Dairy Products Containing Additional Animal-Origin Ingredients for Human Consumption

Effective July 1, 2021, dairy products, including those containing egg products, intended for human consumption must be certified by USDA's Agricultural Marketing Service. Exporters may find more information on AMS' website at: https://www.ams.usda.gov/services/imports-exports/dairy-exports.

On occasion, these products intended for human consumption may contain gelatin and/or collagen derived from hides or skins of any species (e.g. cheesecakes). In this instance, exporters will also need to obtain an export certificate from APHIS for the gelatin/collagen component of the product, in addition to the export certificate from AMS for the dairy +/- egg component. The guidance below is intended for completion of the export certificate from APHIS related to the gelatin/collagen component of the product.

As a general reminder, 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 of the product.

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 Regulations (IREGS) for Animal Products.
- 2. The manufacturer should prepare a notarized affidavit with the required certification statements as noted under the notarized affidavit line in the "Export Certification Requirements" below. If assistance is needed in preparing a properly notarized affidavit, please work with the Veterinary Services (VS) office that will be endorsing the export certificates.
- 3. In the section of the VS Form 16-4 for "Name and Address of Exporter," include the name and address of the manufacturer of the product (not the gelatin/collagen ingredient) following the name and address of the exporter. The manufacturer's information should be preceded by "Manufactured by:" and if the exporter and the manufacturer are the same, note "same as exporter."
- 4. In the block for "Product," list the type of product and all animal species from which the ingredients are derived (not just the gelatin/collagen) contained within the product. Type of package, number of packages, and gross and net weight should all be included in this block. It is strongly recommended to include the specific product names in addition to the more generic product type in this block (using an additional page of the certificate if necessary) to avoid detained shipments at the port upon arrival. For example, "cheesecake ("Joe's Classic NY Style Cheesecake") containing bovine gelatin, bovine dairy, and poultry eggs".
- 5. Complete all other applicable sections of the VS Form 16-4, following the general instructions provided on the home page for Korea on the IREGS for Animal Products. If assistance is needed, please contact the VS office endorsing the export certificate.

VS Form 16-4: Guidance for Additional Declarations

- 1. Certification statements #1-3 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 Products Headquarters staff. Certification statement #4 should only be included for products containing bovine-origin gelatin or collagen.
- 2. The certification statements will be endorsed by VS on the basis of a notarized affidavit from the manufacturer. Inspection of the exporting/manufacturing facility by VS will not generally be required. However, the endorsing VS office may request supporting documentation and/or inspection of the manufacturing/exporting facility if deemed necessary.

Last updated: November 3, 2021

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Export Certification Requirements

The following certification statements 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 added or deleted.

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.

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

- 1. The gelatin and/or collagen was derived exclusively from hides/skins.
- 2. The product was manufactured in accordance with U.S. laws and regulations, and was produced at an establishment registered with the Competent Authority of the United States and is authorized for export to Korea.
- 3. The product was produced, stored and transported in such a manner to prevent contamination by communicable animal disease pathogens transmissible through the product.
- 4. [delete as appropriate to be included for bovine-origin collagen or gelatin]
 The gelatin and/or collagen was derived from the hides/skins of cattle that passed antemortem slaughter inspection and whose carcasses passed post-mortem slaughter inspection
 in official establishments under the control of the Competent Authority of the exporting
 country.

Last updated: November 3, 2021