

Bovine/Porcine Hide/Skin-Derived Gelatin

This protocol is intended to cover gelatin products comprised of both bovine hide-derived gelatin and porcine skin-derived gelatin for export to Korea primarily for human consumption.

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) National Center for Import and Export (NCIE) Animal Products Exports 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 Area Office. The Area Office will contact the pertinent Regional Import/Export Coordinator (IEC) or NCIE 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 (MAR 2010), "Export Certificate for Animal Products" which can be accessed at the following link through 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 Area Office that will be endorsing your export certificates. Contact information for VS Area Offices can be found at: http://www.aphis.usda.gov/animal_health/area_offices/
3. If you are the exporter, but not the manufacturer of the gelatin product, the VS Area Office may require a notarized affidavit from the actual manufacturer to support your notarized affidavit.
4. In the section of the VS Form 16-4 for "Name and Address of Exporter", include the name and address of the gelatin manufacturer following the name and address of the exporter. The manufacturer's information should be preceded by "Manufacturer:" and if the exporter and the manufacturer are the same, note "same as exporter."
5. In the block for "Product", the brand name of the product may be used, but the type of product (gelatin) and animal species of origin (bovine and porcine) should be noted.
6. Complete all other applicable sections of the VS 16-4, following general instructions provided on the Korea home page of the International Animal Product Regulations: http://www.aphis.usda.gov/regulations/vs/iregs/products/product_korea.shtml. If assistance is needed, please contact the VS Area Office 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 (MAR 2010). These statements must not be modified, and statements may not be deleted or added without permission from the VS NCIE Animal Products Exports Staff.
2. As agreed to bilaterally, certification statement #3 attests that the hides used to produce the bovine gelatin component of the product did not contain and were not derived from “specified risk materials (SRMS).” SRMs as noted here is the U.S. definition for products for human consumption: the brain, skull, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, and the vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum) from cattle 30 months of age or older; and the tonsils and distal ileum from cattle of all ages. This definition should not be included in the certification statement.
3. The certification statements will be endorsed by the VS Area Office on the basis of a notarized affidavit. Inspection of the exporting/manufacturing facility by VS will not generally be required. The endorsing VS Area Office, however, may request supporting documentation and/or inspection of the manufacturing/exporting facility, if deemed necessary.
4. The certification statements must be preceded by the notarized affidavit line as noted in the “Export Certification Requirements” section below.

Export Certification Requirements

The following certification statements must be included in the “Additional Declarations” section of the VS Form 16-4 (MAR 2010). These statements must not be modified, and statements may not be added or deleted without permission from the VS NCIE Animal Products Exports Staff.

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

1. The product is derived solely from the hides and skins of healthy pigs and cattle obtained through the slaughter process.
2. The product is highly processed and is not likely to spread communicable diseases of livestock.
3. The hides used to produce the gelatin component of the product did not contain and were not derived from specified risk materials (SRMs).
4. The hides used to produce the bovine gelatin component of the product were subjected to an acid or alkali treatment followed by one or more rinses and then pH adjustment. The gelatin was extracted by one or a series of heat treatments in succession followed by purification through means of filtration and sterilization.
5. The final product, a blend of porcine and bovine hide/skin-derived gelatin, was handled and transported in a manner intended to prevent subsequent contamination of the product.