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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

drawing up lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificates requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption¹ and in particular Articles 8(1) and 9(4) thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption², and in particular Article 11 (1) thereof,

Whereas:

- (1) Regulation (EC) No 854/2004 requires products of animal origin to be imported only from a third country or a part of third country that appears on a list drawn up in accordance with that Regulation.
- (2) Commission Decision 2003/812/EC³ draws up lists of third countries from which Member States are to authorise imports of certain products for human consumption subject to Council Directive 92/118/EEC⁴. Those lists include a list of third countries or parts of third countries from which imports of gelatine intended for human consumption are authorised. However, there is no list which covers collagen, or raw materials for the production of gelatine and collagen, for human consumption. It is appropriate to draw up such lists.

¹ OJ L 18, 23.1.2003, p. 11.

² OJ L 139, 30.4.2004, p. 206.

³ Commission Decision 2003/812/EC of 17 November 2003 drawing up lists of third countries from which Member States are to authorise imports of certain products for human consumption subject to Council Directive 92/118/EEC (OJ L 305, 22.11.2003, p. 17).

⁴ Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and import 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, Directive 90/425/EEC (OJ L 62, 15.3.1993, p. 49).

- (3) In accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council⁵, food business operators importing products of animal origin are to ensure that the documents accompanying the consignment meet the requirements of Article 14 of Regulation (EC) No 854/2004. Commission Regulation (EC) No 2074/2005⁶ lays down model certificates for imports of certain products of animal origin intended for human consumption. Those model certificates include outdated references to previous legislation that need to be updated.
- (4) Third countries, parts of third countries and territories listed in Annex II to Commission Decision 2006/766/EC⁷, in Part 1 of Annex I to Commission Regulation (EC) No 798/2008⁸, in Part 1 of Annex I to Commission Regulation (EC) No 119/2009⁹ or in Part 1 of Annex II to Commission Regulation (EU) No 206/2010¹⁰ meet the Union requirements with regard to imports of fresh meat and certain fishery products. Those lists could also be used for imports of raw materials for the production of gelatine and collagen. However, less strict requirements should apply if those raw materials have been subjected to certain treatments as provided for in Sections XIV and XV of Annex III to Regulation (EC) No 853/2004.
- (5) Raw materials for the production of gelatine and collagen, whether or not treated, introduced into the Union for transit to a third country, pose a negligible risk to public health. Such raw materials, even when treated, should, however, comply with the relevant animal health requirements. Accordingly, a list of third countries, parts of third countries or territories should be drawn up and model certificates for transit, and storage before transit, of raw materials and treated raw materials for the production of gelatine and collagen should be laid down.
- (6) Due to the geographical situation of Kaliningrad, specific animal health conditions should be laid down for transit via the Union of consignments of raw materials and treated raw materials for the production of gelatine or collagen to and from Russia, which only concern transit through Latvia, Lithuania and Poland.
- (7) In the interest of clarity and simplification of Union legislation, the lists of third countries, parts of third countries and territories from which Member States are to

⁵ 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 (OJ L 139, 30.4.2004, p. 55).

⁶ Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338, 22.12.2005, p. 27).

⁷ Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted (OJ L 320, 18.11.2006, p. 53).

⁸ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

⁹ Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for import into, or transit through, the Community of meat and wild leporidae, of certain wild land mammals and farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12).

¹⁰ Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

authorise the introduction of frogs' legs, snails, gelatine, collagen, raw materials and treated raw materials for the production of gelatine and collagen, and honey, royal jelly and other products of apiculture for human consumption, and the model certificates for those products, should be set out in an Annex to this Regulation. Consequently, the corresponding existing certificates should be deleted from Annex VI to Regulation (EC) No 2074/2005.

- (8) In order to ensure the safety of certain highly refined products of animal origin, specific requirements have been inserted in Annex III to Regulation (EC) No 853/2004. Therefore it is appropriate to draw up the list of countries from which those products may be imported and lay down a model certificate for those products.
- (9) As the lists of third countries, parts of third countries and territories from which Member States are to authorise imports of furred farm game meat products and feathered farm game meat products and leporidae (rabbit and hare) meat and their meat products have been laid down in Commission Decision 2007/777/EC¹¹ and in Regulation (EC) No 119/2009 respectively, Decision 2003/812/EC becomes redundant and should be repealed.
- (10) It is appropriate to introduce a transitional period to allow Member States and food business operators to adapt to the new requirements laid down in this Regulation.
- (11) 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:

CHAPTER 1 IMPORTS OF CERTAIN PRODUCTS OF ANIMAL ORIGIN

Article 1

Lists of third countries, parts of third countries and territories

The third countries, parts of third countries and territories from which Member States are to authorise the import of the following products of animal origin intended for human consumption are set out in the relevant Parts of Annex I:

- (a) frogs' legs, Part I;
- (b) snails, Part II;
- (c) gelatine and collagen, Part III;
- (d) raw materials for the production of gelatine and collagen, Part IV;
- (e) treated raw materials for the production of gelatine and collagen, Part V;
- (f) honey, royal jelly and other products of apiculture, Part VI;
- (g) the following highly refined products, Part VII:
 - (i) chondroitin sulphate,

¹¹ Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC (OJ L 312, 30.11.2007, p. 49).

