

Export of Swine Products Intended for Pharmaceutical or Medical Device Use to Korea

These requirements apply to porcine only products intended for use in pharmaceuticals or medical devices. Products containing other animal-origin materials or intended for other purposes may not be certified under this protocol.

GENERAL INFORMATION

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 Veterinary Services (VS) Export Products headquarters staff. If an exporter has an official import permit from the Korean government with required certification statements that differ from this protocol, they should provide an English translation of the document to their [local VS Service Center](#). The VS Service Center will contact headquarters staff for guidance. [NOTE: Exporters are not required to present a copy of an import permit from Korea as a condition for export of this commodity.]

Please review the information on the main IREGs page for Korea carefully, and follow all instructions noted.

Export health certificates for Korea must be endorsed PRIOR to the date the product is shipped. If the date the product is shipped precedes the date of endorsement of the export certificate, the shipment will be refused entry by Korea.

APHIS Veterinary Services (VS) will not back-date certificates. Export certificates are dated with the actual date they are endorsed. APHIS will also not be able to facilitate release of shipments refused entry by the Korean authorities because the product was certified for export after the product was shipped. Exporters must ensure that the export certificates are endorsed prior to the date the product is shipped to Korea.

CERTIFICATION OF PRODUCTS FOR EXPORT

Product must be certified using the VS Form 16-4 “Export Certificate for Animal Products” with the following required statements. Use the fillable version of this form, which can be accessed through the “VS Export Certificates and Instructions” tab on the home page of the IREGs [website](#).

The exporter should prepare a notarized affidavit with the required certification statements (only those numbered statements noted below the affidavit line). Please refer to the next section of this document for additional information needed on the notarized affidavit. If assistance is needed in preparing a proper notarized affidavit, please contact the local VS Service Center that will be endorsing the export certificates.

The following statements must be provided in the “Additional Declarations” section of the VS Form 16-4:

The United States has been free of foot-and-mouth disease and classical swine fever (feral swine excepted) for 12 months; rinderpest and swine vesicular disease for 24 months; and African swine fever for 3 years prior to export. Vaccination against these diseases is prohibited in the United States.

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

1. The certified products are of United States origin and were derived from animals born and raised in the United States or that were resident in the United States for at least 3 months prior to slaughter, and that were slaughtered in slaughterhouses which were approved by the government of the exporting country and from animals that passed ante mortem examination and were presented for post mortem inspection by government authorities of the exporting country.
2. The product was produced, stored, and transported in such a manner as to prevent contamination by communicable animal disease pathogens.
3. The product is intended for pharmaceutical or medical device use.

AFFIDAVIT INFORMATION

In general, VS inspection of manufacturing facilities is not required under this protocol. Certification will be done on the basis of a notarized affidavit. However, the first certification statement requires verification that the product was derived only from animals born and raised in the United States or that were resident in the United States for at least 3 months prior to slaughter. This statement is not true for all products, and requires additional verification by VS prior to certificate issuance. To facilitate the additional required verification, the affidavit must list the slaughter facilities where the material was sourced (including the plant name and FSIS establishment number).