

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 28 October 1999

amending Annex II to Council Directive 92/118/EEC 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

(notified under document number C(1999) 3493)

(Text with EEA relevance)

(1999/724/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 Directive 97/79/EC⁽²⁾, and in particular the second paragraph of Article 15,

- (1) Whereas specific rules applicable to the preparation of gelatine intended for pharmaceutical, cosmetic or other technical use and medical devices are under preparation; whereas, therefore, the regulation of these products may be excluded from the scope of this Decision;
- (2) Whereas the specific public health conditions applicable to the preparation of gelatine intended for human consumption should be laid down; whereas, provided that these conditions are the same for gelatine intended for human consumption and gelatine not intended for human consumption and provided that hygiene conditions are also the same, both types of gelatine may be produced and/or stored in the same establishment;
- (3) Whereas the authorisation and registration, inspection and hygiene requirements which establishments preparing gelatine must meet should be determined;

whereas 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 Directive 97/76/EC⁽⁴⁾, and in Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs⁽⁵⁾, are relevant for the preparations of gelatine;

- (4) Whereas the Scientific Steering Committee adopted an opinion on safety of gleetine on 26 and 27 March 1998 which was updated on 18 and 19 February 1999; whereas this opinion addresses the questions under which conditions of sourcing of the material and/or of type of material used and/or production process gelatine destined for human consumption can be considered free of bovine spongiform encephalopathy (BSE) infectivity; whereas in this opinion, the Scientific Steering Committee distinguishes the recommended measures between different categories of geographical risk; whereas a final implementation can only follow after classification of countries and regions; whereas on 21 May 1999, at the general session of the International Office of Epizootics (IOE) Committee, a proposal of the IOE International Animal health Code Commission concerning the criteria for the determination of the BSE status of a country or zone was adopted; whereas in

⁽¹⁾ OJ L 62, 15.3.1993, p. 49.

⁽²⁾ OJ L 24, 30.1.1998, p. 31.

⁽³⁾ OJ L 26, 31.1.1977, p. 85.

⁽⁴⁾ OJ L 10, 16.1.1998, p. 25.

⁽⁵⁾ OJ L 175, 19.7.1993, p. 1.

accordance to the procedure laid down in Commission Recommendation 98/477/EC ⁽¹⁾, concerning information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiform encephalopathies, certain Member States and third countries submitted data necessary to allow assessment of their geographical risk; whereas, considering recent development of the IOE Code on BSE, pending the above scientific assessment and the subsequent decision making, the entry into force of rules for the production of gelatine derived from ruminant bones should be suspended until Community legislation concerning classification of countries or regions as regards their BSE status is applicable; whereas the Commission will initiate the procedure for the entry into force of rules for the production of gelatine derived from ruminant bones without delay after the adoption of Community legislation concerning classification of countries or regions as regards their BSE status;

- (5) Whereas the Commission as adopted Decision 97/534/EC ⁽²⁾, as last amended by Council Decision 98/745/EC ⁽³⁾ on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies;
- (6) Whereas the Commission has adopted Decision 98/272/EC ⁽⁴⁾ on epidemio-surveillance for transmissible spongiform encephalopathies and amending Decision 94/474/EC; whereas this Decision lays down measures to be applied in case of animals suspected of having a transmissible spongiform encephalopathy (TSE);
- (7) Whereas a revision of the Animal Health Code of the (IOE) on BSE (IOE Code on BSE) was adopted in the general assembly of the IOE in Paris on 29 May 1998; whereas Article 3.2.13.3 of that Code recommends that if gelatine and collagen are prepared exclusively from hides and skins derived from healthy animals, veterinary administration can authorise, without restriction, the import and transit through their territories of this gelatine and collagen, regardless the status of the exporting countries; whereas Article 3.2.13.15 of that Code recommends under which sourcing and processing conditions gelatine and collagen prepared from bones can be traded;
- (8) Whereas gelatine is prepared from bones, farmed ruminant and wild game hides and skins, pig and poultry skins, tendons and sinews and fish skins and bones; whereas supervised hygienic slaughtering of cattle in a slaughterhouse prevents contamination of hides with material presenting risks as regards transmissible spongiform encephalopathies; whereas it is appropriate that these raw materials originate from healthy animals and are dealt with hygienically when being collected, transported stored and handled; whereas in order to guar-

antee traceability of these raw materials it is appropriate to require collection centres and tanneries which intend to supply these materials to be authorised and registered, whereas, furthermore, it is appropriate to lay down a model of commercial document which should accompany these raw materials during transportation a time of delivery in the collection centres and in the tanneries and in the gelatine processing plants;

