**Export of bovine and porcine gelatine to the United States of America**

Exporters Declaration to be used by establishments providing materials/products intended for export to USA as per the certification requirements of EHC 8108 V3.

**Note:**

The managing director (or equivalent) of the company should provide a letter giving the

Name(s):



and

Job title(s):



of those authorised to give the declaration and the basis on which the declaration is made.

**EXPORTERS DECLARATION**

As the exporter of the product/s described on health certificate(s) Serial Number(s):



I hereby declare that:

1. The product described at I (a) contains:
2. \*Bulk gelatine only;
3. \*Gelatine capsules only;
4. \*Gelatine capsules filled with the following material(s) of animal origin and from the following species:



1. \*Gelatine capsules filled with material(s) not of animal origin.
2. Regarding the use of material of Bovine origin:

Either \*(i) the consignment does not contain any gelatine derived from materials of bovine origin;

OR \*(ii) the consignment contains gelatine derived from materials of bovine origin and that the gelatine:

Either

\*1. Is derived from bovine hides and skins and has not been co-mingled with materials ineligible for entry into the United States;

And/Or

\*2. Is derived from bones of bovines and originates in a region of negligible risk for BSE and is being exported from:

 [state the BSE risk classification of the exporting region]

And has not co-mingled with materials ineligible for entry into the United States;

And/Or

\*3. Is derived from bones of bovines and originates in a region of \*controlled / \*undetermined risk for BSE and is being exported from:

 [state the BSE risk classification of the exporting region]

And

Meets the requirements of A, through D below:

1. The bones from which the gelatine was derived were derived from bovines that passed ante-mortem and post-mortem inspection;

And

1. The bones from which the gelatine was derived did not include the skulls of bovines or the vertebral column of bovines 30 months of age or older;

And

1. The bones were subjected to:

\*Either a process that includes all of the following steps:

· Degreasing;

· Acid demineralization;

· Acid or Alkaline treatment;

· Filtration; and

· Sterilization at 138 °C (280.4 °F) or greater for a minimum of 4 seconds;

\*Or to the following process which has been recognised by APHIS as being at least as

effective in reducing BSE infectivity:



And

1. The gelatine has not been co-mingled with materials ineligible for entry into the United States;

3.

|  |  |  |  |
| --- | --- | --- | --- |
| NAME OF GELATIN MANUFACTURING ESTABLISHMENT  (Note one company may declare sites in a number of countries;  if so, list & check each) | COUNTRY WHERE GELATIN MANUFACTURING ESTABLISHMENTS LOCATED | BSE STATUS ON APHIS  [USDA APHIS | Animal Health Status of Regions](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions) | EU APPROVAL NUMBER  (FOR EU AND THIRD COUNTRY CHECK  [Approved EU food establishments (europa.eu)](https://food.ec.europa.eu/safety/biological-safety/food-hygiene/approved-eu-food-establishments_en)) |

























4. Regarding the use of material of Porcine origin:

Either

\*(i) The consignment does not contain any gelatine derived from materials of porcine origin

OR

\*(ii) The consignment contains gelatine derived from materials of porcine origin and has not been co-mingled with materials ineligible for entry into the United States.

1. \*Import permit conditions[[1]](#footnote-1), if required, are below and fulfilled.

If not, insert N/A



\* Delete as appropriate

I am an authorised signatory for the company  and am aware that making a false declaration is an offence.

I accept full responsibility if any problems arise with the export should there be any dispute with the matters being declared.

**IMPORTANT:**

Where required I have supporting documentary evidence from the supplier of incoming ingredients or final product as appropriate.

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name in Capitals:

Date: 

Position in company: 

1. Insert any sanitary and phytosanitary statements as specified in the import permit, as applicable. Health statements listed on this declaration must match exactly those on the accompanying permit. [↑](#footnote-ref-1)