

COMMISSION

COMMISSION DECISION

of 29 September 2003

amending Council Directive 92/118/EEC as regards requirements for collagen intended for human consumption and repealing Decision 2003/42/EC

(notified under document number C(2003) 3393)

(Text with EEA relevance)

(2003/721/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 ⁽¹⁾, as last amended by Commission Decision 2003/42/EC ⁽²⁾, and in particular the second paragraph of Article 15 thereof,

Whereas:

- (1) Specific public health conditions for the preparation of collagen intended for human consumption should be laid down. Provided that these conditions are the same for collagen intended for human consumption and collagen not intended for human consumption, and provided that hygiene conditions are also the same, it should be possible to produce and/or store both types of collagen in the same establishment.
- (2) The authorisation and registration, inspection and hygiene conditions for the establishments preparing collagen should be set. Certain health conditions contained in Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin ⁽³⁾, as last amended by Regulation (EC) No 807/2003 ⁽⁴⁾, and in Council Directive 93/43/EEC of 14 June 1993 on the hygiene of food-stuffs ⁽⁵⁾, are relevant for the preparation of collagen.

- (3) Article 2.3.13.7 of the International Animal Health Code (2001) issued by the International Office of Epizootics on BSE recommends that if gelatine and collagen are prepared exclusively from hides and skins, veterinary administrations should authorise their import and transit through their territories without restriction, regardless of the status of the exporting countries.

- (4) Under Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽⁶⁾, as last amended by Commission Regulation (EC) No 1234/2003 ⁽⁷⁾, hides and skins within the meaning of Directive 92/118/EEC, derived from healthy ruminants and collagen derived from such hides and skins are not subject to restrictions on placing on the market.

- (5) The Scientific Steering Committee adopted an opinion on the safety of collagen on 10 and 11 May 2001, addressing the question of the safety in relation to transmissible spongiform encephalopathies (hereinafter TSE) of collagen produced from ruminant hides.

- (6) The raw material used for the production of collagen consists mainly of bovine connective tissue of hides and tendons, calf skins, sheep skins and pig skins. To ensure the safety of the raw material, it must derive from animals that pass *ante* and *post mortem* inspections as fit for human consumption. Such material must also be collected, transported, stored and handled in the most hygienic ways possible.

⁽¹⁾ OJ L 62, 15.3.1993, p. 49.

⁽²⁾ OJ L 13, 18.1.2003, p. 24.

⁽³⁾ OJ L 26, 31.1.1977, p. 85.

⁽⁴⁾ OJ L 122, 16.5.2003, p. 36.

⁽⁵⁾ OJ L 175, 19.7.1993, p. 1.

⁽⁶⁾ OJ L 147, 31.5.2001, p. 1.

⁽⁷⁾ OJ L 173, 11.7.2003, p. 6.

- (7) To guarantee traceability of the raw material, collection centres and tanneries, which intend to supply the raw material, should be authorised and registered. A model commercial document should also be prescribed to accompany the raw material during transportation and at time of delivery to the collection centres, tanneries and collagen processing plants.
- (8) It is appropriate to amend the current commercial document for raw material destined for the production of gelatine for human consumption, to take into account particulars in relation to control procedures in certain Member States.
- (9) The standards for the finished product should be fixed to ensure that it is not contaminated with substances or micro-organisms presenting a risk to consumer health. Pending a scientific evaluation of such standards, it is appropriate to include, on a provisional basis, generally accepted standards as regards contamination. The requirements for packaging, storage and transport of the finished product should also be laid down.
- (10) It is necessary to lay down specific health rules for the importation of collagen and raw material destined for the production of collagen intended for human consumption. Specimens of health certificates to accompany the imported collagen and raw material destined for the production of collagen for human consumption should be drawn up. It is also necessary for the Commission to recognise conditions offering equivalent guarantees based on a proposal submitted by a third country.
- (11) The adoption of specific rules for the production of collagen should be without prejudice to the adoption of rules for the prevention and control of TSE.
- (12) Directive 92/118/EEC should therefore be amended accordingly.
- (13) Decision 2003/42/EC amended Directive 92/118/EEC, with effect from 30 September 2003, as regards the specific health conditions for collagen intended for human consumption and certification requirements for collagen and raw material for collagen production, intended for dispatch to the European Community for human consumption.
- (14) The Community imports from third countries raw material and collagen, including collagen meeting certain technical requirements which is not available in the Community.
- (15) The United Kingdom has requested a postponement of the application of the new specific health conditions to enable account to be taken of its producers who are dependent on imports from third countries.
- (16) The negotiations to find a resolution to problems in relation to imports of collagen aimed at allowing such imports to continue in full compliance with the new specific health conditions can now be considered concluded.
- (17) It is appropriate to allow time for the conclusion of the administrative steps of those negotiations but that period should be as short as possible.
- (18) An error has been found in the Annex to Decision 2003/42/EC in that the commercial document model for raw material destined for the production of collagen unintentionally requires a stamp of an official veterinarian. That error should be corrected.
- (19) For the sake of clarity, Decision 2003/42/EC should therefore be repealed and replaced by the present Decision.
- (20) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Annex II to Directive 92/118/EEC is amended in accordance with the Annex to this Decision.