- (9) Whereas the Scientific Steering Committee in the above opinion strongly recommends that gelatine manufacturers implement and respect hazard analysis and critical control points procedures; whereas the measures relating to establishments' own checks provided for in Article 7 of Directive 77/99/EEC are relevant for own checks carried out by establishments producing gelatine as referred to in Article 4(2) of Directive 92/118/EEC;
- (10) Whereas standards for the finished product should be fixed in order to ensure that it is not contaminated by substances or micro-organisms presenting a threat to the health of consumers; whereas pending a scientific evaluation of such standards, it is appropriate to provisionally include generally accepted standards as regards contamination;
- (11) Whereas requirements as regards packaging, storage and transport of the finished product should be laid down;
- (12) Whereas it is necessary to lay down specific health rules governing the importation of raw materials destined to the production of gelatine intended for human consumption and of gelatine intended for human consumption; whereas where it is possible to recognise conditions offering equivalent guarantees, a third country may submit a proposal for such recognition to the Commission for appropriate consideration;
- (13) Whereas the adoption of specific rules for gelatine production is without prejudice to the adoption of rules for the organisation of the prevention and control of transmissible spongiform encephalopathies;
- (14) Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

The second indent of Chapter 2 of Annex II to Directive 92/118/EEC is hereby deleted.

Article 2

The Annex to this Decision is hereby added as Chapter 4 to Annex II to Directive 92/118/EEC.

⁽¹⁾ OJ L 212, 30.7.1998, p. 58.

⁽²⁾ OJ L 216, 8.8.1997, p. 95.

⁽³⁾ OJ L 358, 31.12.1998, p. 113.

⁽⁴⁾ OJ L 122, 24.4.1998, p. 59.

Article 3

The Annex to this Decision may be amended in accordance with the procedure provided for in Article 18 of Directive 92/118/EEC, in particular to take into account scientific and technological developments, and in light of the advice of the appropriate Scientific Committee of the Commission.

Article 4

This Decision shall apply from 1 June 2000. It does not apply to gelatine intended for human consumption which was produced before that date.

Nevertheless, Part II, point 2 and Part IV, point 1, first indent, of the Annex shall apply from such time as the Commission,

acting in accordance with the procedure laid down in Article 18 of Directive 92/118/EEC, shall determine.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 28 October 1999.

For the Commission

David BYRNE

Member of the Commission

ANNEX

CHAPTER 4

SPECIFIC HEALTH CONDITIONS FOR THE GELATINE INTENDED FOR HUMAN CONSUMPTION

This chapter lays down the health conditions applicable to putting on the market and for imports of gelatine intended for human consumption, but excluding gelatine destined to pharmaceutical, cosmetic or other technical use and medical devices.

For the purpose of this chapter, the following definitions apply:

- gelatine: natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry),
- hides and skins: all cutaneous and subcutaneous tissues,
- tanning: the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents,
- category 1 country or region: country or region classified as BSE free in accordance with Community legislation,
- category 2 country or region: country or region classified as provisionally BSE free with accordance to Community legislation,
- category 3 country or region: country or region classified as low BSE risk in accordance with Community legislation,
- category 4 country or region: country or region classified as high BSE risk in accordance with Community legislation.

Gelatine intended for human consumption shall comply with the following conditions:

I. Conditions for establishments producing gelatine

Gelatine intended for human consumption shall come from establishments which:

1. comply with the conditions laid down in Chapters I, II, V, VI, VII, VIII, IX and X of the Annex to Directive 93/43/EEC;
2. are authorised and registered in accordance with Article 11 of Directive 77/99/EEC;
3. are subject to supervision of production conditions by the competent authority in accordance with Chapter IV of Annex B to Directive 77/99/EEC as appropriate;
4. carry out an own-checks programme in accordance with Article 7(1) and (3) of Directive 77/99/EEC;
5. keep records for two years on the sources of all incoming raw material and on all outgoing products;
6. introduce and implement a system that makes it possible to link each production batch dispatched, the incoming raw material consignments, the production conditions and the time of production.

