michigan; Baudette, Minnesota; Opheim, Raymond, and Sweetgrass, Montana; Alexandria Bay, Buffalo, and Champlain, New York; Dunseith, Pembina, and Portal, North Dakota; Derby Line and Highgate Springs, Vermont; Oroville and Sumas, Washington.

(c) *Mexican border ports.* The following land border ports are designated as having inspection facilities for the entry of animal semen from Mexico: Douglas, Naco, Nogales, San Luis, and Sasabe, Arizona; Calexico and San Ysidro, California; Antelope Wells, Columbus, and Santa Teresa, New Mexico; Brownsville, Del Rio, Eagle Pass, El Paso, Hidalgo, Laredo, and Presidio, Texas.

(d) *Limited ports.* The following limited ports are designated as having inspection facilities for the entry of animal semen: Anchorage and Fairbanks, Alaska; San Diego, California; Jacksonville, St. Petersburg-Clearwater, and Tampa, Florida; Atlanta, Georgia; Honolulu, Hawaii; Chicago, Illinois; New Orleans, Louisiana; Portland, Maine; Baltimore, Maryland; Boston, Massachusetts; International Falls and Minneapolis, Minnesota; Great Falls, Montana; Portland, Oregon; San Juan, Puerto Rico; Memphis, Tennessee; Galveston and Houston, Texas; Seattle, Spokane, and Tacoma, Washington.

(e) *Designation of other ports.* The Secretary of the Treasury has approved the designation as quarantine stations of the ports specified in this section. In special cases other ports may be designated as quarantine stations under this section by the Administrator, with the concurrence of the Secretary of the Treasury.

[55 FR 31558, Aug. 2, 1990. Redesignated at 56 FR 55809, Oct. 30, 1991, and amended at 58 FR 37643, July 13, 1993; 60 FR 16045, Mar. 29, 1995; 60 FR 25120, May 11, 1995; 64 FR 23179, Apr. 30, 1999; 65 FR 38178, June 20, 2000; 67 FR 68022, November 8, 2002]

§98.34 Import permits for poultry semen and animal semen.

(a) *Application for permit; reservation required.* (1) For poultry semen and animal semen, intended for importation from any part of the world, except as otherwise provided for in §98.36, the importer shall first apply for and obtain from APHIS an import permit. The application shall specify the name and address of the importer; the species, breed, quantity of animal semen to be imported; the purpose of the importation; individual animal identification (except poultry) which includes a description of the animal, name, age, markings, if any, registration number, if any, and tattoo or eartag; the region of origin; the name and address of the exporter; the port of embarkation in the foreign region; the mode of transportation, route of travel, and the port of entry in the United States; the proposed date of arrival of the animal semen to be imported; and the name of the person to whom the animal semen will be delivered and the location of the place in the United States to which delivery will be made from the port of entry. Additional information may be required in the form of certificates concerning specific diseases to which the animals are susceptible, as well as vaccinations or other precautionary treatments to which the animals or animal semen have been subjected. Notice of any such requirements will be given to the applicant in each case.

(2) An application for permit to import will be denied for semen from ruminants or swine from any region where it has been declared, under section 306 of the Act of June 17, 1930, that foot-and-mouth disease or rinderpest has been determined to exist, except as provided in paragraph (c) of this section.

(3) An application for permit to import poultry semen or animal semen may also be denied because of: Communicable disease conditions in the area or region of origin, or in a region through which the shipment has been or will be transported; deficiencies in the regulatory programs for the control or eradication of animal diseases and the unavailability of veterinary services in the above mentioned regions; the importer's failure to provide satisfactory evidence concerning the origin, history, and health status of the animals or animal semen; the lack of satisfactory information necessary to determine that the importation will not be likely to transmit any communicable disease to livestock or poultry

of the United States; or any other circumstances which the Administrator believes require such denial to prevent the dissemination of any communicable disease of livestock or poultry into the United States.

(b) *Permit.* When a permit is issued, the original and two copies will be sent to the importer. It shall be the responsibility of the importer to forward the original permit and one copy to the shipper in the region of origin, and it shall also be the responsibility of the importer to insure that the shipper presents the copy of the permit to the carrier and makes proper arrangements for the original permit to accompany the shipment to the specified U.S. port of entry for presentation to the collector of customs. Animal semen intended for importation into the United States for which a permit has been issued, will be received at the specified port of entry within the time prescribed in the permit which shall not exceed 14 days from the first day that the permit is effective for all permits. Poultry semen and animal semen for which a permit is required by these regulations will not be eligible for entry if a permit has not been issued; if unaccompanied by such a permit; if shipment is from any port other than the one designated in the permit; if arrival in the United States is at any port other than the one designated in the permit; if the animal semen offered for entry differs from that described in the permit; or if the animal semen is not handled as outlined in the application for the permit and as specified in the permit issued.