Article 2

Article 1 of this Decision shall apply from 31 December 2003.

It shall not apply to collagen intended for human consumption that was produced or imported before that date.

Article 3

Decision 2003/42/EC is repealed with immediate effect.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 29 September 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Chapter 4 of Annex II to Directive 92/118/EEC is amended as follows:

1. The heading 'Section A' is inserted before the title.
2. In Part VIII, point II, under the headings 'Other animal products plant', 'Centres of collection' and 'Tannery', the second line is replaced by the following: 'Registration number'.
3. The following section B is added:

'SECTION B**SPECIFIC HEALTH CONDITIONS FOR THE COLLAGEN INTENDED FOR HUMAN CONSUMPTION****I. General**

1. This Section lays down the health conditions for putting on the market and imports of collagen intended for human consumption.
2. For the purposes of this Section, the definitions of "hides and skins" and "tanning" in section A shall apply.

The following definitions shall also apply:

- (a) "collagen" means protein-based product derived from hides, skins and tendons of animals, including bones in the case of pigs, poultry and fish only, manufactured using the method set in Part V below.
 - (b) "collagen intended for human consumption" means collagen intended for consumption either as food or incorporated into or wrapped around food or product to be consumed by humans.
3. Collagen intended for human consumption shall comply with the conditions in Parts II to X below.

II. Establishments producing collagen

Collagen intended for human consumption shall come from establishments that fulfil the conditions in Part I of Section A.

III. Raw materials and establishments supplying them

1. The following raw materials may be used for the production of collagen intended for human consumption:
 - (a) hides and skins of farmed ruminant animals;
 - (b) pig skins, bones and intestines;
 - (c) poultry skin and bones;
 - (d) tendons;
 - (e) wild game hides and skins; and
 - (f) fish skin and bones.
2. The use of hides and skins submitted to tanning processes is prohibited.
3. The raw materials shall meet the following requirements:
 - for the raw materials listed in paragraph 1(a) to (d) above, the requirements set in Paragraph 4 of Part II of Section A apply;
 - for the raw material referred to in paragraph 1(e) above, the requirements set in Paragraph 5 of Part II of Section A apply;
 - for the raw materials listed in paragraph 1(a) to (e) above, the requirements set in Paragraph 6 of Part II of Section A apply, except that no raw material shall come from plants degreasing ruminant bones; and
 - for the raw material referred to in paragraph 1(f) above, the requirements set in Paragraph 7 of Part II of Section A apply.

4. The collection centres and tanneries supplying the raw material for the production of collagen intended for human consumption shall be specifically authorised for the purpose and registered by the competent authorities and fulfil the requirements set in Paragraph 8 of Part II of Section A.

IV. Transport and storage of the raw material

1. Transport and storage of the raw material destined for the production of collagen shall be done in accordance with Part III of Section A.
2. During transportation and at the time of delivery at the collection centres, tanneries and collagen processing plants, raw materials must be accompanied by a commercial document in conformity with the model laid down in Part IX of this Section.

V. Manufacture of collagen

1. Collagen must be produced by a process that ensures that the raw material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion; or by an equivalent process approved by the Commission after consultation of the appropriate Scientific Committee.
2. After having been subjected to the process referred to at paragraph 1 above, collagen may undergo a drying process.
3. Collagen not intended for human consumption may be produced and stored in the same establishment as collagen intended for human consumption only if it is produced and stored using exactly the same conditions set in this Section.
4. The use of preservatives other than those permitted under Community legislation is prohibited.

