

Certification for Export to Korea: Non-Human Primate (NHP) Materials for Laboratory Use Only

This protocol is intended to cover non-human primate (NHP) materials (i.e., organs, parts or tissues, including blood) being exported to Korea for laboratory (including research) use only.

The bilaterally negotiated certification statements included in this protocol are not to be amended or revised (except as noted below for statements 2 and 3, where the species of NHP and the specific organs, parts or tissues are to be listed, respectively). 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 NCIE for guidance.

Exporters are also advised to follow the general instructions provided on the Korea page of the International Animal Product Regulations. **NOTE: Export certificates MUST be endorsed PRIOR to shipping. If the date on the shipping documents precedes the date of endorsement of the export certificate, Korea will refuse entry.**

General 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. Complete the “Additional Declarations” section of the VS Form 16-4 using the guidance provided below.
4. Complete all other applicable sections of the VS Form 16-4, following the general instructions provided on the Korea 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. The certification statement regarding U.S. freedom from Ebola hemorrhagic fever and Marburg disease must be a direct attestation by APHIS Veterinary Services (VS).
2. All other certification statements are to be made on the basis of a notarized affidavit which must be provided by the manufacturer/exporter. Statements made on the basis of a notarized affidavit must be preceded by the notarized affidavit line as noted in the “Export Certification Requirements” section below.

3. Statement number two must include the species (scientific name) of the non-human primates (NHP) from which the materials for export to Korea were derived. NOTE: The NHP materials for export should be harvested or collected in the United States; however, the source animals may have been legally imported into the United States.
4. Statement number three must include a list of all the organs, parts, or tissues (including blood) that are being exported to Korea.
5. For statement number four, specified risk materials (SRM) include the following: the skull, brain, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, 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 of cattle of all ages.
6. For statement number five, the source animals must not have been inoculated with, or otherwise exposed to, livestock pathogens, including *Mycobacterium bovis* (bovine tuberculosis).

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 except as noted (the notarized affidavit line should include the actual name of the manufacturer/exporter; statements two and three must include the requested information).

The United States is free of Ebola hemorrhagic fever (including the Ebola Reston strain) and Marburg disease.

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

1. The product is intended for laboratory use only.
2. The product is U.S. origin and was sourced from the following species of non-human primates: [*list species/scientific name*].
3. The product was derived from the following organs, parts or tissues of the above listed non-human primates: [*list organs, parts and/or tissues*].
4. The product was manufactured, processed, and handled in such a manner as to prevent cross-contamination with BSE-related materials (e.g., specified risk materials [SRM] or any materials contaminated with SRM).
5. The product was derived from non-human primates that had not been inoculated with, or otherwise exposed to, livestock pathogens; therefore, the product is not likely to transmit infectious or contagious livestock diseases.