Model health certificate for gelatine derived from ruminant bones or pigskins, intended for human consumption, intended for dispatch from the United States

GBHC162 v3.0 May 2022

HEALTH CERTIFICATE

For gelatine derived from ruminant bones or pigskins, intended for human consumption, intended for dispatch from the United States to Great Britain, Channel Islands and Isle of Man

Note for the importer: This certificate is for veterinary purposes only and must accompany the consignment until it reaches the border control post.

Reference number of the health certificate: ……

Country of destination: ……...

Country of origin: UNITED STATES OF AMERICA

Responsible ministry: FOOD AND DRUG ADMINISTRATION

Certifying department: CENTER FOR FOOD SAFETY & APPLIED NUTRITION

I. Identification of gelatine

Type of products: ……

Date of manufacture: ……

Type of packaging: ……

Number of packages: ……

Guaranteed storage period: ……..

Net weight (kg): ……..

II. Origin of gelatine

Address(es) and firm establishment identifier number(s) of production establishment(s) on the responsible ministry's list of export-eligible firms:

……

……

III. Destination of gelatine

The gelatine will be sent:

from: ……..……... (*place of loading*)

to: …….. (*country and place of destination*)

By the following means of transport [(1)]: ……

Name and address of consignor: ……

Name and address of consignee: ……

IV. Health attestation

I, the undersigned, certify that the consignment of gelatine described above,

- was wrapped, packaged, stored and transported in compliance with the relevant United States public health standards requirements of the Code of Federal Regulations which have been recognised for this purpose as equivalent to standards and requirements applicable in Great Britain under retained EU law as prescribed in Council Decision 98/258/EC as last amended by Decision 2003/833/EC ;

- comes from an establishment subject to periodic inspection by FDA that has been shown by such inspections

  a) to comply with the relevant US public health standards requirements of the Code of Federal Regulations which have been recognised for this purpose as equivalent to standards and requirements applicable in Great Britain under retained EU law as prescribed in Council Decision 98/258/EC; and

  b) to maintain records that are subject to review by FDA, during an inspection or otherwise, that substantiate and verify the information contained in the manufacturer's legally binding declaration to FDA specific to this consignment (copy attached).

This declaration has been verified by periodic, on-site inspections by State regulatory officials and confirms, subject to criminal penalties for falsification, that the gelatine has been:

- produced exclusively from ruminant bones or pigskins

  a) derived from animals that have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante and post mortem inspection, and, for ruminants, which have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rodshaped instrument introduced into the cranial cavity; and

  b) transported directly from the slaughterhouse or cutting plants to the gelatine establishments in compliance with the relevant US public health standards requirements of the Code of Federal Regulations, which have been recognised for this purpose as equivalent to standards and requirements applicable in Great Britain under retained EU law as prescribed in Council Decision 98/258/EC;

  c) which do not contain and are not derived from specified risk material as defined in Annex 11, section A, to Regulation (EC) No 999/2001 of the European Parliament and of the Council or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals.

This declaration also confirms, subject to criminal penalties for falsification, that the gelatine has been:

- manufactured by a process which ensures that the raw material is subjected to treatment with acid or alkali, followed by one or more rinses, gelatine is then extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation; during this process no preservatives have been used, other than sulphur dioxide and hydrogen peroxide,

- shown by periodic, representative analyses of finished gelatine products conducted by an accredited, private laboratory and coordinated and reviewed by State regulatory officials not to exceed the following criteria:

- Total aerobic bacteria - 10^3/g
- Coliforms (30°C) - 0/g
- Coliforms (44,5 °C) - 0/10g
- Anaerobic sulphite - reducing bacteria (no gas production) - 10/g
- Clostridium perfringens - 0/g
- *Staphylococcus aureus* - 0/g
- *Salmonella* - 0/25g
- As - 1 ppm
- Pb - 5 ppm
- Cd - 0,5 ppm
- Hg - 0,15 ppm
- Cr - 10 ppm
- Cu - 30 ppm
- Zn - 50 ppm
- Moisture (105°C) ~ 15%
- Ash (550°C) - 2%
- SO_2 - 50 ppm
- H_2O_2 - 10 ppm

Notes

References to European Union legislation within this certificate are references to direct EU legislation which has been retained in Great Britain (retained EU law as defined in the European Union (Withdrawal) Act 2018) and can be viewed on the UK legislation website (legislation.gov.uk).