II. Requirements for raw materials to be used for the production of gelatine

1. For the production of gelatine intended for human consumption, the following raw materials may be used:
 - bones,
 - hides and skins of farmed ruminant animals,
 - pig skins,
 - poultry skin,
 - tendons and sinews,
 - wild game hides and skins,
 - fish skin and bones.

2. The use of bones obtained from ruminant animals born, reared or slaughtered in category 4 countries or regions is prohibited.
3. The use of hides and skins submitted to tanning processes is prohibited.
4. Raw materials listed in the first five indents of paragraph 1 shall be derived from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante and post mortem inspection.
5. Raw material listed in the sixth indent of paragraph 1 shall be derived 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 ⁽¹⁾.
6. Raw materials listed in the first six indents of paragraph 1 shall come from slaughterhouses, cutting plants, meat processing establishments, wild game processing plants, bone degreasing plants, tanneries, collection centres, retail shops, or premises adjacent to sales points where the cutting and the storage of meat and poultrymeat is performed for the sole purpose of supplying the final consumer directly.
7. Raw material listed in the last indent of paragraph 1 shall come from plants manufacturing fish products for human consumption approved or registered in accordance with Council Directive 91/493/EEC ⁽²⁾.
8. The collection centres and tanneries which intend to supply raw material for the production of gelatine intended for human consumption shall be specifically authorised for this purpose and registered by the competent authorities and fulfil the following requirements:
 - (a) they must have storage rooms with hard floors and smooth walls which are easy to clean and disinfect;
 - (b) where appropriate, they must be provided with refrigeration facilities;
 - (c) the storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials;
 - (d) if raw material not in conformity to this part is stored and/or processed in these premises, it must be segregated throughout the period of receipt, storage, processing and dispatch from raw material in conformity to this part;
 - (e) they must be inspected by the competent authority at regular intervals in order to ensure that this chapter is being complied with and to check accounting documents and/or health certificates which enable the origin of the raw material to be traced.
9. Imports into the Community of raw material destined to the production of gelatine intended for human consumption are subject to the following provisions:
 - Member States shall authorise the importation of this raw material only from third countries which appear on the list laid down in Council Decision 79/542/EEC ⁽³⁾ or in Commission Decision 94/85/EC ⁽⁴⁾ or in Commission Decision 97/296/EC ⁽⁵⁾ or in Decision 94/86/EC ⁽⁶⁾, as appropriate,
 - each consignment is accompanied by a certificate that conforms to the model laid down in accordance with the procedure provided for in Article 18 of this Directive.

III. Transport and storage of raw materials

1. Transports of raw materials destined to the production of gelatine must be carried out under clean conditions using appropriate means of transport.

During transportation, at the time of delivery in the collection centre and in the tannery and in the gelatine processing establishment, raw materials must be accompanied by a commercial document in conformity with the model laid down in Part VIII of this chapter.

2. Raw materials must be transported and stored chilled or frozen, unless they are processed within 24 hours after their departure.

By way of derogation from the preceding subparagraph, degreased and dried bones or ossein, salted, dried and limed hides and skins and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

3. The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

⁽¹⁾ OJ L 268, 14.9.1992, p. 35.

⁽²⁾ OJ L 268, 24.9.1991, p. 15.

⁽³⁾ OJ L 146, 14.6.1979, p. 15.

⁽⁴⁾ OJ L 44, 17.2.1994, p. 31.

⁽⁵⁾ OJ L 122, 14.5.1997, p. 21.

⁽⁶⁾ OJ L 44, 17.2.1994, p. 33.

IV. Conditions to be complied with for the manufacture of gelatine

1. Gelatine must be produced by a process which ensures that:
 - all ruminant bone material which is derived from animals born, reared and slaughtered in category 3 countries or regions is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 % and pH < 1,5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (pH > 12,5) for a period of at least 20 days with a sterilisation step of 138-140 °C during four seconds or by an equivalent process approved by the Commission after consultation of the appropriate Scientific Committee,
 - other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.
2. After having been subjected to the processes listed in paragraph 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
3. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.
4. Provided the requirements for gelatine not intended for human consumption are exactly the same as for gelatine intended for human consumption, production and storage may be undertaken in the same establishment.