VI. Finished products

Appropriate measures, including tests shall be carried out to ensure that each production batch of collagen meets the microbiological and residues criteria set in Part V of Section A, but where necessary to achieve desired products such as collagen-based casings, no moisture and ash limit shall apply.

VII. Packaging, storage and transport

1. Collagen intended for human consumption must be wrapped, packaged, stored and transported under satisfactory hygiene conditions and, in particular, fulfil the conditions set in Paragraph 1 of Part VI of Section A.
2. Wrappings and packages containing collagen must bear an identification mark giving the particulars listed in the first indent of Paragraph 2 of Part VI of Section A, and carry the words "Collagen fit for human consumption" and the date of preparation and the batch number.
3. During transportation collagen must be accompanied by a commercial document, in accordance with Article 3(A)(9)(a) of Directive 77/99/EEC, bearing the words "Collagen fit for human consumption" and the date of preparation and the batch number.

VIII. Import from third countries of collagen and raw materials intended for the production of collagen for human consumption

1. Member States shall authorise import into the Community of collagen intended for human consumption only if it:
 - (a) comes from third countries listed in Part XIII of the Annex to Commission Decision 94/278/EC ⁽¹⁾;
 - (b) comes from establishments meeting the conditions laid down in Part II of this Section;

⁽¹⁾ OJ L 120, 11.5.1994, p. 44.

- (c) has been produced from raw material that met the requirements of Parts III and IV of this Section;
 - (d) has been manufactured in compliance with the conditions set out in Part V of this Section;
 - (e) satisfies the criteria in Part VI and the wrapping, packaging, storage and transport conditions in Part VII(1) of this Section;
 - (f) bears on its wrappings and packages an identification mark giving the particulars specified in the sixth indent of Part VII(A) of Section A; and
 - (g) is accompanied by a health certificate that conforms to the model laid down in Part X(a) of this Section.
2. Member States shall authorise import into the Community of the raw material listed in Part III(1) of this Section for the production of collagen intended for human consumption only if:
- (a) it comes from third countries listed in Council Decision 79/542/EEC ⁽¹⁾ or in Commission Decision 94/85/EC ⁽²⁾ or in Decision 94/86/EC ⁽³⁾ or in Commission Decision 97/296/EC ⁽⁴⁾, as appropriate; and
 - (b) a health certificate conforming to the model laid down in Part X(b) of this Section accompanies each consignment of the raw material.
3. The health certificates referred to in paragraphs 1(g) and 2(b) above shall consist of one sheet, and shall be completed in at least one official language of the Member State through which the consignment first enters the Community, and in at least one official language of the Member State of destination.
4. The Commission may recognise, in accordance with the procedure of Article 18, the health measures applied by a third country for the production of collagen intended for human consumption as offering guarantees equivalent to those offered for putting collagen on the market in the Community, if the third country concerned supplies objective proof in this respect. When the Commission recognises such equivalence, it shall adopt in accordance with the same procedure, the conditions governing the importation of collagen for human consumption.

⁽¹⁾ OJ L 146, 14.6.1979, p. 15.

⁽²⁾ OJ L 44, 17.2.1994, p. 31.

⁽³⁾ OJ L 44, 17.2.1994, p. 33.

⁽⁴⁾ OJ L 122, 14.5.1997, p. 21.

IX. Commercial document model
for raw material destined for the production of collagen intended for human consumption

Commercial document number:

1. Identification of the raw material

Nature (e.g. hides and skin):

Animal species (e.g. bovine, pig):

Net weight (kg):

Identification mark (pallet or container):

2. Origin of the raw material

— *Slaughterhouse*

Address of the establishment:

.....

Veterinary approval/registration number:

— *Cutting plant*

Address of the establishment:

.....

Veterinary approval/registration number:

— *Meat products plant*

Address of the establishment:

.....

Veterinary approval/registration number:

— *Other animal products plant*

Address of the establishment:

.....

Registration number:

— *Wild game processing plant*

Address of the establishment:

.....

Veterinary approval number:

— *Fish products plant*

Address of the establishment:

.....

