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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.1.2007

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:

- (1) [Initial capital...].
- (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. Section I of Annex III is amended in accordance with Annex I to this Regulation.
2. Section XIV of Annex III is amended in accordance with Annex II to this Regulation.

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.

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

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission

ANNEX I

[Cold Stores][freezing date for food; traceability document (Article 7; ...)]

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 classified as having a low incidence of BSE 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 $\text{pH} < 1,5$) over a period of at least two days. This treatment is followed either by an alkaline treatment of saturated lime solution ($\text{pH} > 12,5$) for a period of at least 20 days or by an acid treatment with $\text{pH} < 3,5$ during 10 hours minimum. Gelatine is subject to a sterilisation step of 138°C minimum during four seconds at least. This above treatment may be replaced by a heat-and-pressure process (133°C , 20 mn, 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 sterilisation.
2. If a food business operator manufacturing gelatine complies with the requirements applying to gelatine intended for human consumption in respect of all the gelatine that it produces, it may produce and store gelatine not intended for human consumption in the same establishment."

- 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

- 3) 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

Type of products:

Date of manufacture:

Type of packaging:

Number of packages:

Guaranteed storage period:

Net weight (kg):

II. Origin of raw material

Address(es) and registration number(s) of the approved 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:

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

Date