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This protocol describes the conditions required to import semen from domestic swine (*Sus scrofa*) according to regulations found in 9 CFR Part 98 from a region of the European Union (EU) recognized by USDA APHIS as low-risk for Classical Swine Fever (CSF) (<u>USDA APHIS | Animal Health Status of Regions</u>).

Note: In accordance with this protocol, USDA APHIS reserves the right to inspect and/ or audit the collection and export facilities as needed in order to ensure USDA APHIS imports standards are met.

#### 1. GENERAL REQUIREMENTS

1.1. The importer must obtain an Import Permit from the:

U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) Strategy & Policy, (S&P) Unit 39 4700 River Road Riverdale, MD 20737-1231

Telephone: (301) 851-3300 Fax: (301) 734-4704

The application, VS Form 17-129, "Application for Import or in Transit Permit," may be obtained by emailing <u>laipermits@usda.gov</u>, by downloading it from the <u>APHIS website</u>, or filed electronically using the <u>eFile system</u>.

(Note: The animal disease status of various countries may be obtained at this webpage: USDA APHIS | Animal Health Status of Regions)

- 1.2. This protocol is only applicable to Member States of the EU recognized by the USDA as low-risk for CSF, defined in Title 9, Code of Federal Regulations (9 CFR), Parts 93 and 94, as an "APHIS-defined EU CSF region."
- 1.3. A restricted zone for classical swine fever (CSF), as defined in 9 CFR, Part 94, refers to 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 CSF in domestic swine, or detection of the disease in wild boar, and from which the movement of domestic swine is restricted.
- 1.4. An official health certificate is required to be issued within 30 days of export and is required on entry into the United States. The official health certificate must be issued by an Official Veterinarian recognized by the competent veterinary authority of the EU Member State in the APHIS-defined EU CSF region attesting to the certifications and tests required in this protocol. Results and dates of all required official tests must be included in the certification.

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1.5. The semen must originate from a semen collection center (SCC) approved for export by the competent veterinary authority of the EU Member State in the APHIS-defined EU CSF region. All porcine animals in the SCC must be established as residents only if admitted by a formal process of quarantine, observation, and testing as required by legislation in force, in particular Council Directive 90/429/EEC, as amended, or in subsequent updates.

## 2. CERTIFICATIONS (see model health certificate)

- 2.1. The EU Member State, \_\_\_\_\_\_, is designated by the USDA to be free of foot-and-mouth disease (FMD), African swine fever, and swine vesicular disease, as indicated in 9 CFR Part 94 and other official publications.
- 2.2. The semen donors have not been imported into (EU Member State), \_\_\_\_\_\_\_, from countries/regions designated by the USDA in 9 CFR Part 94 and other official publications as affected with FMD, African swine fever, or swine vesicular disease.
- 2.4. With regard to the APHIS-defined EU CSF region, the semen must not have been collected from a donor that was in any of the following regions or zones, and must not have been commingled with swine that have been in any of the following regions or zones, unless the semen was collected after the periods described in 2.4.1 and 2.4.2 below:
  - 2.4.1. In a restricted zone in the APHIS-defined EU CSF region established because of an outbreak 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 an EU 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 which ever period of time is later.
  - 2.4.2. In 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 EU Member State.
- 2.5. The semen must not have been collected from a donor boar that has transited any region or zone described in 2.4.1 and 2.4.2 of this section, unless moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact on arrival at

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the point of destination, or unless the semen was collected after the periods described in 2.4.1 and 2.4.2 above.

- 2.6. During the 60 days prior to the collection of the semen for export to the United States, the donors (and teasers, if used) were not corralled, pastured, or held with other animals that were under restrictions that would make them ineligible for export to the United States.
- 2.7. Since birth, or during the 12 months prior to the collection of semen for export to the United States, there was no clinical evidence of tuberculosis, brucellosis, or Aujeszky's disease found in the donors or any other animals in contact with them.
- 2.8. Each semen donor (and teasers, if used)was established as a resident of an approved SCC only if admitted by a formal process of quarantine, observation, and testing, in accordance with Animal Health Law (Regulation (EU) 2016/429) or in subsequent updates and was transported to the SCC in a vehicle that was cleaned and disinfected.
- 2.9. 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 the equipment and materials have first been cleaned and disinfected.

## 3. ADDITIONAL (POST-COLLECTION) CERTIFICATIONS

- 3.1. Any outbreaks of communicable disease reported by the SCC after collection from the donors listed in this certificate, but prior to the time of the shipment's consignment to the United States, have been investigated and resolved by the national Competent Authority.
- 3.2. There have been no cases reported or suspected of foot-and-mouth disease, African swine fever or swine vesicular disease in the country or region of origin between the time when the semen for export to the United States was last collected and the date of shipment.

#### 4. SEMEN STORAGE AND SHIPMENT

- 4.1. After semen processing, the ampules/collection units must be segregated in a storage area separate from other semen not intended for export to the United States and must be maintained under official supervision until such time as the ampules/collection units are placed in the shipping tank and sealed with official government seals. The seal numbers must be recorded on the health certificate.
- 4.2. The shipping tank must be new or cleaned and disinfected, and only virgin liquid nitrogen must be used to charge the tank if the semen is shipped frozen.
- 4.3. The shipment must be routed directly to the United States with no stops en route other than those provided for on the USDA import permit.

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#### 5. ADDITIONAL GUIDELINES

Check the animal health regulations of the importing state of destination for possible additional regulations and requirements for the proposed import (<u>State Regulations and Import Requirements</u>). These requirements are the responsibility of the importer.

## 6. ARRIVAL AND INSPECTION AT THE PORT OF ENTRY

- 6.1. On arrival at the port of entry, the importer or the importer's agent must present the port veterinarian with the original health certificate and the original import permit for the semen.
- 6.2. The shipping container and all straws or ampules containing semen must be made available for inspection at the port of entry and may not be removed from such port of entry until an inspector determines that the semen is eligible for importation in accordance with this protocol and releases the shipment.

# 7. SEMEN SHIPMENTS REFUSED ENTRY

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