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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 04.04.2007

Draft

COMMISSION REGULATION (EC) No .../..

of [...]

**amending Regulation (EC) No 853/2004 of the European Parliament and the Council
laying down specific hygiene rules for food of animal origin**

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**amending Regulation (EC) No 853/2004 of the European Parliament and the Council
laying down specific hygiene rules for food of animal origin**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to [...]¹, and in particular Article [...] thereof,

Whereas:

[Initial capital...]. Article 26 of Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund² defines as 'small-scale coastal fishing' fishing carried out by fishing vessels of an overall length of less than 12 metres.

(1)

(2) The measures provided for in this Regulation are in accordance with the opinion of the [...] Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 853/2004 is amended as follows:

1. Annex III is amended in accordance with Annex I to this Regulation.
2. Annex III is amended in accordance with Annex II to this Regulation.
3. Annex III is amended in accordance with Annex III to this Regulation.

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¹ OJ L L223, 15.8.2006 [...], [...], p. [...]. [Name of act] as [last]amended by [Name and number of act] (OJ L [...], [...], p. [...]).

Article 2

This Regulation shall enter into force on the [...] day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX I

Section VIII to Annex III of Regulation (EC) No 853/2004 is amended as follows:

1) Point 3 (a) is replaced by the following:

"(a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of Annex I to that Regulation. In case of fishermen carrying out their activities on board fishing vessels of an overall length of less than 12 metres, the obligation to keep records as foreseen at point 7 of Annex I is not required."

2) Chapter I Part I,A is replaced by the following:

"A. Requirements for all vessels

1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.

2. With the exception of fishing vessels of an overall length of less than 12 metres to which general hygiene provisions as established in Annex I part A II point 4. (a), (b),(d),(e),(f),(g) and point 6 to Regulation (EC) 852/2004 should only apply, surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.

3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect. For fishing vessels of an overall length of less than 12 metres , equipment and material used for working on fishery products must be made of material that is easy to clean and disinfect

4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply."

ANNEX II

Section XIV to Annex III of Regulation (EC) No 853/2004 is amended as follows:

1) Chapter III is replaced by the following:

"CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF GELATINE

1. The production process for gelatine must ensure that:

- (a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions with a controlled or undetermined BSE risk in accordance with Community legislation 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. This treatment is followed either:
- by an alkaline treatment of saturated lime solution (pH>12.5) for a period of at least 20 days with a heat treatment step of 138°C minimum during at least four seconds, or
 - by an acid treatment with pH < 3,5 during 10 hours minimum with a heat treatment step of 138°C minimum during at least four seconds, or
 - by a heat-and-pressure process for at least 20 minutes with saturated steam of 133°C at more than 3 bars, or
 - by any approved equivalent process.

And

- (b) 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 heat treatment.
2. 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.

Alternative proposal:

2. A food business operator may produce and store both gelatine intended for human consumption and gelatine not intended for human consumption in the same establishment provided that the raw materials and the production process comply with the requirements applying to gelatine intended for human consumption."

2) Chapter IV is replaced by the following:

"CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that gelatine complies with the residue limits set out in the following table:

Residue	Limit
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 (European Pharmacopoeia 2005)	50 ppm
H ₂ O ₂ (European Pharmacopoeia 2005)	10 ppm

"

ANNEX III

1. Chapter III of Section XV to Annex III of Regulation (EC) No 853/2004 is replaced by the following:

'CHAPTER III: REQUIREMENTS FOR THE 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 approved equivalent process. The extrusion step may be not carried out when manufacturing low molecular collagen from raw materials of non-ruminant origin.
2. After having been subjected to the process referred to in paragraph 1 above, collagen may undergo a drying process.
3. Provided the requirements for collagen not intended for human consumption are exactly the same as for collagen intended for human consumption, production and storage may be undertaken in the same establishment.

Alternative proposal:

3. A food business operator may produce and store both collagen intended for human consumption and collagen not intended for human consumption in the same establishment provided that the raw materials and the production process comply with the requirements applying to collagen intended for human consumption.'

2. The Appendix to Annex III is replaced by the following:

'Appendix to ANNEX III

MODEL DOCUMENT TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF GELATINE OR COLLAGEN INTENDED FOR HUMAN CONSUMPTION

Number of the commercial document:

I. Identification of raw material

Nature of the raw material:

Animal species:

Type of packaging:

Number of packages:

Net weight (kg):

II. Origin of raw material

Type, address and approval/registration/authorisation number of the production establishment(s):

.....

III. 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:

Name and address of consignor:

Name and address of consignee:

Done at, on

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