

Serum and Serum Products for Technical Purposes General Information

These requirements apply only to blood products intended for technical use, and do not apply to blood products for animal consumption (feed use).

Exporters should have their importers in Taiwan confirm prior to shipment that the shipment and documentation meet all Taiwanese requirements for entry.

Taiwanese importers must obtain an import permit from the Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) prior to importing serum for technical purposes.* APHIS Veterinary Services (VS) does not require U.S. exporters to present a copy of the Taiwanese import permit prior to endorsing certificates for shipments unless the exporter has received an exemption from the requirements as noted herein.

*The U.S. exporter is responsible for ensuring that the Taiwanese importer has a current, valid import permit covering the type, quantity, and intended end-use (in vitro/in vivo; commercial/research) of the product(s) being exported.

For bovine serum and serum products only: As of January 1, 2019, Taiwan will no longer require the Taiwanese importer to present a “Plant Certificate” prior to issuance of an import permit for bovine serum and serum products (including fetal bovine serum). However, these facilities will need to maintain annual APHIS VS inspection and approval to verify the facility meets the requirements to export. BAPHIQ will verify the facility processing the bovine serum (or fetal bovine serum) has been approved by APHIS VS and is listed on the BAPHIQ website prior to import permit issuance.

General Instructions for Exporters

1. Use the fillable VS Form 16-4 “Export Certificate for Animal Products” which can be accessed through the [home page](#) of the International Animal Product Export Regulations (IREGs).
2. Prepare a notarized affidavit with the required certification statements listed under the notarized affidavit line in the “Export Certification Requirements” below. If assistance in needed in preparing a properly notarized affidavit, please work with the [VS Service Center](#) that will be endorsing the export certificate(s).
3. Complete all applicable sections of the VS Form 16-4, including product description. Please see general instructions on the home page of the IREGs. If further assistance is needed, please contact the pertinent VS Service Center.
4. In situations where the lot number identified on the export certificate to Taiwan does not match the lot number identified on the laboratory results presented with the certificate at the time of endorsement, the facility should provide a lot-specific notarized affidavit from the exporter* linking the two lot numbers together.

*In instances where the exporter is not the manufacturer of the product, a lot-specific multi-part affidavit should be provided. For assistance in the formatting of this document, please contact the endorsing VS Service Center.

Additionally, all facilities¹ processing serum for export to Taiwan must be inspected and approved by APHIS VS annually. In situations where the above scenario is occurring, the

¹ Excluding facilities processing bovine serum albumin (BSA) or BSA for use in cell culture media

Serum and Serum Products for Technical Purposes General Information

inspector must verify traceability of all lot numbers assigned to a product through documentation provided by the facility.

Example:

Background:

- *Facility 1 and Facility 2 collect and package raw unfiltered serum, which is then shipped to Facility 3.*
- *Facility 3 filters, bottles and tests serum per Taiwanese requirements. The product is physically shipped out of Facility 3.*
- *Facility 4 is listed as the exporter for the product on the export health certificate. They are not handling the product directly, but are involved in the sale of the product (e.g. broker).*
- *Facility 4 assigns the lot number(s) identified on the export health certificate and the final product labels during the filtration process at Facility 3. Facility 3 assigns an anonymized sample ID for purposes of laboratory testing only – this anonymized sample ID is reflected on the laboratory results that are presented to the Service Center with the export certificate.*

In this instance, the following documentation should be provided to the Service Center at the time the export health certificate is presented for endorsement:

- *Lot-specific notarized affidavit from Facility 4 linking to a notarized affidavit from Facility 3. This affidavit should include the following components:*
 - *Lot-specific notarized affidavit from Facility 3 linking the two lot-numbers together in addition to verifying the relevant declarations made on the export health certificate; AND*
 - *Notarized affidavits from Facility 1 and Facility 2 verifying the relevant declarations made on the export health certificate.*
- *Lot-specific laboratory results; AND*
- *Export health certificate per the relevant guidance on the IREGS*

The Service Center should verify that Facility 1, Facility 2 and Facility 3 have been inspected and approved by APHIS for the production of serum and that the facility has provided documentation that can verify traceability for all lot numbers assigned to a product.

Export Certification Requirements

Please see entries for the different types of serum for specific entry and certification requirements.