Veterinary approval/registration number:

— *Collection centres*

Address of the establishment:

.....

Registration number:

.....

— *Tannery*

Address of the establishment:

.....

Registration number:

— *Retail shop*

Address:

.....

— *Premises adjacent to sales points, where the cutting and the storage of meat and poultry is performed for the sole purpose of supplying the final consumer directly*

Address:

3. Destination of the raw material

Name of the collection centre/tannery/collagen plant ⁽¹⁾ where the raw material is sent:

.....

Address:

.....

4. Declaration

I, the undersigned, declare that I have read and understood the provisions of Parts III and IV of Section B of Chapter 4 of Annex II to Directive 92/118/EEC, and that:

— hides and skins from farmed ruminant animals/pig skins, bones and intestines/poultry skin and bones/tendons described above are derived from animals that have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following *ante* and *post mortem* inspections, and/or ⁽¹⁾

— hides and skins from wild game described above are derived from killed animals whose carcasses have been found fit for human consumption following the inspection laid down in Article 3 of Council Directive 92/45/EEC (OJ L 268, 24.9.1991, p. 15), and/or ⁽¹⁾

— fish skin and bones described above come from plants manufacturing fishery products for human consumption or registered in accordance with Council Directive 91/493/EEC (OJ L 268, 24.9.1991, p. 15) ⁽¹⁾.

Done at on

(place)

(date)

.....

(Signature of the owner of the plant or his/her representative) ⁽²⁾

.....

(Name in block letters)

⁽¹⁾ Delete as appropriate.

⁽²⁾ The signature must be of a colour different from that of printing.

X(a) Health Certificate Model
for collagen intended for dispatch to the European Community for human consumption

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:

Exporting country:

Responsible Ministry:

Certifying department:

1. Identification of collagen

Type of products:

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

.....

Date of manufacture:

Type of packaging:

Number of packages:

Guaranteed storage period:

Net weight (kg):

Address(es) and registration number(s) of authorised and registered production establishment(s):

.....

2. 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 consigner:

.....

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.

3. Health attestation

I, the undersigned, declare that I am aware of the provisions of Section B of Chapter 4 of Annex II to Directive 92/118/EEC, and certify that the collagen described above:

- comes from establishments meeting the conditions laid down in Part II of that Section;
- has been produced from raw materials which met the conditions in Parts III and IV of that Section;
- has been produced in compliance with the conditions in Part V of that Section; and
- satisfies the conditions in Parts VI and VII(1) of that Section.

Done at on
(place) (date)

.....
(Signature of official veterinarian⁽²⁾)

.....
(Name in block letters)



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

X(b) Health Certificate Model

for raw material intended for dispatch to the European Community for the production of collagen for human consumption

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:

Exporting country:

Responsible Ministry:

Certifying department:

1. Identification of the raw material

Animal species and nature (e.g. bovine skin and hides, pig skin):

Date of production:

Type of packaging:

Number of packages:

Guaranteed storage period:

Net weight (kg):

2. Origin of raw material

Address(es) and registration number(s) of authorised and registered production establishment(s):

.....

3. Destination of raw material

The raw material will be sent from:

(place of loading)

to:

(country and place of destination)

by the following means of transport ⁽¹⁾:

Name and address of consigner:

.....

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.

3. Health attestation

I, the undersigned, declare that I am aware of the provisions of Section B of Chapter 4 of Annex II to Directive 92/118/EEC, and certify that the raw material described above complies with the requirements of Part III of that Section and, in particular that:

- hides and skins of farmed ruminant animals/pig skins, bones and intestines/poultry skin and bones/tendons described above derive from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following *ante* and *post mortem* inspections; and/or ⁽²⁾
- wild game hides and skins described above derive from killed animals whose carcasses have been found fit for human consumption following the inspections laid down in Article 3 of Council Directive 92/45/EEC, and/or ⁽²⁾
- fish skin and bones described above derive from plants manufacturing fish products for human consumption authorised for export ⁽²⁾.

Done at on
(place) (date)

.....
(Signature of official veterinarian ⁽³⁾)

.....
(Name in block letters)

Stamp of official
veterinarian ⁽³⁾

⁽²⁾ Delete as appropriate.

⁽³⁾ The signature and the stamp must be of a colour different from that of printing.