COMMISSION

COMMISSION DECISION
of 2 December 2003
on health certificates for the importation of animal products from the United States of America

(notified under document number C(2003) 4444)

(Text with EEA relevance)

(2003/863/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 98/258/EC of 16 March 1998 on the conclusion of the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products [1], and in particular Article 3 thereof,

Having regard to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries [2], as last amended by Regulation (EC) No 807/2003 [3], and in particular Article 11(2) and Article 22(2) thereof, and the corresponding provisions of the other directives establishing sanitary conditions and models of certificates for the importation of live animals and animal products from third countries,

Whereas:

(1) Annex V to the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products (the Agreement) establishes, *inter alia*, the sanitary measures for fresh meat, meat products and certain other animal products traded with the United States for which equivalence has been determined.

(2) Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC [4], as last amended by Commission Decision 2003/721/EC [5], provides for special certification requirements for animals and products of animal origin to prevent the spread of animal and human diseases.

(3) Article 10 of Directive 92/118/EEC requires that gelatine and collagen for human consumption intended for import into the EC must be accompanied by a health certificate corresponding to the specimen drawn up in Annex II, chapter 4.

(4) By Commission Decision 2003/833/EC [6] approving on behalf of the European Community amendments to the Annexes to the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products, the recommendations made by the Joint Management Committee established under the Agreement concerning the equivalence of the United States standards for gelatine and collagen with Community standards have been approved and should be implemented; model certificates for the importation of gelatine and collagen from the United States into the Community providing the corresponding guarantees should be established accordingly.

(5) It is appropriate for the Community to implement the recognition of equivalence so granted to the United States on a provisional basis, pending confirmation by the United States of their approval of the changes made to the Agreement.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

[1] OJ L 118, 21.4.1998, p. 1.
[2] OJ L 302, 31.12.1972, p. 28.
[3] OJ L 122, 16.5.2003, p. 36.
[4] OJ L 62, 15.3.1993, p. 49.
[5] OJ L 260, 11.10.2003, p. 21.
[6] OJ L 316, 29.11.2003, p. 20.

HAS ADOPTED THIS DECISION:

Article 1

The Member States shall authorise the import from the United States of gelatine and collagen for human consumption, provided that they are accompanied by an official health certificate(s) in accordance with the models referred to respectively in Annex A and Annex B.

Article 2

This Decision shall apply from 15 December 2003.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 2 December 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX A

HEALTH CERTIFICATE

For gelatine derived from ruminant bones or pigskins, intended for human consumption, intended for dispatch from the United States to the European Community

Note for the importer: This certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection 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 the European Community standards as prescribed in Council Decision 98/258/EC (2) as last amended by Decision 2003/833/EC (3);

(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) OJ L 118, 21.4.1998, p. 1.
(3) OJ L 316, 29.11.2003, p. 20.

— 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 the European Community standards 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 gelatine has been:

— produced exclusively from ruminant bones 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 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 the European Community standards 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 XI, section A, to Regulation (EC) No 999/2001 of the European Parliament and of the Council [4] 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) — 0/10 g

— 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.

Done at ..... on .....
(place) (date)

.....
(Stamp and signature of official competent authority) [5]

.....
(Name in block letters)

[4] OJ L 147, 31.5.2001, p. 1.
[5] The signature and stamp must be in a colour different to that of the printing.

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 the European Community

Country of destination: .....

Exporting country: UNITED STATES OF AMERICA

Responsible ministry: FOOD AND DRUG ADMINISTRATION

Certifying department: CENTER FOR FOOD SAFETY AND 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 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.

This product does not contain and is not derived from specified risk material as defined in Annex XI, 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 or 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 satisfies the following specifications as determined by analysis:

— Total aerobic bacteria — 10^3/g

— Coliforms (30 °C) — 0/ g

— Coliforms (44,5 °C) — 0/10 g

— 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 acknowledgement**

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 European Union. 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 the European Union.

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.

Signed: .....

Name/position: .....

Department: .....

Street: .....

City, State: .....

Date: .....

ANNEX B

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 the European Community

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

(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.

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 the European Community standards as prescribed in Council Decision 98/258/EC [2] as last amended by Decision 2003/833/EC [3],

— 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 the European Community standards 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 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 the European Community standards 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 the European Community standards as prescribed in Council Decision 98/258/EC,

(d) which do not contain and are not derived from specific risk materials as defined in Annex XI, section A, to Regulation (EC) No 999/2001 of the European Parliament and of the Council [4], 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 use by both the European Communities 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) — 0/10 g
— 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.

[2] OJ L 118 , 21.4.1998, p. 1.
[3] OJ L 316, 29.11.2003, p. 20.
[4] OJ L 147, 31.5.2001, p. 1.

Done at ..... on .....
(place) (date)

.....
(Stamp and signature of official competent authority)

.....
(Name in block letters)

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

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 the European Community

Country of destination: .....

Exporting country: UNITED STATES OF AMERICA

Responsible ministry: FOOD AND DRUG ADMINISTRATION

Certifying department: CENTER FOR FOOD SAFETY AND 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 of production establishment:

.....

.....

.....

III. **Destination of collagen**

The collagen will be sent

from: .....

.....

to: .....

.....

by the following means of transport (1): .....

.....

(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.

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 the European Community standards as prescribed in 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 the European Community standards as prescribed in Decision 98/258/EC.

This product does not contain and is not derived from specified risk material as defined in Annex XI, 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 the European Community 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) — 0/10 g

— Anaerobic sulphite-reducing bacterial (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 acknowledgement**

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 European Union. 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 the European Union.

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.

Signed: .....

Name/position: .....

Department: .....

Street: .....

City, State: .....

Date: .....