(c) *Animal semen from regions where rinderpest or foot-and-mouth disease exists.* Importation of semen of ruminants or swine, originating in any region designated in paragraph (a) of § 94.1 of this subchapter as a region where rinderpest or foot-and-mouth disease is determined to exist, is prohibited, except that semen from ruminants or swine originating in such a region may be offered for entry into the United States at the port of New York and later released from such port provided the following conditions have been fulfilled:

(1) The importer has applied for and obtained an import permit for the semen in accordance with the provisions of this section and related requirements concerning application therefor, which permit is in effect at the time of importation, and has deposited with the Department prior to the issuance of the permit sufficient funds so as to be available for defraying estimated expenses to be incurred in connection with the proposed semen importation and following the issuance of the permit has deposited such other amounts as may be required from time to time to defray unanticipated costs or increased expenses. Such an import permit may be denied for the reasons specified in paragraph (a)(3) of this section. Furthermore, an import permit will be revoked unless the following conditions have been complied with:

(i) The donor animal shall have been inspected on the farm of origin or on another premises (the inspection may be on another premises only if a veterinarian of the Department has traced the donor animal back to its farm of origin) by a veterinarian of the United States Department of Agriculture who, in cooperation with the veterinary service of the region of origin of the donor animal, shall have determined, insofar as possible, that the donor animal was never infected with rinderpest or foot-and-mouth disease; that the donor animal was never on a farm or other premise where rinderpest or foot-and-mouth disease then existed; that the donor animal has not been on a premise that had an animal that was susceptible to the virus of rinderpest or foot-and-mouth disease and that was exposed to either disease during the 12 months immediately prior to the date of inspection of the donor animal; that the donor animal, if a ruminant, has never been vaccinated against rinderpest; that the donor animal, if a swine, has never been vaccinated against rinderpest or foot-and-mouth disease; and that the donor animal was free from evidence of other communicable disease;

(ii) The donor animal shall have been permanently identified in a manner satisfactory to a veterinarian of this Department; a blood sample and an oesophageal-pharyngeal tissue sample (O-P sample) from such a donor ruminant and a blood sample from such a donor swine for tests as specified in

paragraph (c)(1)(iv) of this section or other tests shall have been collected by a veterinarian of the United States Department of Agriculture and transported by air to the New York Port Veterinarian for delivery to the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York, in containers approved by a veterinarian of this Department, sealed in the region of origin by a veterinarian of this Department; and pending the results of the tests, the donor animal shall have been kept in isolation on the farm of origin or other acceptable location under the supervision of a veterinarian of this Department, and during such isolation period no animal susceptible to rinderpest or foot-and-mouth disease shall have been permitted to enter such farm or location and no other source of exposure to rinderpest or foot-and-mouth disease shall have been present;

(iii) The blood samples from the donor animal shall have been negative to the tests specified in paragraph (c)(1)(iv) of this section made at the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York, and to any other test for rinderpest, foot-and-mouth disease or other communicable disease prescribed by the Administrator.

(iv) In the case of a ruminant, each blood sample collected pursuant to paragraph (c)(1)(ii) or (vi) of this section shall have been tested for foot-and-mouth disease using the virus infection associated (VIA) test and each O-P sample collected pursuant to paragraph (c)(1)(ii) or (iv) of this section shall have been tested for foot-and-mouth disease using the virus isolation test. In the case of a swine, each blood sample collected pursuant to paragraph (c)(1)(ii) or (vi) of this section shall have been tested for foot-and-mouth disease using the virus infection associated (VIA) test and the virus neutralization test.''[1]

(v) Following isolation, preliminary veterinary inspection, and testing while the donor animal was on the farm of origin or other acceptable location, the donor animal shall have been transported, under such conditions as the Department veterinarian prescribed to prevent exposure of the animal to the virus of rinderpest or foot-and-mouth disease, to an isolation facility properly equipped for the necessary care and maintenance of the donor animal and for the proper collection and handling of semen, approved by a veterinarian of this Department and under the direct supervision of such veterinarian;