V. Requirements for finished products

Each production batch of gelatine shall be subjected to tests to ensure that it meets the following criteria:

1. Microbiological criteria

Microbiological parameters	Limit
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
<i>Clostridium perfringens</i>	0/g
<i>Staphylococcus aureus</i>	0/g
<i>Salmonella</i>	0/25 g

2. Residues

Elements	Limit
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 (Reith Williems)	50 ppm
H ₂ O ₂ (European Pharmacopia 1986 (V ₂ O ₂))	10 ppm

VI. Packaging, storage and transport

1. Gelatine intended for human consumption must be wrapped, packaged, stored and transported under satisfactory hygiene conditions, in particular:
 - a room must be provided for storing, wrapping and packaging materials,
 - wrapping and packaging must take place in a room or in a place intended for that purpose.
2. Wrappings and packages containing gelatine must:
 - bear an identification mark giving the following particulars:
 - the name or initial letter or letters of the consigning country in printed capitals, i.e.: AT-B-DK-D-EL-E-FI-IRL-I-L-NL-P-SE-UK, followed by the registration number of the establishment and one of the following sets of initials: CE-EC-EF-EG-EK-EY
 - and
 - carry the words "Gelatine for human consumption".
3. Gelatine must be accompanied during transportation by a commercial document, in accordance with Article 3(A)(9)(a) of Directive 77/99/EEC, which must bear the words "Gelatine for human consumption" and the date of preparation.

VII. Importation of gelatine from third countries

- A. Member States shall ensure that gelatine destined to human consumption is imported only if:
 - it comes from third countries which appear on the list of Part XIII of the Annex to Commission Decision 94/278/EC⁽¹⁾,
 - it comes from establishments meeting the conditions laid down in Part I of this chapter,
 - it has been produced from raw material which met the requirements of Parts II and III of this chapter,
 - it has been manufactured in compliance with the conditions set out in Part IV of this chapter,
 - it satisfies the criteria of Part V and the requirements of part VI.1 of this chapter,
 - it bears on its wrappings and packages an identification mark giving the following particulars:
 - the ISO Code reference of the country of origin followed by the registration number of the establishment
 - and
 - it is accompanied by a certificate that conforms to the model laid down in accordance with the procedure provided for in Article 18 of this Directive.
- B. In accordance with the procedure of Article 18 of this Directive, the Commission may recognise the health measures applied by a third country to the production of gelatine for human consumption, as offering guarantees equivalent to those applied for putting on the market in the Community, if the third country supplies objective proof in this respect.

When the Commission recognises such equivalence of the health measures of a third country, it shall adopt in accordance with the same procedure, the conditions governing the importation of gelatine for human consumption including the health certificate which must accompany the product.

⁽¹⁾ OJ L 120, 11.5.1994, p. 44.

VIII. Model of commercial document for raw material destined to the production of gelatine for human consumption

COMMERCIAL DOCUMENT

For raw material destined to the production of gelatine for human consumption

Number of the commercial document:

I. Identification of the raw material

Nature of the raw material:

Raw material derived from the following animal species:

.....

Net weight:

Identification mark (pallet or container):

II. 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:

Veterinary registration number:

Wild game processing establishment

Address of the establishment:

Veterinary approval number:

Fish products plants

Address of the establishment:

Veterinary approval/registration number:

Centres of collection

Address of the establishment:

Veterinary registration number:

Tannery

Address of the establishment:

Veterinary registration number:

Retailshop

Address:

(!) Delete as appropriate.

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

Address:

III. Destination of the raw material

The raw material will be sent to the following establishment (centre of collection/tannery/gelatine plant) (¹):

Name:

Address:

IV. Declaration

I, the undersigned, declare that I read and understood the provisions of Part II and III of Chapter 4 of Annex II to Directive 92/118/EEC and that (¹):

- hides and skins from farmed ruminant animals, bones, pig skins, poultry skin and tendons and sinews described above are derived from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante and post mortem inspection
and/or
- hides and skins from wild game described above are derived from killed animals whose carcasses have been found fit for human consumption following the inspections laid down in Article 3 of Directive 92/45/EEC
and/or
- fish skin and bones described above come from plants manufacturing fish products for human consumption or registered in accordance with Directive 91/493/EEC.

Done at, on

.....
(Signature of the owner of the plant or its representatives)

¹) Delete as appropriate.