Fetal Bovine Serum

This protocol is intended to cover fetal bovine serum for export to Korea for technical (non-animal feed) uses. Korea prohibits the importation of bovine blood products for animal feeding.

The bilaterally negotiated certification statements included in this protocol are not to be amended or revised. Statements must not be added or deleted without express permission from the APHIS VS Animal Products Exports (APE) Staff.

If exporters are issued an official import permit by the Korean government with required certification statements that differ from this protocol, they should provide an English translation of the document to the VS Service Center. The VS Service Center will contact the pertinent Import/Export Coordinator (IEC) or APE Staff for guidance.

In addition to the following information, exporters are advised to follow the general instructions provided on the Korea home page of the International Animal Product Regulations. **Export certificates MUST be endorsed PRIOR to shipping. If the date on the shipping documents precedes the date of endorsement of the animal health (export) certificate, Korean officials will refuse entry.**

Instructions for Exporters

1. Use the fillable VS Form 16-4, "Export Certificate for Animal Products" which can be accessed at the home page of the International Animal Product Regulations: http://www.aphis.usda.gov/regulations/vs/iregs/products/
2. Prepare a notarized affidavit with the required certification statements noted under the notarized affidavit line in "Export Certification Requirements" below. If assistance is needed in preparing a proper notarized affidavit, please work with the VS Service Center that will be endorsing your export certificates.
3. If you are the exporter, but not the manufacturer of the fetal bovine serum product, the VS Service Center may require a notarized affidavit from the actual manufacturer to support your notarized affidavit.
4. Complete all applicable sections of the VS 16-4, following general instructions provided on the Korea home page of the International Animal Product Regulations. If assistance is needed, please contact the VS Service Center that will be endorsing your export certificates.

VS Form 16-4: Guidance for Additional Declarations

1. All of the certification statements noted under "Export Certification Requirements" below must be included in the "Additional Declarations" section of the VS Form 16-4. These statements must not be modified, and statements may not be deleted or added without permission from the APHIS VS Animal Products Exports Staff.
2. The certification statements below the notarized affidavit line will be endorsed by the VS Service Center on the basis of a notarized affidavit. Inspection of the exporting/manufacturing facility by VS will not generally be required. The endorsing VS Service Center, however, may request supporting documentation and/or inspection of the manufacturing/exporting facility, if deemed necessary.

Export Certification Requirements

The following certification statements must be included in the "Additional Declarations" section of the VS Form 16-4.

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 United States has been free of foot-and-mouth disease and classical swine fever (feral swine excepted) for 12 months; swine vesicular disease, rinderpest, and contagious bovine pleuropneumonia for 24 months; peste des petits ruminants, lumpy skin disease, sheep pox, and African swine fever for 3 years; and Rift Valley fever for 4 years prior to export. Vaccination against these diseases is prohibited in the United States.

The United States is officially recognized by the World Organization for Animal Health (OIE) as having a negligible risk status for bovine spongiform encephalopathy (BSE).

The certified product is from cattle not known to be related to any herd affected by BSE.

The United States bans the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants, and this ban has been effectively enforced.

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

1. *The product was derived from the fetuses of cattle that were born and raised in the United States or that were resident in the United States for at least 3 months prior to export of the certified product.*
2. *The product was derived from the fetuses of clinically healthy cattle subjected to official slaughter inspection by the competent authority of the United States at approved slaughter facilities.*
3. *The cattle from which the fetuses were collected were not subjected to a stunning process, prior to slaughter, with a device injecting air or gas into the cranial cavity, or to a pithing process.*
4. *The product was processed, stored, and transported in such a manner as to prevent contamination by communicable animal disease pathogens.*