- (ii) hyaluronic acid,
- (iii) other hydrolysed cartilage products,
- (iv) chitosan,
- (v) glucosamine,
- (vi) rennet,
- (vii) isinglass,
- (viii) amino acids that are authorised as food additives in accordance with Commission Regulation (EU) No 1333/2008.

Article 2
Model certificates

1. The model certificates for imports into the Union of the products referred to in Article 1 are set out in Annex II as follows:

- (a) frogs' legs, Part I;
- (b) snails, Part II;
- (c) gelatine, Part III;
- (d) collagen, Part IV;
- (e) raw materials for the production of gelatine and collagen, Part V;
- (f) treated raw materials for the production of gelatine and collagen, Part VI;
- (g) honey, royal jelly and other products of apiculture, Part VII;
- (h) the following highly refined products, Part VIII
 - (i) chondroitin sulphate,
 - (ii) hyaluronic acid,
 - (iii) other hydrolysed cartilage products,
 - (iv) chitosan,
 - (v) glucosamine,
 - (vi) rennet,
 - (vii) isinglass,
 - (viii) amino acids that are authorised as food additives in accordance with Commission Regulation (EU) No 1333/2008.

Those certificates must be completed in accordance with the explanatory notes set out in Annex IV and the notes in the relevant certificate.

2. Electronic certification and other systems agreed between the Union and the third country concerned may be used.

CHAPTER 2 TRANSIT OF CERTAIN PRODUCTS OF ANIMAL ORIGIN

Article 3

Lists of third countries, parts of third countries and territories

The third countries, parts of third countries and territories from which Member States are to authorise the transit through the Union of raw materials and treated raw materials for the production of gelatine and collagen intended for human consumption bound for a third country, either by immediate transit or after storage in the Union in accordance with Article 12(4) and Article 13 of Council Directive 97/78/EC¹², are set out in Parts IV and V of Annex I to this Regulation, respectively.

Article 4

Model certificate

1. The model certificate for the transit through the Union of the raw materials and treated raw materials referred to in Article 3 is set out in Annex III.
That certificate must be completed in accordance with the notes set out in Annex IV and in the relevant model certificate.
2. Electronic certification and other systems harmonised at Union level may be used.

Article 5

Derogation for transit through Latvia, Lithuania and Poland

1. By way of derogation from Article 3, transit by road or by rail between the specific designated border inspection posts in Latvia, Lithuania and Poland, listed and marked with special remark 13 in Annex I to Commission Decision 2009/821/EC¹³, of consignments of the raw materials or treated raw materials referred to in Article 3 of this Regulation coming from and bound for Russia, directly or via another third country, shall be authorised where the following conditions are met:
 - (a) the consignment is sealed with a serially numbered seal by the official veterinarian at the border inspection post of entry;
 - (b) the documents accompanying the consignment, as provided for in Article 7 of Directive 97/78/EC, are stamped with the words “Only for transit to Russia via the EU” on each page by the official veterinarian at the border inspection post of entry;
 - (c) the procedural requirements provided for in Article 11 of Directive 97/78/EC are complied with;
 - (d) the consignment is certified as acceptable for transit on the common veterinary entry document issued by the official veterinarian at the border inspection post of entry.

¹² Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

¹³ Commission Decision 2009/821/EC of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces (OJ L 296, 12.11.2009, p. 1).

2. The consignments referred to in paragraph 1 shall not be unloaded or put into storage, as referred to in Article 12(4) or in Article 13 of Directive 97/78/EC, within the Union.
3. Regular audits shall be conducted by the competent authority to ensure that the number of consignments referred to in paragraph 1 and the corresponding quantities of products leaving the Union correspond with the number and quantities which have been introduced in the Union.

CHAPTER 3 FINAL PROVISIONS

Article 6 Amendment

Annex VI to Regulation (EC) No 2074/2005 is amended as follows:

- (1) in Section I, Chapters I, II, III and VI are deleted;
- (2) Appendices I, II, III and VI are deleted.

Article 7 Repeal

Decision 2003/812/EC is repealed.

Article 8 Transitional provisions

Consignments of products of animal origin in respect of which the relevant model certificates have been issued in accordance with Regulation (EC) No 2074/2005 may continue to be introduced into the Union provided that the certificate was signed before XX/XX/2016 [6 months after the date of entry into force of this Regulation].

Article 9 Entry into force

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,

*For the Commission
The President
Jean Claude JUNCKER*