(vi) The semen of the donor animal shall have been collected at the approved isolation facility under the direct supervision of a veterinarian of this Department (any number of collections may be made); such veterinarian shall take a 0.5 ml sample of semen from each semen collection; and all handling procedures, such as examination, dilution, refrigeration, and preparation of the semen for shipment, shall have been under the direct supervision of a veterinarian of this Department. In the case of a ruminant, a blood sample and an O-P sample shall have been taken from the donor animal by a veterinarian of the Department within 7 days after the final semen collection, and between 21 to 28 days after the taking of these samples another blood sample shall have been taken from the donor animal by a veterinarian of the Department. In the case of a swine, a blood sample shall have been taken from the donor animal by a veterinarian of the Department within 7 days after the final semen collection, and between 21 to 28 days after the taking of the sample, another blood sample shall have been taken from the donor animal by a veterinarian of the Department.

(2) The semen collected at the approved isolation facility shall have been at all times, except during air transportation to New York, in the custody of a veterinarian of this Department.

(3) The semen for which an import permit has been issued shall have been transported by air to the port of New York in liquid nitrogen containers approved by a veterinarian of this Department; sealed in the region of origin

[1] The test procedures for the virus infection associated (VIA) test, the virus isolation test, and the virus neutralization test are available from the Chief, Foreign Animal Disease Diagnostic Laboratory, National Veterinary Services Laboratories, P.O. Box 848, Greenport, NY 11944.

by a veterinarian of this Department; and accompanied by a statement by such veterinarian showing the identification of the donor animal and the dates the semen was collected, along with a certificate regarding the health status of the donor animal as of the date of shipment of the semen to the port of New York. All semen received at the port of New York shall be held under quarantine in liquid nitrogen storage at such port in the custody of APHIS until released or otherwise disposed of as provided in this section.

(4) The donor animal shall have been retained at the approved isolation facility in the region where the semen was collected until all of the applicable samples referred to in paragraph (c)(1)(vi) of this section have been collected by a veterinarian of the Department for tests as specified in paragraph (c)(1)(iv) of this section at the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York, and any other tests as required by the Administrator.

(5) The semen sample from each collection shall have consisted of unprocessed semen without any added substances, and shall have been tested at the Foreign Animal Disease Diagnostic Laboratory, Greenport, New York. Such tests shall have been performed by injecting the semen samples into test animals which are susceptible to rinderpest or foot-and-mouth disease. The semen collected at the approved isolation facility, other than the semen samples, may be held in the region of origin or at the port of New York, at the option of the importer, until all of the testing required to be conducted under this section is completed.

(6) If it is determined that the requirements set forth in this paragraph have been complied with and there are no indications that the donor animal or the semen from the donor animal harbors the virus of rinderpest or foot-and-mouth disease or any other communicable disease and if the donor animal, blood samples from the donor animal, O-P samples (if applicable) from the donor animal, and semen samples from the donor animal are negative to all other tests required, the semen shall be released for shipment to the consignee listed by the importer; otherwise the semen shall be destroyed or disposed of as the Administrator, may direct.

(7) *Porcine semen from the People's Republic of China.* In addition to the other requirements of this part, porcine semen may be imported into the United States from the People's Republic of China (PRC) only after the official veterinary organization (OVO) of the PRC has certified that the PRC is free of African swine fever, rinderpest, and Teschen's disease, and after the following conditions have been fulfilled:

(i) The donor boars must pass a 60-day isolation/collection period in a facility jointly approved by the OVO of the PRC and the USDA as adequate to prevent exposure of the donor boars to infectious diseases. Any other swine at the isolation facility, such as teaser animals, must also meet the requirements of this paragraph. No animals may be added to the group after the start of the 60-day isolation/collection period. The Department will permit collection of semen to be initiated at the beginning of the isolation/collection period. The facility shall be cleaned and disinfected with a 4 percent sodium carbonate solution used in accordance with applicable label instructions in the presence of OVO quarantine personnel prior to the start of the isolation. During the isolation/collection period, personnel handling the animals shall not have contact with other domestic farm livestock (this term does not include pets such as dogs and cats). Raw animal food wastes (garbage) shall not be fed to the donor boars while in isolation. At the start of the isolation/collection period, and again after 14 days of isolation, all animals offered for collection of semen must be given an intramuscular injection of dihydrostreptomycin at a rate of 25 mg/kg dosage as a precautionary treatment for leptospirosis. Feed and bedding used during the isolation/collection period shall not originate from areas infected with epizootic diseases and must meet veterinary hygienic requirements established by the OVO of the PRC concerning freedom of the feed and bedding from contamination that could transmit diseases. During the isolation/collection period the swine at

the collection center shall not have direct contact with, or exposure to, any other animals not included in the group at the isolation facility. Exposure consists of contact with yards, pens, or other facilities or vehicles that have been in contact with animals and have not been cleaned and disinfected.

