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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard 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[(1)], and in particular Article 10(1) thereof,

Whereas:

(1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. That Regulation provides in particular that food business operators are to ensure compliance with specific requirements for raw materials for the production of gelatine and collagen intended for human consumption.

(2) It is necessary to ensure that raw materials for the production of gelatine and collagen for human consumption come from sources that meet the public and animal health requirements laid down in Union legislation.

(3) The Union is highly dependent on imports of raw materials for the production of gelatine and collagen. Establishments producing those raw materials apply specific treatments to exclude public and animal health risks linked to those raw materials. It is therefore appropriate to allow those treatments prior to placing on the market in the Union.

(4) It is appropriate to adapt the requirements for the production process for collagen to allow practical changes in cases where a change does not result in a different level of public health protection.

(5) Analytical methods for verifying residue limits in gelatine and collagen should be adapted to the most appropriate and most recently validated methods.

(6) In order to ensure the safety of certain highly refined products, to ensure the enforcement of EU provisions and to ensure fair competition as regards raw materials coming from within the Union and from third countries, it is appropriate to harmonise conditions and lay down specific requirements for the production of certain highly refined products of animal origin intended for human consumption. The import of other

products of animal origin for which Annex III to Regulation (EC) No 853/2004 does not lay down specific requirements, remains allowed in accordance with Commission Regulation (EU) No 1079/2013[(2)].

(7) Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) Section XIV is amended as follows:

(a) in Chapter I, point 4 is replaced by the following:

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 points (b)(i) and (b)(ii) 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.;

(b) in Chapter II, the following point 3 is added:

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 gelatine 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.;

(c) 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, latest edition)	50 ppm
H_2O_2 (European Pharmacopoeia, latest edition)	10 ppm

(2) Section XV is amended as follows:

(a) in the introduction, point 1 is replaced by the following:

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.;

(b) in Chapter I, point 4 is replaced by the following:

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.;

(c) in Chapter II, the following point 3 is added:

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.;

(d) in Chapter III, point 1 is replaced by the following:

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.;

(e) Chapter IV is replaced by the following:

CHAPTER 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

(3) the following Section XVI is added:

SECTION XVI: HIGHLY REFINED CHONDROITIN SULPHATE, HYALURONIC ACID, OTHER HYDROLYSED CARTILAGE PRODUCTS, CHITOSAN, GLUCOSAMINE, RENNET, ISINGLASS AND AMINO ACIDS

1. Food business operators manufacturing the following highly refined products of animal origin:

   (a) chondroitin sulphate,

   (b) hyaluronic acid,

   (c) other hydrolysed cartilage products,

   (d) chitosan,

   (e) glucosamine,

   (f) rennet,

   (g) isinglass,

   (h) amino acids that are authorised as food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council[(3)],

   must ensure that the treatment of the raw materials used eliminates any animal or public health risk.

2. The raw materials used for the manufacturing of the highly refined products referred to in point 1 must derive from:

   (a) animals, including feathers thereof, which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante-mortem and post-mortem inspection, or;

(b) fishery products complying with Section VIII.

Human hair may not be used as a source for the manufacture of amino acids.

Article 2

This Regulation shall enter into force on the twentieth 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, 11 March 2016.

For the Commission

The President

Jean-Claude JUNCKER

(**1**) OJ L 139, 30.4.2004, p. 55.

(**2**) Commission Regulation (EU) No 1079/2013 of 31 October 2013 laying down transitional measures for the application of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council (OJ L 292, 1.11.2013, p. 10).

(**3**) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).'