Fetal Bovine Serum for Technical Purposes to Taiwan

These requirements apply only to fetal bovine serum including fetal bovine serum in cell culture media intended for technical use, and do not apply to blood products for animal consumption (feed use) or NON-bovine serum.

FACILITY INSPECTION

The processing/exporting facility must be inspected by APHIS Veterinary Services (VS) at least annually to verify that the facility meets the requirements for export and provide APHIS supervision. To arrange for an inspection, the exporter should contact their pertinent VS Service Center. Upon completion of the inspection, the VS inspector forwards the completed inspection checklist to the Export Products staff in Riverdale for review and APHIS approval. Following issuance of APHIS approval, the Export Products staff will forward the facility name and address to Taiwan's Animal and Plant Health Inspection Agency (APHIA) for publication to their website. Once a facility has received APHIA approval, they may begin exporting fetal bovine serum to Taiwan. APHIS approval must be checked in the APHIS internal database prior to each certificate endorsement to ensure each lot of product intended for Taiwan meets the requirements of the facility's approval.

ADDITIONAL REQUIREMENTS

Country of Origin: Fetal bovine serum and products must be collected from fetuses from cattle that were, at the time of slaughter, resident in one of the following countries that have been recognized by Taiwan's Ministry of Agriculture, Executive Yuan as free of foot-and-mouth disease and contagious bovine pleuropneumonia[1]:

> Australia, Austria, Belgium, Brazil (state of Santa Catarina), Canada, Chile, Costa Rica, Czech Republic, Denmark, Finland, France, Honduras, Hungary, Iceland, Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Norway, Panama, Poland, Spain, Sweden, Switzerland, United Kingdom, United States*

*This list is based upon the most recent information provided to APHIS by the Animal and Plant Health Inspection Agency (APHIA). As always, the exporter is responsible for having their importer confirm, prior to shipment, that Taiwan will accept the exported materials.

Source of Fetal Bovine Serum: Fetal bovine serum may be collected from fetuses collected from cattle that passed ante-mortem inspection and dressed carcasses passed post-mortem inspection by the competent authority of the country in which the slaughterhouse is located. In addition, prior to slaughter, the cattle must not be subjected to a stunning process with a device injecting compressed gas or air into the cranial cavity nor to a pithing process.

Taiwanese Import Permit: The Taiwanese importer is required to apply for and obtain an import permit from APHIA prior to import. Only government agencies, publically owned enterprises, academic institutions and corporations are permitted to import these products. The exporter is responsible for confirming prior to export that his importer has obtained the required import permit.

Fetal bovine serum imported from the United States is prohibited from being used for the production of biological products for ruminant use, or for in-vivo tests/research purposes in Taiwan.

[1] The following link may be referenced for the most up-to-date country recognition status:
https://www.aphia.gov.tw/en/ws.php?id=21841

Fetal Bovine Serum for Technical Purposes to Taiwan

Production/Handling of Fetal Bovine Serum: Facilities may process fetal bovine serum designated for Taiwan in the same facility as ineligible serum or derivatives. However, appropriate measures must be taken to effectively segregate the fetal bovine serum for export to Taiwan from ineligible materials.

The exporter should be advised that Taiwan has indicated that the consignment must meet the relevant regulations of the International Air Transport Association (IATA). APHIS does not verify anything regarding the regulations of IATA and this requirement may not be referenced on the VS Form 16-4.

The information presented on the inner package label must include the product name and lot number.

PROCEDURES FOR CERTIFICATE ENDORSEMENT

In addition to meeting other APHIS VS requirements regarding issuance of zoosanitary (animal health) export certificates, the exporter must present the following with the draft VS Form 16-4 to the pertinent VS Service Center:

1. A properly notarized affidavit containing all certification statements appearing in the "Additional Declarations" section of the VS Form 16-4 under the affidavit line. The pertinent VS Service Center can provide details on how to prepare a proper notarized affidavit.
2. Laboratory results must be presented with the certificate showing that the materials have been tested (with negative results) for the following: mycoplasma, bovine viral diarrhea, infectious bovine rhinotracheitis, and exotic bluetongue. In case of imported products, the government certificate may contain certification of this testing as noted below.
3. For imported materials: A certificate[2] (for the specific lot of raw material that the exported materials are derived from) endorsed by a full-time salaried veterinarian of the agency responsible for animal health in the country of origin stating:
    a. That the materials are derived from fetuses from cattle that were, at the time of slaughter, resident in [*insert one of the following:* Australia, Austria, Belgium, Brazil (state of Santa Catarina), Canada, Chile, Costa Rica, Czech Republic, Denmark, Finland, France, Honduras, Hungary, Iceland, Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Norway, Panama, Poland, Spain, Sweden, Switzerland, United Kingdom, United States].
    b. That the materials are derived from fetuses collected from cattle that have passed ante-mortem and whose dressed carcasses have passed post-mortem inspection by the competent authority of [*insert name of country of origin*].
    c. [*If blood is filtered or irradiated in the country of origin*] That the materials have been filtered through a filter of 0.22µm or less or has been irradiated with gamma-rays at a dosage of 25 kGray (2.5MRad) or more, and has been tested and found free from mycoplasma, bovine viral diarrhea, infectious bovine rhinotracheitis, and exotic bluetongue. [If testing is performed in the U.S., laboratory results must be presented with the certificate showing that the materials have been tested (with negative results) for the listed diseases.]

[2] An easily readable copy is acceptable.

Fetal Bovine Serum for Technical Purposes to Taiwan

CERTIFICATION STATEMENTS

The following exact text must appear in the "Additional Declarations" section of the VS Form 16-4. No additional text may be added.

This is to certify that rinderpest, foot-and-mouth disease, classical swine fever, swine vesicular disease, African swine fever, and contagious bovine pleuropneumonia do not exist in the United States of America.

The below described bovine serum product was processed at the following facility, a premises which is under the supervision of the United States government: [*insert name and address of processing facility*] in the United States.

This office has on file a notarized affidavit from [*insert processing company name*] verifying the accuracy of the statements below.

1. The above referenced processing facility only manufactures and/or handles blood products eligible for export to Taiwan.
   OR
   The above referenced processing facility has an effective protocol in place to prevent cross-contamination or commingling of eligible products with ineligible materials.

2. The product was derived from fetuses collected from cattle that were, at the time of slaughter, resident in [insert <the United States> and/or <countryname(s), a country that has been (or countries that have been) recognized by the Ministry of Agriculture as free of foot-and-mouth disease and contagious bovine pleuropneumonia. >].
   ***Red text should be deleted if the facility only uses materials from U.S. slaughter houses. Include only applicable information. At the time of this posting, the only countries acceptable other than the United States include Australia, Austria, Belgium, Brazil (state of Santa Catarina), Canada, Chile, Costa Rica, Czech Republic, Denmark, Finland, France, Honduras, Hungary, Iceland, Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Norway, Panama, Poland, Spain, Sweden, Switzerland, and United Kingdom.*

3. The product was derived from fetuses collected from cattle which have passed ante-mortem and dressed carcasses have passed post-mortem inspection at the time of slaughter by the official competent authority of the country where the slaughterhouse is located and these cattle were not subjected to a stunning process with a device injecting air or gas in the cranial cavity, or a pithing process.

4. The product has been filtered through a filter of 0.22 micrometers or less, or has been irradiated with gamma-rays at the dose of 25kGray (2.5MRad) or more, and has been tested and found free from mycoplasma, bovine viral diarrhea, infectious bovine rhinotracheitis, and exotic bluetongue.

5. The product was produced, stored and transported in such a manner as to prevent contamination by communicable animal disease pathogens transmissible through the product.

Fetal Bovine Serum for Technical Purposes to Taiwan

Information to include in the "Product" section of the VS Form 16-4:
Product name (must state that the products are bovine serum products), quantity and unit of measure.

Information to include in the "Name and Address of Consignee" section of the VS Form 16-4:

Destination including country, name and address of importer in Taiwan.

If you have any questions about any of the above information, please contact the pertinent VS Service Center for additional assistance.