(ii) Donor boars shall be selected from premises which are solely swine breeding operations. These premises must be located at the center of an area with a 16 km radius that was free of foot-and-mouth disease (FMD), swine vesicular disease (SVD), and classical swine fever for three years prior to semen collection. Donor boars shall not have been vaccinated against these diseases. There shall have been no cases of these diseases on these premises for five years prior to the collection of semen. There shall have been no animal introduced into these premises from farms affected with these diseases for three years prior to the collection of semen. There shall have been no evidence of brucellosis, tuberculosis, or pseudorabies on these premises or on premises adjacent to these premises for one year prior to the collection of semen.

(iii) During the 60-day isolation/collection period, the boars offered for collection of semen shall be subjected to the following tests,[2] in lieu of the tests required by paragraphs (c)(1)(iv) and (vi) of this section. If test samples from any donor boars are lost, damaged, or destroyed prior to testing, or if test results are inconclusive, the donor boars involved shall be subjected to retesting:

(A) Foot-and-mouth disease:

(*1*) Microtiter virus neutralization (VN) test for types, A, O, C, and Asia. (The PRC will test for types A and O, and the United States will test for types C and Asia at the USDA Foreign Animal Disease Diagnostic Laboratory (FADDL)).

(*2*) Agar gel immunodiffusion (AGID) test using virus infection associated antigen (VIAA) in serum. (Animals having responses to the AGID test or reacting to the VN test at 1:10 dilution or greater shall be eliminated as semen donors, and all other swine in contact with them shall be retested within 30 days. If the whole group does not have the above responses and there is no clinical evidence of FMD, the group shall be eligible for collection of semen with respect to FMD. Otherwise, none of the group shall qualify as donors of semen for export.)

(B) Brucellosis: Standard tube test (STT) at less than 30 IU/ml, and card test (antigen and protocol to be supplied by USDA).

(C) Swine vesicular disease: Virus neutralization test at 1:40 dilution (serums to be tested at FADDL).

(D) Classical swine fever: Fluorescent antibody neutralization (FAN) test at 1:16 dilution.

(E) Japanese B encephalitis: Hemagglutination inhibition (HI) test, negative according to PRC standards.

(F) Pseudorabies: Virus neutralization at 1:4 dilution.

(G) Tuberculosis: Intradermal test using bovine PPD tuberculin (Positive animals will be necropsied. If there are lesions of TB in the test positive pigs, the whole group will be ineligible as semen donors. If no lesions are found, the rest of the pigs will be eligible as semen donors with respect to tuberculosis.

All samples of the above tests, except as noted for FMD, SVD, and TB, will be submitted to laboratories designated by the OVO of the PRC. At least 21 days after the final collection of semen for exportation, the donor animals will be retested for the diseases listed above, with the exception of tuberculosis and Japanese encephalitis. In addition, aliquots of each ejaculate of semen collected shall be submitted to FADDL for pathogen isolation tests for FMD, brucellosis, swine vesicular disease, classical swine fever, Japanese encephalitis, and pseudorabies.

(iv) The semen will not be eligible for release in the United States until all tests in paragraph (c)(7)(iii) of this section have been completed with negative results.

(v) Each semen straw or ampule for export must be identified with the name or identification number of the

[2]Technical information on laboratory methods and procedures for these tests may be obtained from the Administrator, c/o Director, National Veterinary Services Laboratories, P.O. Box 844, Ames, IA 50010.

donor boar and with the date of collection. A USDA veterinarian shall certify that he or she has supervised the collection and processing of the semen and its storage until the time it is shipped to the United States. Each shipment will be accompanied by a USDA veterinarian unless the semen is shipped directly to the port of New York, with no stops en route. Shipment to the United States will be in accordance with the terms of a USDA import permit. Semen imported in accordance with this section shall be released by USDA to the importer only after all requirements of this section have been met.

