

Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 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 certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/759

of 28 April 2016

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 certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC

(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 consumption⁽¹⁾ 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 consumption⁽²⁾, 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/EC⁽³⁾ 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/EEC⁽⁴⁾. 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.
- (3) In accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council⁽⁵⁾, 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 2074/2005⁽⁶⁾ lays down model certificates for imports of certain products of animal origin intended for

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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/EC⁽⁷⁾, in Part 1 of Annex I to Commission Regulation (EC) No 798/2008⁽⁸⁾, in Part 1 of Annex I to Commission Regulation (EC) No 119/2009⁽⁹⁾ or in Part 1 of Annex II to Commission Regulation (EU) No 206/2010⁽¹⁰⁾ 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 and 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, and without prejudice to Commission Decision 2003/863/EC⁽¹¹⁾, the lists of third countries, parts of third countries and territories from which Member States are to 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/EC⁽¹²⁾ 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.

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- (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

F1 Article 1

[^{F1}Lists of third countries, parts of third countries and territories]

Textual Amendments

- F1** Deleted by [Commission Implementing Regulation \(EU\) 2019/626 of 5 March 2019 concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption, amending Implementing Regulation \(EU\) 2016/759 as regards these lists \(Text with EEA relevance\).](#)

F2 Article 2

[^{F2}Model certificates]

Textual Amendments

- F2** Deleted by [Commission Implementing Regulation \(EU\) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation \(EC\) No 2074/2005 and Implementing Regulation \(EU\) 2016/759 as regards these model certificates \(Text with EEA relevance\).](#)

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

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with Article 12(4) and Article 13 of Council Directive 97/78/EC⁽¹³⁾, 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/EC⁽¹⁴⁾, 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^[F3]]
- ^[F4]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.]

^{F4}₂

^{F4}₃

Textual Amendments

F3 Substituted by Commission Delegated Regulation (EU) 2019/2124 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transshipment and onward transportation through the Union, and amending Commission Regulations (EC) No 798/2008, (EC) No 1251/2008, (EC) No 119/2009, (EU) No 206/2010, (EU) No 605/2010, (EU) No 142/2011, (EU) No 28/2012, Commission Implementing Regulation (EU) 2016/759 and Commission Decision 2007/777/EC (Text with EEA relevance).

F4 Deleted by Commission Delegated Regulation (EU) 2019/2124 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transshipment and onward transportation through the Union, and amending Commission Regulations (EC) No 798/2008, (EC) No 1251/2008,

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(EC) No 119/2009, (EU) No 206/2010, (EU) No 605/2010, (EU) No 142/2011, (EU) No 28/2012, Commission Implementing Regulation (EU) 2016/759 and Commission Decision 2007/777/EC (Text with EEA relevance).

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 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 3 December 2016.

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.

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^{F1} ANNEX I

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^{F2} ANNEX II

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ANNEX III

**MODEL CERTIFICATE FOR THE TRANSIT THROUGH THE
UNION, IMMEDIATE TRANSIT OR AFTER STORAGE, FOR**

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I.25. Commodities certified for:			
Production of gelatine / collagen for human consumption <input type="checkbox"/>			
I.26. For transit through EU to third country <input type="checkbox"/>		I.27.	
Third country	ISO code		
I.28. Identification of the commodities			
Species (scientific name)	Manufacturing plant	Number of packages	Net weight

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COUNTRY		Model TRANSIT/STORAGE	
II. Health information	II.a. Certificate reference number	II.b.	
Part II: Certification	II.1. Public Health Attestation		
	<p>I, the undersigned official veterinarian, hereby certify, that the raw materials or treated raw materials described in Part I:</p> <p>II.1.1. come from a country or region authorised for imports into the EU as laid down in Part 1 of Annex I to Commission Regulation (EC) 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) or in Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12) or in Part 1 of Annex II to 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), and</p> <p>II.1.2. comply with the relevant animal health conditions as laid down in the animal health attestation in the model certificate in Part V or VI of Annex II to Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 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 certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC (OJ L 126, 14.5.2016, p. 13).</p>		
Notes			
<p>This certificate is meant for transit and storage in accordance with Article 12(4) or Article 13 of 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) of raw materials or treated raw materials for the production of gelatine/collagen for human consumption of:</p> <ol style="list-style-type: none"> (1) domestic bovine animals (including <i>Bubalus</i> and <i>Bison</i> species and their cross-breeds); (2) domestic ovine animals (<i>Ovis aries</i>) or domestic caprine animals (<i>Capra hircus</i>); (3) domestic porcine animals (<i>Sus scrofa</i>); (4) domestic solipeds (<i>Equus caballus</i>, <i>Equus asinus</i> and their cross-breeds); (5) farmed non-domestic animals of the order Artiodactyla (excluding bovine animals (including <i>Bison</i> and <i>Bubalus</i> species and their cross-breeds), <i>Ovis aries</i>, <i>Capra hircus</i>, Suidae and Tayassuidae), and of the families Rhinocerotidae and Elephantidae; (6) wild non-domestic animals of the order Artiodactyla (excluding bovine animals (including <i>Bison</i> and <i>Bubalus</i> species and their cross-breeds), <i>Ovis aries</i>, <i>Capra hircus</i>, Suidae and Tayassuidae), and of the families Rhinocerotidae and Elephantidae; (7) farmed non-domestic animals belonging to the Suidae, Tayassuidae, or Tapiridae families; (8) wild non-domestic animals belonging to the Suidae, Tayassuidae, or Tapiridae families; (9) wild solipeds belonging to the subgenus <i>Hippotigris</i> (zebra); (10) wild leporidae (rabbits and hares); (11) wild land mammals other than ungulates and leporidae; (12) farmed rabbits; (13) poultry; (14) farmed ratites; (15) wild game; (16) fish. 			

