

§ 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.

¹The 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.

(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 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:

²Technical 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.

(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 dis-

ease, 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 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.

[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]

§ 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