(d) *Sheep and goat semen from regions where scrapie exists.* Importation of semen of sheep and goats is subject to the requirements in § 98.35(e). Applications for a permit to import sheep and goat semen must include statements that:

(1) All first generation (F1) progeny resulting from imported semen will be identified with a permanent official identification consistent with the provisions of § 79.2 of this chapter; and

(2) Records of any sale of F1 progeny, 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.

[55 FR 31558, Aug. 2, 1990. Redesignated at 56 FR 55809, Oct. 30, 1991, and amended at 58 FR 37644, July 13, 1993; 59 FR 26596, May 23, 1994; 62 FR 56026, Oct. 28, 1997; 68 FR 16940, Apr. 7, 2003; 72 FR 64128, Nov. 15, 2007]

§ 98.35 Declaration, health certificate, and other documents for animal semen.

(a) The certificates, declarations, and affidavits required by the regulations in this subpart shall be presented by the importer or his or her agent to the collector of customs at the port of entry, upon arrival of animal semen at such port, for the use of the veterinary inspector at the port of entry.

(b) For all animal semen offered for importation, the importer or his or her agent shall first present two copies of a declaration which shall list the port of entry, the name and address of the importer, the name and address of the broker, the origin of the animal semen, the number, breed, species, and purpose of the importation, the name of the person to whom the animal semen will be delivered, and the location of the place to which such delivery will be made.

(c) All animal semen intended for importation into the United States shall be accompanied by a health 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.

(d) The health certificate must state:

(1) The name and address of the place where the semen was collected;

(2) The name and address of the veterinarian who supervised the collection of the semen;

(3) The date of semen collection;

(4) The identification and breed of the donor animal;

(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 animal as a condition for importing the semen;

(7) The seal number on the shipping container;

(8) The names and addresses of the consignor and consignee; and

(9) That the semen is being imported into the United States in accordance with subpart C of 9 CFR part 98.

(e) The certificate accompanying sheep or goat semen intended for importation from any part of the world shall, in addition to the statements required by paragraph (d) of this section, state that:

(1) The donor animals:

(i) Are permanently identified, to enable traceback to their establishment of origin; and

(ii) Have been kept since birth in establishments in which no case of scrapie had been confirmed during their residency; and

(iii) Neither showed clinical signs of scrapie at the time of semen collection

nor developed scrapie between the time of semen collection and the export of semen to the United States; and

(iv) The dam of the semen donor is not, nor was not, affected with scrapie.

(2) In the region where the semen originates:

(i) Scrapie is a compulsorily notifiable disease; and

(ii) An effective surveillance and monitoring system for scrapie is in place; and

(iii) Affected sheep and goats are slaughtered and completely destroyed; and

(iv) The feeding of sheep and goats with meat-and-bone meal or greaves derived from ruminants has been banned and the ban effectively enforced in the whole region; and

(3) Semen originating in regions other than Australia and New Zealand is to be transferred to females in a flock that is listed in the Scrapie National Database as part of the Scrapie Program in the United States. Imported semen may be further distributed to any other listed flock with written notification to the APHIS Veterinary Services area office.

(f) All shipping containers carrying animal semen for importation into the United States must be sealed with an official seal of the national veterinary service of the region of origin. The health certificate must show the seal number on the shipping container. The semen must remain in the sealed container until arrival in the United States and, at the U.S. port of entry, an inspector determines that either:

(1) The seal numbers on the health certificate and shipping container match; or

(2) The seal numbers on the health certificate and shipping container do not match, but an APHIS representative at the port of entry is satisfied that the shipping container contains the semen described on the health certificate, import permit, declaration, and any other accompanying documents.

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

[55 FR 31558, Aug. 2, 1990. Redesignated at 56 FR 55809, Oct. 30, 1991, as amended at 58 FR 37644, July 13, 1993; 61 FR 15184, Apr. 5, 1996; 61 FR 17242, Apr. 19, 1996; 62 FR 56026, Oct. 28, 1997; 65 FR 56777, Sept. 20, 2000; 72 FR 64128, Nov. 15, 2007]

§98.36 Animal semen from Canada.

(a) *General importation requirements for animal semen from Canada.*

If the product is . . .	Then . . .
(1) Equine semen	There are no importation requirements under this part.
(2) Sheep or goat semen	The importer or his agent, in accordance with §§98.34 and 98.35 of this part, must present: (i) An import permit; (ii) Two copies of a declaration; and (iii) A health certificate.
(3) Animal semen other than equine, sheep, or goat semen.	See paragraph (b) of this section.

