Model health certificate for collagen derived from bovine hides and/or pigskins, intended for human consumption, intended for dispatch from the United States

GBHC163 v3.1 November 2022

HEALTH CERTIFICATE

For collagen derived from bovine hides and/or pigskins, intended for human consumption, intended for dispatch from the United States of America 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 collagen

Type of products: ……

Animal species and nature of the raw materials used (e.g. bovine hides and skins):

……

Date of manufacture: ……

Type of packaging: ……

Number of packages: ……

Guaranteed storage period: ……..

Net weight (kg): ……..

II. Origin of collagen

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 collagen

The collagen 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 collagen described above,

- was wrapped, packaged, stored and transported 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 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 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 collagen has been:

- produced exclusively from bovine hides and/or pigskins

  (a) derived from animals which 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 rod-shaped instrument introduced into the cranial cavity, and

  (b) transported directly from the slaughterhouses or cutting plants to the collagen 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, or

  (c) transported from a tannery subject to periodic inspection by FDA that has been shown by such inspections 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,

  (d) which do not contain and are not derived from specified risk materials as defined in Annex 11, Section A to Regulation 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 collagen has been:

- manufactured by a process which ensures that the raw material is subjected to treatment involving washing, pH adjustment using acid or alkali, followed by one or more rinses, filtration and extrusion. During this process no preservatives have been used, other than those authorised for such by both Great Britain and the United States,

- shown by periodic, representative analyses of finished collagen 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
  - 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 collagen derived from bovine hides and/or pigskins, intended for human consumption, intended for dispatch from the United States 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 collagen

Type of products: ……

Animal species and nature of the raw materials used (e.g. bovine hides and skins):

……

Date of manufacture: ……

Type of packaging: ……

Number of packages: ……

Guaranteed storage period: ……..

Net weight (kg): ……..

II. Origin of collagen

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

……

……

III. Destination of collagen

The collagen will be sent:

from: ……..…….....

to: ……..

By the following means of transport [3]: ……

Name and address of consignor: ……

Name and address of consignee: ……

IV. Production and analysis information

The product has been made exclusively from bovine hides and/or pigskins 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 bovine hides and/or pigskins have been either:

(1) transported directly from the slaughterhouse or cutting plants to the collagen 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; or

(2) transported from a tannery subject to periodic inspection by FDA that has been shown by such inspections 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.

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 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 involving washing, pH adjustment using acid or alkali, followed by one or more rinses, filtration and extrusion. During this process no preservatives have been used other than those authorised by both Great Britain and the United States.

The collagen satisfies 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
- 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 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 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.

(3) 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)

Signed: …….

Name/position: …….

Department: …….

Street: …….

City, State: …….

Date: …….