[X1ANNEX III

SPECIFIC REQUIREMENTS

Editorial Information

X1 Substituted by Corrigendum to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (Official Journal of the European Union L 139 of 30 April 2004).

SECTION XV:

COLLAGEN

[F1 1. Food business operators manufacturing collagen must ensure compliance with the requirements of this section. Without prejudice to other provisions, products derived from collagen must be made from collagen which complies with the requirements of this section.]

Textual Amendments

F1 Substituted by Commission Regulation (EU) 2016/355 of 11 March 2016 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the specific requirements for gelatine, collagen and highly refined products of animal origin intended for human consumption (Text with EEA relevance).

2. For the purpose of this section, ‘tanning’ means 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.

CHAPTER I:

REQUIREMENTS FOR RAW MATERIALS

[F2 1. For the production of collagen intended for use in food, the following raw materials may be used:

(a) bones, other than specified risk materials as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;

(b) hides and skins of farmed ruminant animals;

(c) pig skins;

(d) poultry skin;

(e) tendons and sinews;

(f) wild game hides and skins; and

(g) fish skin and bones.]

Textual Amendments

F2 Substituted by Commission Regulation (EU) No 558/2010 of 24 June 2010 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin (Text with EEA relevance).

2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.

3. Raw materials listed in point 1(a) to (d) must derive 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 or, in the case of hides and skins from wild game, found fit for human consumption.

[F1 4.

(a) Raw materials that have not undergone any preserving treatment other than chilling, freezing or quick-freezing must come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.

(b) The following treated raw materials may be used:

(i) bones other than specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001 coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:

— crushed to pieces of approximately 15 mm and degreased with hot water at a temperature of minimum 70 °C for at least 30 minutes, minimum 80 °C for at least 15 minutes, or minimum 90 °C for at least 10 minutes, and then separated and subsequently washed and dried for at least 20 minutes in a stream of hot air with an initial temperature of minimum 350 °C, or for 15 minutes in a stream of hot air with an initial temperature of more than 700 °C,

— sun-dried for a minimum of 42 days at an average temperature of at least 20 °C,

— acid treatment such that the pH is maintained at less than 6 to the core for at least 1 hour before drying;

(ii) hides and skins of farmed ruminant animals, pig skins, poultry skins and wild game hides and skins coming from establishments under the control of and listed by the competent authority, and that have been subjected to one of the following treatments:

— treatment with alkali to establish a pH > 12 to the core followed by salting for at least 7 days,

— drying for at least 42 days at a temperature of at least 20 °C,

— acid treatment such that the pH is maintained at less than 5 to the core for a minimum of 1 hour,

— alkali treatment throughout at a pH > 12 for at least 8 hours;

(iii) bones other than specified risk material defined in Article 3(1)(g) of Regulation (EC) No 999/2001, hides and skins of farmed ruminant animals, pig skins, poultry skins, fish hides and wild game hides and skins that have undergone any other treatment than those specified in point (i) or (ii) and

that come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.

For the purposes of the first 2 indents of point (b)(ii), the duration of the treatments may include the time of transportation.

The treated raw materials referred to in point (b) must be derived from:

— domestic and farmed ruminant animals, pigs and poultry which have been slaughtered in a slaughterhouse and the carcasses of which have been found fit for human consumption following ante- and post-mortem inspection, or

— from killed wild game whose carcasses have been found fit for human consumption following post-mortem inspection.**]**

5. Collection centres and tanneries may also supply raw material for the production of collagen intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.

(a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.

(b) 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.

(c) If raw material not in conformity with this chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this chapter throughout the period of receipt, storage, processing and dispatch.

CHAPTER II:

TRANSPORT AND STORAGE OF RAW MATERIALS

1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the collagen-processing establishment.

2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

[[F3]3. After the veterinary checks provided for in Directive 97/78/EC, and without prejudice to the conditions laid down in Article 8(4) of that Directive, raw materials for the production of collagen for human consumption, for which animal health certification is required, must be transported directly to the establishment at the place of destination.

All precautions, including safe disposal of animal by-products, waste, unused or surplus material, shall be taken to avoid risks of spreading diseases to animals.**]**

Textual Amendments

F3 Inserted by Commission Regulation (EU) 2016/355 of 11 March 2016 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the specific requirements for

gelatine, collagen and highly refined products of animal origin intended for human consumption (Text with EEA relevance).

CHAPTER III:

REQUIREMENTS FOR THE MANUFACTURE OF COLLAGEN

[F1 1. The production process for collagen 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 as determined in accordance with Article 5 of Regulation (EC) No 999/2001 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 a minimum concentration of 4 % and pH < 1,5) over a period of at least 2 days; this treatment must be followed by pH adjustment using acid or alkali followed by:

(i) either one or more rinses and at least one of the following processes:
— filtration,
— milling,
— extrusion,

(ii) or any approved equivalent process;

(b) raw materials other than that referred to in point (a) must be subjected to a treatment involving washing, pH adjustment using acid or alkali followed by:

(i) either one or more rinses and at least one of the following processes:
— filtration,
— milling,
— extrusion,

(ii) or any approved equivalent process.]

2. After having been subjected to the process referred to in point 1, collagen may undergo a drying process.

[F4 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.]

Textual Amendments

F4 Substituted by Commission Regulation (EC) No 1243/2007 of 24 October 2007 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin (Text with EEA relevance).

[F1CHAPTER IV:

REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that collagen 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, latest edition)	50 ppm
H_2O_2 (European Pharmacopoeia, latest edition)	10 ppm]

CHAPTER V:

LABELLING

Wrapping and packaging containing collagen must bear the words ‘collagen fit for human consumption’ and indicate the date of preparation.]

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 853/2004 of the European Parliament and of the Council, SECTION XV:.