The content of the certificate is based on the EU decisions referred to in this certificate and the model referred to in Decision 2003/863.

References to Great Britain in this certificate include Channel Islands and Isle of Man.

(1) Indicate the name or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship). This information is to be updated in the case of unloading and reloading).

(2) The signature and stamp must be in a colour different to that of the printing.

Done at: …… (*Place*) on: …… (*Date*)

……
(Stamp and signature of official competent authority)(2)

……
(Name in block letters)

Reference number:

DECLARATION TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION

For gelatine derived from pigskins or ruminant bones, intended for human consumption, intended for dispatch from the United States of America to Great Britain, Channel Islands and Isle of Man

Country of destination: ……...

Exporting country: UNITED STATES OF AMERICA

Responsible ministry: FOOD AND DRUG ADMINISTRATION

Certifying department: CENTER FOR FOOD SAFETY & APPLIED NUTRITION

I. Identification of gelatine

Type of products: ……

Date of manufacture: ……

Type of packaging: ……

Number of packages: ……

Guaranteed storage period: ……..

Net weight (kg): ……..

II. Origin of gelatine

Address and firm establishment identifier number(s) of production establishment:

……

……

III. Destination of gelatine

The gelatine will be sent:

from: ……..…….....

to: ……..

By the following means of transport: ……

Name and address of consignor: ……

Name and address of consignee: ……

IV. Production and analysis information

The product has been made exclusively from pigskins/ruminant bones which have been derived from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following an ante and post mortem inspection.

The product does not contain and is not derived from specified risk material as defined in Annex 11, section A, to Regulation (EC) No 999/2001 or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals. The bovine, ovine or caprine animals, from which this product is derived (excluding that derived from porcine animals), have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

This product has been manufactured by a process which ensures that the raw material is subject to treatment with acid or alkali, followed by one or more rinses. Extraction is by heating one of more times and purification by means of filtration and sterilisation. No preservatives except for sulfur dioxide or hydrogen peroxide have been used (hydrogen peroxide is not allowed in US gelatine as per 21 CFR 184.1366).

The gelatine satisfied the following specifications as determined by analysis:

- Total aerobic bacteria - 10^3/g
- Coliforms (30°C) - 0/g
- Coliforms (44,5 °C) - 0/10g
- Anaerobic sulphite-reducing bacteria (no gas production) - 10/g
- Clostridium perfringens - 0/g
- *Staphylococcus aureus* - 0/g
- *Salmonella* - 0/25 g
- As - 1 ppm
- Pb - 5 ppm
- Cd - 0,5 ppm
- Hg - 0,15 ppm
- Cr - 10 ppm
- Cu - 30 ppm
- Zn - 50 ppm
- Moisture (105°C) ~ 15%
- Ash (550°C) - 2%
- SO_2 - 50 ppm
- H_2O_2 - 10 ppm.

V. Statement and acknowledgment

On behalf of (name of establishment), I authorise the United States Food and Drug Administration (FDA) to share the information contained in the declaration with the Great Britain. I understand that the information may contain confidential commercial or financial information and/or trade secrets, within the meaning of 18 U.S.C. 1905, 21 U.S.C. 331(j), and 5 U.S.C. 52(b)(4), and that it is exempt from public disclosure. Authorisation is given to FDA sending the information without deletion of confidential commercial or financial information and/or trade secrets. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with Great Britain.

As indicated by my signature below, I am authorised to provide this consent on behalf of (name of establishment) and my full name, position, and address are set out below for verification.

(Name of establishment) maintains records to substantiate said declaration and will provide to FDA upon request, during an inspection or otherwise all records supporting the above statement.

(Name of establishment) makes the above statement with full knowledge that submitting false statements is in violation of United States Code title 18, section 1001, and that penalties for such violation include up to USD 250 000 in fines, up to five years imprisonment or both.

Notes

References to European Union legislation within this certificate are references to direct EU legislation which has been retained in Great Britain (retained EU law as defined in the European Union (Withdrawal) Act 2018) and can be viewed on the UK legislation website (legislation.gov.uk).

The content of the certificate is based on the EU decisions referred to in this certificate and the model referred to in Decision 2003/863.

References to Great Britain in this certificate include Channel Islands and Isle of Man.

Signed: …….

Name/position: …….

Department: …….

Street: …….

City, State: …….

Date: …….