

Bovine Serum Albumin (BSA)/ Cell Culture Media Containing BSA for Technical Purposes to Taiwan

These requirements are specific to bovine serum albumin (BSA) and cell culture media containing BSA for technical purposes only being exported to Taiwan. For the export of bovine serum, including fetal bovine serum (FBS) or cell culture media containing bovine serum or FBS, please reference the pertinent IREG on the previous page. Other blood byproducts are evaluated on a case-by-case basis.

Taiwanese Import Permit: The Taiwanese importer must apply for and obtain an import permit from the Taiwanese Animal and Plant Health Inspection Agency (APHIA) 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 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 these instructions.**

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. For imported materials (including instances when the serum was derived from bovine animals slaughtered in a country other than the United States): A certificate¹ endorsed by a full-time salaried veterinarian of the agency responsible for animal health in the country of origin stating:
 - a. That the product (or serum) was derived from cattle that were, at the time of slaughter, resident in *[insert one of the following: Australia, Chile, Costa Rica, Honduras, Hungary, Iceland, Mexico, New Zealand, Nicaragua, Norway or Panama]*.²
3. Other documentation, as needed, to support additional certification statements required by the import permit for the product. The VS Service Center 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.

¹ An easily readable copy is acceptable.

² This list is based upon information provided to APHIS by Taiwanese animal health authorities (APHIA) 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.

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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 unless the statements are required by a current, valid Taiwanese import permit for the product and the statements can be truthfully endorsed and verified.

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.

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

1. For the blood byproduct, [*indicate product name – bovine serum albumin or cell culture media containing bovine serum albumin*] 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(s), a country that has been (or countries that have been) recognized by the Ministry 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 materials from U.S. slaughterhouses. Include only applicable information. At the time of this posting, the only countries acceptable other than the United States include Australia, Chile, Costa Rica, Honduras, Hungary, Iceland, Mexico, New Zealand, Nicaragua, Norway or Panama.*

Information to include in the “Product” section of the VS Form 16-4:

Product name identifying species of origin (bovine serum albumin (BSA) or cell culture media containing BSA), quantity*, lot number.

*A “total weight” is not acceptable if items are individually packaged. Taiwan requires a description (e.g. 50ml (10-5ml vials)).

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.

Please also remember: Taiwan will not accept zoosanitary (animal 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.