(b) *Importation requirements for animal semen other than equine, sheep, or goat semen from Canada.*

If the product is offered for entry at a . . .	And . . .	Or . . .	Then . . .
(1) Canadian land border port listed in § 98.33(b) of this part.	The donor animal was born in Canada or the United States and has never been in a region other than Canada or the United States.	The donor animal was legally imported into Canada, released to move freely in Canada, and has been released in Canada for no less than 60 days.	The importer or his agent, in accordance with § 98.35 of this part, must present: (i) Two copies of a declaration; and (ii) A health certificate.
(2) Canadian land border port listed in § 98.33(b) of this part.	The donor animal does not meet the special conditions listed above in paragraph (b)(1) of this table.		The importer or his agent, in accordance with §§ 98.34 and 98.35 of this part, must present: (i) An import permit; (ii) Two copies of a declaration; and (iii) A health certificate.
(3) Port not listed in § 98.33(b) of this part.			The importer or his agent, in accordance with §§ 98.34 and 98.35 of this part, must present: (i) An import permit; (ii) Two copies of a declaration; and (iii) A health certificate.

[65 FR 56778, Sept. 20, 2000]

§ 98.37 [Reserved]

§ 98.38 Restrictions on the importation of swine semen from the APHIS-defined EU CSF region.

In addition to meeting all other applicable provisions of this part, swine semen imported from the APHIS-defined EU CSF region must meet the following conditions, except as noted in paragraph (h) of this section with regard to swine semen imported from Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom:

(a) The semen must come from a semen collection center approved for export by the competent veterinary authority of the APHIS-defined EU CSF region Member State.

(b) The semen must not have been collected from a donor boar that was in any of the following regions or zones, unless the semen was collected after the periods described:

(1) Any region when the region was classified in §§ 94.9(a) and 94.10(a) of this chapter as one in which classical swine

fever is known to exist, except for the APHIS-defined EU CSF region;

(2) A restricted zone in the APHIS-defined EU CSF region established because of the detection of classical swine fever in domestic swine, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of the Member State or until 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later; or

(3) A restricted zone in the APHIS-defined EU CSF region established because of the detection of classical swine fever in wild boar, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of the Member State.

(c) The semen must not have been collected from a donor boar that was commingled with swine that at any time were in any of the regions or zones described in paragraphs (b)(1) through (b)(3) of this section, unless the semen was collected after the periods described.

(d) The semen must not have been collected from a donor boar that transited any region or zone described in paragraphs (b)(1) through (b)(3) of this section during the periods described, unless the donor boar was moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the semen was collected after the periods described;

(e) The donor boar must be held in isolation for at least 30 days prior to entering the semen collection center.

(f) No more than 30 days prior to being held in isolation as required by paragraph (e) of this section, the donor boar must be tested with negative results with a classical swine fever test approved by the World Organization for Animal Health.

(g) No equipment or materials used in transporting the donor boar from the farm of origin to the semen collection center may have been used previously for transporting swine that do not meet the requirements of this section, unless such equipment or materials have first been cleaned and disinfected.

(h) Except for semen collected from swine in Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom, before the semen is exported to the United States, the donor boar must be held at the semen collection center and observed by the center veterinarian for at least 40 days following collection of the semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of classical swine fever.

(i) The semen must be accompanied by a certificate issued by a salaried veterinary officer of the competent veterinary authority of the APHIS-defined EU CSF region Member State, stating that the provisions of paragraphs (a) through (h) of this section have been met.[3]

(Approved by the Office of Management and Budget under control numbers 0579–0218 and 0579–0265).

[71 FR 29072, May 19, 2006, as amended at 72 FR 67233, Nov. 28, 2007]

PART 99—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER CERTAIN ACTS

Subpart A—General

Sec.
99.1 Scope and applicability of rules of practice.

Subpart B—Supplemental Rules of Practice

99.10 Stipulations.

AUTHORITY: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 48 FR 30095, June 30, 1983, unless otherwise noted. Redesignated at 52 FR 29502, Aug. 10, 1987.

Subpart A—General

§99.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of part 1, subtitle A,

[3] The certification required may be placed on the certificate required under §98.35(c) or may be contained in a separate document.