

Export of Bovine Serum Albumin (BSA)/ Cell Culture Media Containing BSA or Bovine Serum Technical Use Only

Products Covered: These requirements are specific for bovine serum albumin (BSA) and cell culture media containing BSA or bovine serum\ being exported for technical use only. For the export of bovine serum, including fetal bovine serum (FBS), please see instructions posted for “Bovine serum (other than fetal bovine serum), “Fetal bovine serum”. And “Serum for Technical Purposes: General Information.” Other blood byproducts are evaluated on a case-by-case basis.

Import Permit: The Taiwanese importer must apply for and obtain an import permit from the Taiwanese Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) prior to import. The U.S. exporter is responsible for confirming prior to export that the importer has obtained the required import permit, and the import permit covers the product and its intended end use. **APHIS Veterinary Services (VS) will not verify the issuance of the Taiwanese import permit unless the exporter requests endorsement of certification statements in addition to what is posted in this instruction.**

Documentation for Export Certification: The U.S. exporter must meet all APHIS/VS requirements for the issuance of zoosanitary (animal health) export certificates. The following must be provided to the VS Area Office endorsing the export certificate:

1. A draft VS Form 16-4, Export Certificate for Animal Products (Mar 2010 or current version) which includes required information about the product and shipment, as well as the required notarized affidavit line and certification statements in the additional declarations section.
2. A proper notarized affidavit containing all certification statements appearing in the additional declaration section of the VS Form 16-4. [The VS Area Office can provide guidance on how to prepare a proper notarized affidavit.]
3. For imported materials, including instances where the serum was derived from bovine animals slaughtered in a country other than the United States, a certificate (legible copy is acceptable) endorsed by a full-time salaried veterinarian of the agency responsible for animal health in the country of origin, certifying that “the product (or serum) was derived from cattle that were, at the time of slaughter, resident in [indicate country or countries acceptable to Taiwan: Australia, New Zealand, Iceland, Norway, Mexico, Panama, Honduras, Costa Rica, Hungary, Nicaragua, and Chile.]”*
4. Other documentation, as needed, to support additional certification statements required by the import permit for the product. [The VS Area Office will NOT add statements not covered by this instruction unless the U.S. exporter provides a current, valid Taiwanese import permit for the product requiring the statements. Endorsement of the statements is conditional based on whether the statements can be truthfully made and/or verified.]

***This list is based upon information provided to APHIS by the Taiwanese animal health authorities (BAPHIQ), and is subject to change. As always, the exporter is responsible for having the importer confirm, prior to shipment, that Taiwan will accept the product.**

Required Certification Statement for VS 16-4: The following statement must appear in the additional declaration section of the VS 16-4. No additional text may be added unless the statements are required by a current, valid Taiwanese import permit for the product (as presented to the endorsing VS Area Office) and the statements can be truthfully endorsed and verified.

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

For the blood byproduct, [indicate product name – bovine serum albumin or cell culture media containing bovine serum albumin or bovine serum], certified hereon, the serum was derived from cattle that were, at the time of slaughter, resident in [insert <the United States> and/or <country name or names, a country that has been (or countries that have been) recognized by the Council of Agriculture, Executive Yuan as free of foot-and-mouth disease, rinderpest, contagious bovine pleuropneumonia, and bovine spongiform encephalopathy>]. *Red text should be deleted if the facility only uses material from U.S. slaughter houses. Include only applicable information. At the time of this posting, the only countries acceptable other than the United States are Australia, New Zealand, Iceland, Norway, Mexico, Panama, Honduras, Costa Rica, Hungary, Nicaragua, and Chile.*

Additional Information for VS 16-4:

In the section for “PRODUCT (type of product, quantity, unit of measure, and animal product species of origin,” include product name identifying also species of origin (bovine serum albumin (BSA) or cell culture media containing BSA or bovine serum), quantity*, lot number. *A “total weight” is not acceptable if items are individually packaged. Taiwan wants a description, - for example, “50 ml (10 5 mil vials).”

In the section for “NAME AND ADDRESS OF CONSIGNEE,” enter full destination information, to include the name, address, and country for the Taiwanese importer.

If you have questions about any of the above information, please contact your APHIS/VS Area Office for assistance.

*****Please also see “IMPORTANT information regarding the Export of Animal Products to Taiwan (including requirement for certificate date):**

http://www.aphis.usda.gov/regulations/vs/iregs/products/downloads/tw_im.pdf

Taiwan will NOT accept zoosanitary health (export) certificates endorsed after the date of shipment of the product. To avoid rejection of shipments, please be sure to obtain the required health certificate prior to shipping.