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COUNTRY		Model TRANSIT/STORAGE	
II. Health information	II.a. Certificate reference number	II.b.	
Part I:			
<ul style="list-style-type: none"> — Box reference I.8: Provide the code of territory as appearing in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Part 1 of Annex I to Regulation (EC) No 119/2009 or Part 1 of Annex I to Regulation (EC) No 798/2008 or Annex II to 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). — Box reference I.11: Place of origin: name and address of the dispatch establishment. — Box reference I.12: Address (and approval number if known) of the warehouse in a free zone, free warehouse, customs warehouse or ship chandler shall be included. — Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the BIP of entry into the EU. — Box reference I.19: Use the appropriate Harmonised System (HS) code under the heading of 02.08, 03.05, 05.04, 05.05, 05.06, 05.11.91, 05.11.99, 41.01, 41.02, 41.03. — Box reference I.20: Indicate total gross weight and total net weight. — Box reference I.23: For containers or boxes, the container number and the seal number (if applicable) should be included. — Box reference I.28: <i>Manufacturing plant</i>: provide the registration number, approval number or competent authority identification number of establishment as appropriate. It includes slaughterhouse, factory vessel, cutting plant, game handling establishment and processing plant. 			
Official veterinarian or Official inspector			
Name (in capital letters):		Qualification and title:	
Date:		Signature:	
Stamp:			

ANNEX IV

EXPLANATORY NOTES FOR COMPLETING THE CERTIFICATES

(referred to in Articles 2(1) and 4(1))

- (a) Certificates shall be issued by the exporting third country, based on the models set out in Annexes II and III according to the layout of the model that corresponds to the products of animal origin concerned.

They shall contain, in the numbered order that appears in the model, the attestations that are required for any third country and, as the case may be, those supplementary guarantees that are required for the exporting third country or part thereof.

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If the Member State of destination imposes, for the products of animal origin concerned, additional certification requirements, attestations to certify that those requirements are fulfilled shall also be incorporated in the original form of the certificate.

- (b) Where the model certificate states that certain statements shall be kept as appropriate, statements which are not relevant, may be crossed out and initialled and stamped by the certifying officer, or completely deleted from the certificate.
- (c) A separate and unique certificate must be provided for the products of animal origin that are exported from a territory or territories or zone or zones of the same exporting country listed or referred to in Annex I which are consigned to the same destination and transported in the same railway wagon, lorry, aircraft or ship.
- (d) The original of each certificate shall consist of a single sheet of paper, or, where more text is required it must be in such a form that all sheets of paper required are part of an integrated whole and indivisible.
- (e) The certificate shall be drawn up in at least one of the official languages of the Member State of the border inspection post of entry of the consignment into the EU and of the Member State of destination. However, those Member States may authorise the certificate to be drawn up in the official language of another Member State, and accompanied, if necessary, by an official translation.
- (f) If for reasons of identification of the items of the consignment (schedule in point I.28 of the model certificate), additional sheets of paper are attached to the certificate, those sheets of paper shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying officer, on each of the pages.
- (g) When the certificate, including additional sheets of paper referred to in (f), comprises more than one page, each page shall be numbered, (page number) of (total number of pages), at the end of the page and shall bear the certificate reference number that has been designated by the competent authority at the top of the pages.
- (h) The original of the certificate must be completed and signed by an official veterinarian or by another designated official inspector where this is provided for in the model certificate. The competent authorities of the exporting third country shall ensure that rules of certification equivalent to those laid down in Council Directive 96/93/EC⁽¹⁵⁾ are followed.

The colour of the signature shall be different from that of the printing. This requirement also applies to stamps other than those embossed or watermarked.
- (i) The certificate reference number referred to in boxes I.2 and II.a. must be issued by the competent authority.

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- (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](#)).
- (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](#)).
- (11) Commission Decision 2003/863/EC of 2 December 2003 on health certificates for the importation of animal products from the United States of America ([OJ L 325, 12.12.2003, p. 46](#)).
- (12) 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](#)).
- (13) 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](#)).
- (14) 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](#)).
- (15) Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products ([OJ L 13, 16.1.1997, p. 28](#)).

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